

TDMS No. 99007 - 06
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
Time Report Requested: 12:25:59
First Dose M/F: 05/12/03 / 05/12/03
Lab: SRI

F1_Rev.1_M3

C Number: C99007B
Lock Date: 08/29/2006
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

DAY ON TEST	0 0																									
	7 7 7 6 7 7 7 7 7 7 7 7 7 6 7 6 7 7 7 7 7 7 7 7 7																									
ANIMAL ID	3 3 3 7 3 3 3 3 3 3 2 3 3 3 3 8 3 3 2 3 3 2 3 3 3																									
	1 0 0 7 0 0 0 0 0 0 1 9 1 0 2 1 1 0 1 9 0 1 9 1 0 1																									
B6C3F1 MICE MALE	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 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																									
0 PPM																										males (cont...)

ALIMENTARY SYSTEM

Esophagus	+ +																								
Gallbladder	+ + + M + + + + + + + + + + A + M + + + + + + + + + + +																								
Intestine Large, Cecum	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Intestine Large, Colon	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Intestine Large, Rectum	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Intestine Small, Duodenum	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Intestine Small, Ileum	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Intestine Small, Jejunum	+ + + A + + + + + + + + + + + + + + + A + + + + + + + + + + +																								
Hyperplasia, Lymphoid																									
Liver	+ +																								
Basophilic Focus																									
Clear Cell Focus																									
Eosinophilic Focus	X X																								
Hepatodiaphragmatic Nodule																									
Infiltration Cellular, Lymphocyte	1																								
Infiltration Cellular, Mixed Cell	1																								
Mixed Cell Focus																									

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	7	7	7	6	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	7	7
	3	3	3	7	3	3	3	3	3	2	3	3	3	3	8	3	3	2	3	3	2	3	3	3	3
	1	0	0	7	0	0	0	0	0	1	9	1	0	2	1	1	0	1	9	0	1	9	1	0	1
B6C3F1 MICE MALE	0																								
	0																								
	0																								
	0																								
	0																								
0 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...)																									

Necrosis, Focal	3				2				2																
Hepatocyte, Vacuolization Cytoplasmic	1			1	2																				
Kupffer Cell, Pigmentation														1											
Mesentery	+								+																
Fibrosis																									
Fat, Necrosis	3								2																
Pancreas	+																								
Acinus, Cytoplasmic Alteration													3												
Acinus, Hyperplasia, Focal																									
Salivary Glands	+																								
Infiltration Cellular, Lymphocyte																									
Stomach, Forestomach	+																								
Inflammation, Chronic																									
Ulcer																									
Epithelium, Hyperplasia																									
Stomach, Glandular	+																								
Erosion													3												
Glands, Cyst																									
	X																								

CARDIOVASCULAR SYSTEM

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

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DAY ON TEST	0 0																								
	7 7 7 6 7 7 7 7 7 7 7 7 7 6 7 6 7 7 7 7 7 7 7 7 7																								
ANIMAL ID	3 3 3 7 3 3 3 3 3 3 2 3 3 3 3 8 3 3 2 3 3 2 3 3 3																								
	1 0 0 7 0 0 0 0 0 0 1 9 1 0 2 1 1 0 1 9 0 1 9 1 0 1																								
B6C3F1 MICE 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
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
	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
(cont...)

Thrombosis
 Artery, Inflammation, Chronic

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hypertrophy, Focal					2									1									2		
Capsule, Hyperplasia	1	1	1			1	1	1	1	1	1	2	3	1			2	1		2			1	2	2
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hyperplasia						2						2													
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pars Distalis, Cyst																									
Pars Distalis, Hyperplasia, Focal																									
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Follicle, Degeneration, Focal																									

GENERAL BODY SYSTEM

NONE

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DAY ON TEST	0																								
	7	7	7	6	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	7	7
3	3	3	7	3	3	3	3	3	3	2	3	3	3	3	8	3	3	2	3	3	2	3	3	3	3
1	0	0	7	0	0	0	0	0	0	1	9	1	0	2	1	1	0	1	9	0	1	9	1	0	1
B6C3F1 MICE MALE 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	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	2	3	4	5

males
(cont...)

GENITAL SYSTEM

Epididymis	+ +																								
Preputial Gland	+ +																								
Cyst	X X																								
Inflammation, Suppurative																									
Inflammation, Chronic																									
Prostate	+ +																								
Epithelium, Hyperplasia	2 2																								
Seminal Vesicle	+ +																								
Testes	+ +																								
Germinal Epithelium, Atrophy	3																								

HEMATOPOIETIC SYSTEM

Bone Marrow	+ +																								
Angiectasis																									
Hyperplasia	2 2 2																								
Lymph Node																									
Iliac, Hemorrhage																									

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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
	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
B6C3F1 MICE MALE																									
0 PPM																									

males (cont...)

Lymph Node, Mandibular + M + +

Lymph Node, Mesenteric Hyperplasia, Histiocytic Hyperplasia, Lymphoid + M +

Spleen Hematopoietic Cell Proliferation Hyperplasia Lymphoid Follicle, Hyperplasia +

Thymus Atrophy + + + M + + I + + + + + + + I I M + + + + + + + +

INTEGUMENTARY SYSTEM

Mammary Gland M M M M M M M + M M M M M + M M M M M M M M M M

Skin Inflammation, Chronic Epidermis, Hyperplasia Hair Follicle, Cyst +

MUSCULOSKELETAL SYSTEM

Bone Cranium, Hyperostosis +

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	DAY ON TEST	Animals																								
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
		0	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	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	7	7	7
		3	3	3	7	3	3	3	3	3	2	3	3	3	3	8	3	3	2	3	3	2	3	3	3	
		1	0	0	7	0	0	0	0	0	1	9	1	0	2	1	1	0	1	9	0	1	9	1	0	
B6C3F1 MICE 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		0	0	0	0	0	0	0	0	0	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	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
(cont...)

NERVOUS SYSTEM

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Peripheral Nerve																									
Spinal Cord																									

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Fibrosis																									
Infiltration Cellular, Histiocyte													3												
Infiltration Cellular, Lymphocyte					2				2								2								
Alveolar Epithelium, Hyperplasia													2						1					2	
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Nasolacrimal Duct, Inflammation, Suppurative																									
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

SPECIAL SENSES SYSTEM

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Lab: SRI

B6C3F1 MICE MALE	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	6	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	7	7	7
0 PPM		3	3	3	7	3	3	3	3	3	2	3	3	3	3	8	3	3	2	3	3	2	3	3	3	
		1	0	0	7	0	0	0	0	0	1	9	1	0	2	1	1	0	1	9	0	1	9	1	0	1
	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	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
(cont...)

Eye Inflammation, Acute	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+
Harderian Gland Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst					X												X			X					
Infarct					2																				
Infiltration Cellular, Lymphocyte Inflammation, Suppurative Metaplasia, Osseous																									
Nephropathy	2	1	1		2	2	3	1	2	2	1	2	2		2		2	2	1	2	2		1	2	1
Thrombosis																									
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+

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DAY ON TEST	0																								* TOTALS
	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	4	7	
	3	3	3	6	3	3	3	3	2	3	2	3	5	3	3	0	2	3	3	3	3	3	9	2	
	0	1	0	4	0	0	2	0	9	1	9	0	0	2	0	5	9	1	0	0	0	0	6	9	
ANIMAL ID	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	
	2	2	2	2	3	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	

**B6C3F1 MICE MALE
 0 PPM**

Necrosis, Focal Hepatocyte, Vacuolization Cytoplasmic Kupffer Cell, Pigmentation	2																								2	2.5	6	1.7	1	1.0								
Mesentery Fibrosis Fat, Necrosis																																6	1	2.0	5	2.4		
Pancreas Acinus, Cytoplasmic Alteration Acinus, Hyperplasia, Focal																																49	2	2.5	1	2.0		
Salivary Glands Infiltration Cellular, Lymphocyte																																50	1	2.0				
Stomach, Forestomach Inflammation, Chronic Ulcer Epithelium, Hyperplasia																																50	1	3.0	1	2.0	3	2.3
Stomach, Glandular Erosion Glands, Cyst																																50	1	3.0	1			

CARDIOVASCULAR SYSTEM

Heart Cardiomyopathy																																50	45	1.4		
-------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	----	----	-----	--	--

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	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	
B6C3F1 MICE MALE	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	4	7	
	3	3	3	6	3	3	3	3	2	3	2	3	5	3	3	0	2	3	3	3	3	3	9	2	
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	
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	

Thrombosis																									4	1	4.0		
Artery, Inflammation, Chronic																											2	1	2.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Hypertrophy, Focal	2		1								1	1		1	1			2	1				1			13	1.3	
Capsule, Hyperplasia	1	1	1		3	2	3	2	1	1	1	2		1	2	2	1	1	3	2	1	1		2		39	1.5	
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Islets, Pancreatic	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49		
Hyperplasia		2	2																							4	2.0	
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	M	+	+	M	M	45		
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Pars Distalis, Cyst																											2	
Pars Distalis, Hyperplasia, Focal																									2	2	2.0	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Follicle, Degeneration, Focal		2																	1							5	2.0	

GENERAL BODY SYSTEM

NONE

* .. 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 11

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																								* TOTALS	
	7	7	7	6	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	7	4	7		
B6C3F1 MICE MALE 0 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	50
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	50
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	50
	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	19
	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	1 4.0 1 2.0

GENITAL SYSTEM

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst					X					X								X		X	X		X	X	X	19
Inflammation, Suppurative						4																				1 4.0
Inflammation, Chronic																							2			1 2.0
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Epithelium, Hyperplasia																										2 2.0
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Germinal Epithelium, Atrophy																										1 3.0

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Angiectasis																										1 2.0
Hyperplasia						3							3									2				6 2.3
Lymph Node																										2
Iliac, Hemorrhage																										1 3.0

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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 12

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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	6	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	7	4	7		
	3	3	3	6	3	3	3	3	2	3	2	3	5	3	3	0	2	3	3	3	3	3	3	9	2		
	0	1	0	4	0	0	2	0	9	1	9	0	0	2	0	5	9	1	0	0	0	0	0	6	9		
B6C3F1 MICE MALE 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	
	2	2	2	2	3	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		

Lymph Node, Mandibular	+	+	+	M	+	+	+	+	+	+	+	M	+	M	+	+	+	+	+	+	+	+	+	+	+	46		
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	48	
Hyperplasia, Histiocytic																											2 1.5	
Hyperplasia, Lymphoid				3																	3						3 2.7	
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Hematopoietic Cell Proliferation	1	1				3			1	1				2		2	1	1						2		23 1.7		
Hyperplasia			1		1																					2 1.0		
Lymphoid Follicle, Hyperplasia	2														2				3							4 2.3		
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	44		
Atrophy													4											3		3 3.0		

INTEGUMENTARY SYSTEM

Mammary Gland	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	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Inflammation, Chronic																										1 3.0	
Epidermis, Hyperplasia																										1 2.0	
Hair Follicle, Cyst																										1	

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Cranium, Hyperostosis			3																							1 3.0	

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M .. Missing tissue
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BLANK .. Not examined microscopically
Page 13
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																							
	7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 4 7																							
ANIMAL ID	3 3 3 6 3 3 3 3 2 3 2 3 5 3 3 0 2 3 3 3 3 3 9 2																							
	0 1 0 4 0 0 2 0 9 1 9 0 0 2 0 5 9 1 0 0 0 0 6 9																							
B6C3F1 MICE MALE 0 PPM	0 0																							
	0 0																							
	0 0																							
	2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 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	

NERVOUS SYSTEM

Brain	+ +																								50
Peripheral Nerve																									3
Spinal Cord																									3

RESPIRATORY SYSTEM

Lung	+ +																								50	
Fibrosis																									3	1 3.0
Infiltration Cellular, Histiocyte																									3	2 3.0
Infiltration Cellular, Lymphocyte																									3	2.0
Alveolar Epithelium, Hyperplasia	2																								3	1 6 1.8
Nose	+ +																								50	
Nasolacrimal Duct, Inflammation, Suppurative	2																									1 2.0
Trachea	+ +																								50	

SPECIAL SENSES SYSTEM

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 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 14

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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	
B6C3F1 MICE MALE	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	7	4	7	
0 PPM	3	3	3	6	3	3	3	3	2	3	2	3	5	3	3	0	2	3	3	3	3	3	9	2	
	0	1	0	4	0	0	2	0	9	1	9	0	0	2	0	5	9	1	0	0	0	0	6	9	
																								
	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	
	2	2	2	2	3	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	
																								
Eye Inflammation, Acute	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	A	+	46
																								
Harderian Gland Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
																								
URINARY SYSTEM																									
																								
Kidney Cyst	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Kidney Infarct																								X	4
Kidney Infiltration Cellular, Lymphocyte																									
Kidney Inflammation, Suppurative																									
Kidney Metaplasia, Osseous																									
Kidney Nephropathy	1	1	1		1	2	1	1	2	1	2	1	2	1	2		1	1		1	1	1	1	2	42
Kidney Thrombosis																									
																								
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49

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 2) Mild 4) Marked

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 1 0 0																								
B6C3F1 MICE MALE 3000 PPM	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 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...)																								

ALIMENTARY SYSTEM

Esophagus	+ +																								
Gallbladder	+ A +																								
Intestine Large, Cecum	+ A + + + + + + A + + + + + + + + + + + + + + + + + +																								
Intestine Large, Colon	+ A + + + + + + A + + + + + + + + + + + + + + + + + +																								
Intestine Large, Rectum	+ A + + + + + + A + + + + + + + + + + + + + + + + + +																								
Intestine Small, Duodenum	+ A + + + + + + A + + + + + + + + + + + A + + + + + + + +																								
Intestine Small, Ileum	+ A + + + + + + A + + + + + + + + + + + + + + + + + +																								
Intestine Small, Jejunum Hyperplasia, Lymphoid	+ A + + + + + + A + + + + + + + + + + + + + + + + + + 2																								
Liver	+ +																								
Basophilic Focus	X																								
Clear Cell Focus	X X																								
Cyst	X X																								
Eosinophilic Focus	X X X X																								
Hematopoietic Cell Proliferation	X X X X																								
Hemorrhage	4																								
Hepatodiaphragmatic Nodule																									

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 Page 16

DAY ON TEST	0																								
	7	7	6	7	7	7	7	6	7	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	
	3	0	3	3	3	3	1	7	0	2	2	3	2	3	3	2	3	5	3	2	2	2	3	3	
	1	9	6	1	0	1	3	3	3	9	9	0	9	0	1	9	0	7	1	9	9	9	1	0	
B6C3F1 MICE MALE	0																								
	0																								
	0																								
	0																								
	0																								
3000 PPM	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	

males (cont...)

Infiltration Cellular, Lymphocyte																								2		
Infiltration Cellular, Mixed Cell											1															
Mixed Cell Focus	X												X	X												
Necrosis, Focal																		3								
Tension Lipidosis																				1						
Bile Duct, Hyperplasia																			2	2						
Hepatocyte, Vacuolization				1	1											2										
Cytoplasmic Kupffer Cell, Pigmentation																							1	2		
Mesentery					+											+										
Inflammation, Suppurative																										
Fat, Necrosis																										
Pancreas																										
Acinus, Cytoplasmic Alteration								3																		
Salivary Glands																										
Infiltration Cellular, Lymphocyte																					1					
Stomach, Forestomach																										
Ulcer																					2					
Epithelium, Hyperplasia																		2								
Stomach, Glandular																										
Cyst																X										
Edema													3													

CARDIOVASCULAR SYSTEM

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TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 9 1 0 0																								
B6C3F1 MICE MALE 3000 PPM	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																								
	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...)

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

ENDOCRINE SYSTEM

Adrenal Cortex	+ +																								
Accessory Adrenal Cortical Nodule	2																								
Hypertrophy, Focal	1 2																								
Capsule, Hyperplasia	2 1 1 2 1 2 1 1 1 1 1 1 1 2 1 1 1 1 2 1 2 1 1 1 1																								
Adrenal Medulla	+ +																								
Islets, Pancreatic	+ +																								
Hyperplasia	2 1 1																								
Parathyroid Gland	+ + M + + + + + + + + + + + + + + + + M + + + + + + +																								
Pituitary Gland	+ + + + + + + + M + + + + + + + + + + + + + + + + + +																								
Pars Distalis, Cyst	X X X																								
Thyroid Gland	+ +																								
Follicle, Cyst	X X																								
Follicle, Degeneration, Focal	1																								

GENERAL BODY SYSTEM

NONE

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 Goldenseal root powder
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 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 1 0 0																								
B6C3F1 MICE MALE 3000 PPM	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																								
	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...)

GENITAL SYSTEM

Coagulating Gland
 Inflammation, Suppurative

Epididymis
 Cyst

Preputial Gland
 Cyst
 Hyperplasia
 Inflammation, Suppurative
 Inflammation, Chronic

Prostate
 Inflammation, Suppurative
 Inflammation, Chronic
 Epithelium, Hyperplasia

Seminal Vesicle
 Inflammation, Suppurative

Testes

.....																								
+ +																								
.....																								
+ +																								
X X																								
2																								
2																								
3																								
2 4																								
.....																								
+ +																								
.....																								
+ +																								
.....																								
+ +																								
.....																								

HEMATOPOIETIC SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 9 1 0 0																								
B6C3F1 MICE 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
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
	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	4	5

males (cont...)

Bone Marrow	+ +																								
Depletion Cellular																									
Hyperplasia	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																								
Lymph Node																									
Pancreatic, Hemorrhage	+ + +																								
Renal, Hemorrhage																									
Lymph Node, Mandibular	+ + + + + + + M + + + + + + + + + M + + + + + + +																								
Hyperplasia, Lymphoid	3																								
Lymph Node, Mesenteric	+ A + + + + + + + + + + + M + + + + M + + + + + + +																								
Atrophy																									
Hemorrhage	2																								
Hyperplasia, Lymphoid	2 3																								
Spleen	+ +																								
Atrophy	3 3																								
Hematopoietic Cell Proliferation	1 1 1 2 2																								
Lymphoid Follicle, Hyperplasia	2 3 3 1 2 3 1 1																								
Thymus	+ + + + + M + M + + + + + + + I I I M + + + + + + +																								
Atrophy	4 3																								
Hyperplasia, Lymphoid	2 1																								

INTEGUMENTARY SYSTEM

Mammary Gland	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
---------------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

* .. 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 20
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 1 0 0																								
B6C3F1 MICE MALE 3000 PPM	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																								
	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...)

Skin	+																								
Inflammation, Chronic																									
Ulcer																									
Epidermis, Hyperplasia																									
	4																								

MUSCULOSKELETAL SYSTEM

Bone	+																								
Maxilla, Fibrosis																									
	3																								
Skeletal Muscle	+																								

NERVOUS SYSTEM

Brain	+																								
Peripheral Nerve	+																								
Spinal Cord																									

RESPIRATORY SYSTEM

Lung	+																								
Edema																									

* .. 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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 BLANK .. Not examined microscopically
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 Page 21

TDMS No. 99007 - 06

Test Type: CHRONIC

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

DAY ON TEST	0 0																								
	7 7 6 7 7 7 7 6 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7																								
ANIMAL ID	3 0 3 3 3 3 1 7 0 2 2 3 2 3 3 2 3 5 3 2 2 2 3 3 3																								
	1 9 6 1 0 1 3 3 3 9 9 0 9 0 1 9 0 7 1 9 9 9 9 1 0 0																								
B6C3F1 MICE MALE 3000 PPM	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 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...)

Alveolar Epithelium, Hyperplasia	3	2																							
Nose Glands, Degeneration, Cystic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

SPECIAL SENSES SYSTEM

Eye Cornea, Inflammation, Chronic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Harderian Gland Hyperplasia, Focal	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Lacrimal Gland	+																								

URINARY SYSTEM

Kidney Cyst	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hydronephrosis				X																				
Infarct																								
Infiltration Cellular, Lymphocyte Inflammation, Suppurative																								
Metaplasia, Osseous																								
Nephropathy	1	2		1	1	1	1				1	1	1	1	2	2	1	1	2	2	1	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
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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	6	7	7	7	7	6	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7
		3	0	3	3	3	3	1	7	0	2	2	3	2	3	3	2	3	5	3	2	2	2	3	3
		1	9	6	1	0	1	3	3	3	9	9	0	9	0	1	9	0	7	1	9	9	9	1	0
B6C3F1 MICE 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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	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	
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	

males
(cont...)

Bilateral, Hydronephrosis
Papilla, Necrosis

Ureter

Urinary Bladder
+
Calculus Gross Observation
Infiltration Cellular, Lymphocyte
Inflammation, Chronic
Transitional Epithelium, Hyperplasia

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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|
| | 0731 | 0732 | 0733 | 0734 | 0735 | 0736 | 0737 | 0738 | 0739 | 0740 | 0741 | 0742 | 0743 | 0744 | 0745 | 0746 | 0747 | 0748 | 0749 | 0750 | 0751 | 0752 | 0753 | 0754 | |
| B6C3F1 MICE 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 | |
| 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 | |
| ANIMAL ID | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | 0000 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.2 |
| Mixed Cell Focus | X | | | | | | | X | | | | | | | | | | | | | | | | 1 | 1.0 |
| Necrosis, Focal | | | 1 | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Bile Duct, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.7 |
| Hepatocyte, Vacuolization Cytoplasmic | 2 | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | 3 | 4.0 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | 4 | 2.0 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2.8 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2.8 |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 2.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.2 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 3 | 2.2 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 3.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | X | 5 |
| Edema | | | | | | | | | | | | | | | | | | | | | | | | X | 1 |

CARDIOVASCULAR 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 25

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|----------|
| | 0
7
3
1 | 0
7
2
9 | 0
5
6
3 | 0
7
3
2 | 0
7
2
9 | 0
7
2
9 | 0
7
2
9 | 0
7
3
0 | 0
7
2
9 | 0
7
3
1 | 0
7
2
9 | 0
7
2
9 | 0
7
3
0 | 0
6
7
7 | 0
7
2
9 | 0
7
3
8 | 0
7
3
3 | 0
6
2
2 | 0
6
2
5 | 0
7
5
5 | 0
7
3
0 | 0
7
3
2 | |
| B6C3F1 MICE MALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | * TOTALS |
| 3000 PPM | 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 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|--------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Cardiomyopathy | 1 | 2 | | 1 | | 2 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | | 1 | 2 | 2 | 1 | 2 | 42 1.3 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|--------|----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | |
| Hypertrophy, Focal | | 2 | | | | 2 | 1 | 1 | | | | | 1 | 2 | | 1 | 2 | | | | | | 2 | 1 | | 18 1.6 | | |
| Capsule, Hyperplasia | 1 | 2 | | | | 1 | 1 | 1 | 1 | | | | | 2 | | 1 | 1 | 1 | 1 | | | 1 | | 1 | 2 | 1 | 37 1.2 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Hyperplasia | | | 2 | 2 | | | 1 | | 2 | | | | | | | | | 2 | 2 | | | | | 2 | 1 | | 12 1.7 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | M | + | + | M | 45 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Follicle, Degeneration, Focal | | | | 2 | | | 1 | | 1 | 1 | | | | | | | | | | | | | 1 | | | | 6 1.2 | |

GENERAL BODY SYSTEM

NONE

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 5 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 6 6 5 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 2 6 3 2 2 2 3 2 3 2 2 3 7 2 3 8 3 3 2 2 5 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 9 3 2 9 9 9 0 9 1 9 9 0 7 9 0 0 0 0 4 5 5 0 2 1 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
3000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|---|-------|-------|
| Coagulating Gland
Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | + | 3 | 1 | 1 3.0 | |
| Epididymis
Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | | | X | 50 1 | |
| Preputial Gland
Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | 17 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 2.7 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | 4 3.0 |
| Prostate
Inflammation, Suppurative | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | 2 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Seminal Vesicle
Inflammation, Suppurative | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 |

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 27

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----|------|-----------------|
| | 0731 | 0732 | 0733 | 0734 | 0735 | 0736 | 0737 | 0738 | 0739 | 0740 | 0741 | 0742 | 0743 | 0744 | 0745 | 0746 | 0747 | 0748 | 0749 | 0750 | 0751 | 0752 | 0753 | 0754 | | 0755 | |
| B6C3F1 MICE 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 | 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 | 0 | |
| | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 7 | 7 | |
| | 3 | 2 | 6 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 7 | 2 | 3 | 8 | 3 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | 3 | |
| | 1 | 9 | 3 | 2 | 9 | 9 | 9 | 0 | 9 | 1 | 9 | 9 | 0 | 7 | 9 | 0 | 0 | 0 | 0 | 4 | 5 | 5 | 0 | 2 | 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 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 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 | | * TOTALS |
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Depletion Cellular | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Hyperplasia | 2 | 2 | 3 | | 3 | 2 | | | | 2 | | | | | | | 2 | 2 | 2 | 3 | | | | | | 17 | 2.1 |
| Lymph Node | | | | | + | | | | | + | | | | | | | | | | | | | | | | 5 | |
| Pancreatic, Hemorrhage | | | | | 3 | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Renal, Hemorrhage | | | | | 2 | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Lymph Node, Mandibular | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 46 | |
| Hyperplasia, Lymphoid | | | | | | 3 | | | | | | | | | | | | | | 3 | | | | | | 3 | 3.0 |
| Lymph Node, Mesenteric | + | + | M | + | + | M | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 44 | |
| Atrophy | | | | | | | | 3 | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.5 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | 49 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3.0 |
| Hematopoietic Cell Proliferation | 1 | 2 | 3 | 2 | 3 | 3 | | 4 | 1 | 2 | 2 | | 3 | 1 | | 3 | 3 | 3 | 2 | | 2 | 1 | 1 | 1 | 33 | 1.9 | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | 1 | | | 3 | 2.0 |
| Thymus | + | + | I | + | + | I | + | M | + | + | + | + | + | A | + | + | + | + | M | + | + | + | + | + | 39 | | |
| Atrophy | | | | | 4 | | | | | | | | | | | | 3 | 1 | | | | 4 | 3 | | | 8 | 2.9 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | 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 | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 7 | |
| 3 | 2 | 6 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 7 | 2 | 3 | 8 | 3 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | | |
| 1 | 9 | 3 | 2 | 9 | 9 | 9 | 0 | 9 | 1 | 9 | 9 | 0 | 7 | 9 | 0 | 0 | 0 | 0 | 4 | 5 | 5 | 0 | 2 | 1 | | |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-------|
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 |
| Epidermis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Maxilla, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Peripheral Nerve | | | | | | | + | | | | + | | | | | | | | | | | | | | | | 3 | |
| Spinal Cord | | | | | | | + | | | | + | | | | | | | | | | | | | | | | 2 | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Edema | | | | | | | | | | | | | | | | | | | | | | | | | | | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 7 5 7 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 6 6 5 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 2 6 3 2 2 2 3 2 3 2 2 3 7 2 3 8 3 3 2 2 5 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 1 9 3 2 9 9 9 0 9 1 9 9 0 7 9 0 0 0 0 4 5 5 0 2 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 3000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

Alveolar Epithelium, Hyperplasia 2 2.5

Nose 50
 Glands, Degeneration, Cystic 1 2.0

Trachea 50

SPECIAL SENSES SYSTEM

Eye 50
 Cornea, Inflammation, Chronic 1 2.0

Harderian Gland 50
 Hyperplasia, Focal 1 2.0

Lacrimal Gland 1

URINARY SYSTEM

Kidney 50
 Cyst 3
 Hydronephrosis 1 3.0
 Infarct 4 1.8
 Infiltration Cellular, Lymphocyte 2 1.5
 Inflammation, Suppurative 1 3.0
 Metaplasia, Osseous 1 2.0
 Nephropathy 43 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

TDMS No. 99007 - 06
 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: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | | |
| B6C3F1 MICE MALE | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 6 | 5 | 7 | 7 | 7 | |
| | 3 | 2 | 6 | 3 | 2 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 7 | 2 | 3 | 8 | 3 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | |
| 3000 PPM | 1 | 9 | 3 | 2 | 9 | 9 | 9 | 0 | 9 | 1 | 9 | 9 | 0 | 7 | 9 | 0 | 0 | 0 | 0 | 4 | 5 | 5 | 0 | 2 | 1 | |
| | ----- | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | 1 | |
| | 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 | * TOTALS |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bilateral, Hydronephrosis | | | | | | | | | | | | | | | | | | | 4 | 1 4.0 | | | | | | |
| Papilla, Necrosis | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | | | | | | |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ureter | | | | | | | | | | | | | | | | | | | + | 1 | | | | | | |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Calculus Gross Observation | | | | | | | | | | | | | | | | | | | | X | 1 | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | 3 | 1 3.0 | | | | | |
| Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | 3 | 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 31

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 7 6 7 7 7 7 6 5 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 2 2 5 3 3 3 3 6 3 3 3 3 2 5 3 3 2 2 3 3 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 9 9 1 0 0 0 1 6 1 0 1 0 1 4 1 0 1 9 9 2 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

males
(cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mixed Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis, Focal | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hyperplasia, Focal | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Hypertrophy | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Vacuolization Cytoplasmic | 1 1 1 2 1 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Vacuolization Cytoplasmic, Focal | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Kupffer Cell, Pigmentation | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR 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 - 06
 Test Type: CHRONIC
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | |
| 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 |
| 2 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 2 | 5 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 0 | 0 |
| 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 1 | 6 | 1 | 0 | 1 | 0 | 1 | 4 | 1 | 0 | 1 | 9 | 9 | 2 | 1 | 0 | 9 | 0 | 0 |

| B6C3F1 MICE MALE
9000 PPM | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Blood Vessel | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Cardiomyopathy | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | | | 1 | 1 | 2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hypertrophy, Focal | 2 | | | | | 2 | | | | | 1 | | | | | 1 | 3 | 2 | 1 | | | | | 1 | | | | |
| Capsule, Hyperplasia | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | | | | | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia | 2 | | | | | 2 | 2 | 2 | 2 | | | | | 2 | | | | | 2 | | | | | 2 | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Cyst | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | X | + | + | + | | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 2 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 2 | 5 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 0 |
| 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 1 | 6 | 1 | 0 | 1 | 0 | 1 | 4 | 1 | 0 | 1 | 9 | 9 | 2 | 1 | 0 | 9 | |

| ANIMAL ID | 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 | |
| 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 | 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 | | |

Follicle, Cyst
Follicle, Degeneration, Focal

X
1 1

GENERAL BODY SYSTEM
NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|--|--|--|---|---|---|--|--|--|---|--|---|---|---|---|---|---|---|---|--|---|
| Epididymis
Granuloma Sperm | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Preputial Gland
Atrophy | + | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Cyst | X | X | X | X | X | | | | X | X | X | | | | X | | X | X | X | X | X | X | X | X | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Bilateral, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prostate
Inflammation, Granulomatous
Epithelium, Hyperplasia | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Testes
Germinal Epithelium, 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 35
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 5 7 7 7 7 6 7 7 7 7 6 5 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 2 2 5 3 3 3 3 6 3 3 3 3 2 5 3 3 2 2 3 3 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 9 9 1 0 0 0 1 6 1 0 1 0 1 4 1 0 1 9 9 2 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 |
| 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 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males
(cont...)

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 1 3 2 3 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + + + + + + + + + + + + + + + + M + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 2 2 2 3 2 4 1 1 2 3 2 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Hyperplasia | 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + + M + + + + M + M + + M + + A + + + + I + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | |

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

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | |
| 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 2 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 2 | 5 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 2 | |
| 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 1 | 6 | 1 | 0 | 1 | 0 | 1 | 4 | 1 | 0 | 1 | 9 | 9 | 2 | 1 | 0 | 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 | |
| | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | 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 | + |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst Epithelial Inclusion | | | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | 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 37

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 5 7 7 7 7 6 7 7 7 7 7 6 5 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 2 2 5 3 3 3 3 6 3 3 3 3 3 2 5 3 3 2 2 3 3 3 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 9 9 1 0 0 0 1 6 1 0 1 0 1 4 1 0 1 9 9 2 1 0 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Nose Inflammation, Suppurative | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye Cataract | + + + + A + | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland Atrophy Infiltration Cellular, Lymphocyte | + | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Glomerulosclerosis | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte Metaplasia, Osseous Nephropathy | 2 2 2 1 2 1 1 2 2 1 1 2 1 2 2 1 3 1 1 1 2 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Papilla, Inflammation, Suppurative Renal Tubule, Accumulation, Hyaline Droplet | 2 2 2 1 2 1 1 2 2 1 1 2 1 2 2 1 3 1 1 1 2 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
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1) Minimal 3) Moderate
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TDMS No. 99007 - 06
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 Route: DOSED FEED
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Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
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 First Dose M/F: 05/12/03 / 05/12/03
 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 | 5 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 2 | 3 | 2 | 2 | 5 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | 3 | 3 | 2 | 5 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | |
| | 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 1 | 6 | 1 | 0 | 1 | 0 | 1 | 4 | 1 | 0 | 1 | 9 | 9 | 2 | 1 | 0 | 9 | |
| B6C3F1 MICE 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 | |
| | 0 | 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 | |
| 9000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 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 | males
(cont...) |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | 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

| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 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 | |
| | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 6 | 2 | | 9 | 0 | 2 | 0 | 9 | 1 | 9 | 1 | 0 | 0 | 9 | 0 | 0 | 1 | 9 | 1 | 0 | 9 | 9 | 0 | 2 | 0 | 9 | 3 | 9 | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 11 |
| Eosinophilic Focus | X | | X | | | | | | | | | | | | | | | | | X | X | | X | | X | 14 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.5 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.0 |

* .. 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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 5 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
9000 PPM | 2 3 3 3 2 3 2 3 3 3 2 3 3 3 2 3 3 2 2 3 3 3 2 6 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 2 0 9 1 9 1 0 0 9 0 0 1 9 1 0 9 9 0 2 0 9 3 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 4 4 4 4 5 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|-----|
| Mixed Cell Focus | | | | X | X | X | X | | | | | | | | | | | | X | | | | X | 9 | | | |
| Necrosis, Focal | | | 2 | | | | 2 | 2 | | | | | | | | | | | | | | | | 5 | 1.8 | | |
| Hepatocyte, Hyperplasia, Focal | | | 4 | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 | | |
| Hepatocyte, Hypertrophy | | | | | | | 3 | | | | | | | | | | | | | | | | | 1 | 3.0 | | |
| Hepatocyte, Vacuolization Cytoplasmic | 1 | 2 | | | 1 | | | | | 2 | | | | 1 | | | | 2 | 2 | | | | 2 | 15 | 1.6 | | |
| Hepatocyte, Vacuolization Cytoplasmic, Focal | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | | |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | 2 | | 2 | 2.0 | | |
| Mesentery | | | | + | + | | | + | + | | | | | | | | | | | | | | + | 12 | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 | |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| Fat, Necrosis | | | | 1 | 3 | | | 3 | | | | | | | | | | | | | | | | | 6 | 2.7 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | 1 | | | 1 | | | | | | | | | | | | 2 | 1.0 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 | 3 | 2.3 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | |
| Cyst | | | | | | | | | | | | X | | | | | | | | | | X | | | | 3 | |

CARDIOVASCULAR 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------|
| | 7 5 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 3 3 2 3 2 3 3 3 2 3 3 3 2 3 3 2 2 3 3 3 2 6 2 | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 2 0 9 1 9 1 0 0 9 0 0 1 9 1 0 9 9 0 2 0 9 3 9 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| 9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|--|---|---|--|---|---|---|---|---|---|---|---|---|---|----|-----|
| Blood Vessel | | | | | | | | | | | | | | | | | | | | | | | | + | 1 | |
| Heart | | | | | | | | | | | | | | | | | | | | | | | | + | 50 | |
| Cardiomyopathy | 3 | 1 | 1 | 2 | 1 | 1 | 1 | 2 | 1 | 2 | | 1 | 2 | | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 1 | 2 | 44 | 1.5 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|--|---|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|-----|
| Adrenal Cortex | | | | | | | | | | | | | | | | | | | | | | | | + | 50 | |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 3 3 | |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Capsule, Hyperplasia | 1 | 2 | 1 | 1 | 1 | 2 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 41 | 1.1 |
| Adrenal Medulla | | | | | | | | | | | | | | | | | | | | | | | | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Islets, Pancreatic | | | | | | | | | | | | | | | | | | | | | | | | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 2 3 | |
| Parathyroid Gland | | | | | | | | | | | | | | | | | | | | | | | | + | 47 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | X | |
| Pituitary Gland | | | | | | | | | | | | | | | | | | | | | | | | + | 49 | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | M | |
| Thyroid Gland | | | | | | | | | | | | | | | | | | | | | | | | + | 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 42

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 5 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 3 3 2 3 2 3 3 3 2 3 3 2 3 3 2 2 3 3 3 2 6 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 9 0 2 0 9 1 9 1 0 0 9 0 0 1 9 1 0 9 9 0 2 0 9 3 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicle, Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Follicle, Degeneration, Focal | 1 X 2 X 2 X 1 | | | | | | | | | | | | | | | | | | | | | | | | 6 1.3 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-------|-------|
| Epididymis | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Granuloma Sperm | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 | |
| Preputial Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | X | 25 | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 4 2.0 | |
| Inflammation, Suppurative | 3 | | | | | | | | | | | | | | | | | | | | | | | | 3 | 4 3.3 | |
| Inflammation, Chronic | 3 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 2.7 | |
| Bilateral, Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Prostate | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Inflammation, Granulomatous | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 | |
| Epithelium, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Seminal Vesicle | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Testes | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Germinal Epithelium, Atrophy | 3 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 5 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
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TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 5 | | 7 |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| | 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 |
| 9000 PPM | 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 | 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 | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|--|---|---|---|--|---|--|--|--|--|---|--|--|--|--|--|---|---|---|---|---|----|---|----|-----|--|--|--|--|----|-----|--|--|--|--|---|--|---|--|---|--|--|--|--|--|--|--|--|--|---|-----|---|-----|-----|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | 2 | | 3 | | 1 | | | | | | | | | | | | | | 1 | | 1 | | 1 | | | | | | | | 14 | 1.9 | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | | | | 1 | 2.0 | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 | |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | 2 | | | | | | | | | | | | | | 2 | 2.5 | |
| Hyperplasia, Plasma Cell | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 4 | | | | | | | | | | | | | | | | 1 | 4.0 | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 | 2.0 | |
| Hematopoietic Cell Proliferation | 1 | 1 | 2 | | 1 | 3 | 1 | | 1 | | | | | 1 | | | | | | 1 | 1 | 2 | | 2 | 1 | 1 | 27 | 1.8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | 2 | | | | | | | | | | | | | | | 4 | 1.8 |
| Thymus | + | | | | | | | | | | | | | | | | | | | | | | | | 43 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | | | | | | | | | 1 | 3.0 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | | | | | | | | | | | | 2 | | |

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 44

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|-------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B6C3F1 MICE MALE
9000 PPM | 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | |
| | | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 6 | 2 | |
| | | 9 | 0 | 2 | 0 | 9 | 1 | 9 | 1 | 0 | 0 | 9 | 0 | 0 | 1 | 9 | 1 | 0 | 9 | 9 | 0 | 2 | 0 | 9 | 3 | 9 |
| | 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 | |
| | | 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 | 0 |
| | | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

Mammary Gland

M + M 2

Skin
Cyst Epithelial Inclusion

+ + + + + + + + + + + X + + + + + + + + + + + + + + 50
1

MUSCULOSKELETAL SYSTEM

Bone

+ 50

Skeletal Muscle

+ 3

NERVOUS SYSTEM

Brain

+ 50

Peripheral Nerve

+ 1

Spinal Cord

+ 1

RESPIRATORY SYSTEM

Lung

+ 50

Infiltration Cellular, Histiocyte
Alveolar Epithelium, Hyperplasia

2 1 1.0
3 1.7

* .. 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
Page 45
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | | |
| | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 2 | 6 | 2 | |
| | 9 | 0 | 2 | 0 | 9 | 1 | 9 | 1 | 0 | 0 | 9 | 0 | 0 | 1 | 9 | 1 | 0 | 9 | 9 | 0 | 2 | 0 | 9 | 3 | 9 | |
| B6C3F1 MICE MALE
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 | |
| | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----|-----|--|
| Nose
Inflammation, Suppurative | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 2.0 | |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|-----|---|-----|
| Eye
Cataract | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1 | 1.0 | | |
| Harderian Gland
Atrophy
Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 1 | 3.0 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---|----|-----|-----|
| Kidney
Cyst
Glomerulosclerosis
Infiltration Cellular, Lymphocyte
Metaplasia, Osseous
Nephropathy
Papilla, Inflammation, Suppurative
Renal Tubule, Accumulation, Hyaline
Droplet | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | 9 | 1 | 3.0 | |
| | | | X | | | | | | X | X | | | | | | | | | | | | | X | X | | | | 2 | 2.0 |
| | | | | | | | | 2 | 2 | | | | | | | | | | | | | | | | | | 2 | 1.5 | |
| | 2 | 1 | 1 | | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 1 | 1 | 4 | 2 | 2 | | 1 | 2 | | 46 | 1.5 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | 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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-----------------|-----------------|------------|---|
| | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | 0729 | | | | |
| B6C3F1 MICE 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 | 9000 PPM | 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 | | |
| | 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 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | | 4 | 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 | | * TOTALS | 50 | |
| Urinary Bladder Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 9 3 3 3 3 3 2 2 3 3 3 3 1 3 2 3 2 9 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 1 0 0 6 1 1 1 2 0 9 9 1 0 1 1 0 0 9 0 9 7 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + + + + + + + + + + + + + + + + + A + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum
Hyperplasia, Lymphoid
Epithelium, Hyperplasia | + + + + + + + + + + + + + + + + + A + + + + + A + +
3
2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | X X | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X X X X X X X X | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | X X X X X X 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
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 1) Minimal 3) Moderate
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TDMS No. 99007 - 06

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Date Report Requested: 08/14/2008

Test Type: CHRONIC

Goldenseal root powder

Time Report Requested: 12:25:59

Route: DOSED FEED

CAS Number: GOLDENSEALRT

First Dose M/F: 05/12/03 / 05/12/03

Species/Strain: MICE/B6C3F1

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

| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| B6C3F1 MICE 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 |
| 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 |
| | 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 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|--|--|--|--|--|--|--|---|--|---|--|--|--|--|--|--|--|--|--|---|---|--|---|---|
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | | | | | | | | X | | X | | | | | | | | | | | | | X | X |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatocyte, Vacuolization | | | | | | | | | | | | | | | | | | | | 3 | 1 | | | 3 |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | 1 |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | 2 | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

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

CARDIOVASCULAR SYSTEM

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

* .. 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 49

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
25000 PPM | 3 3 3 3 3 9 3 3 3 3 3 2 2 3 3 3 3 1 3 2 3 2 9 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 1 0 0 6 1 1 1 2 0 9 9 1 0 1 1 0 0 9 0 9 7 0 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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...)

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex
Hypertrophy, Focal
Capsule, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | 1 | 2 | | 1 | 1 | 1 | 1 | | | | 2 | | 1 | 2 | 2 | | 1 | 1 | 2 | 1 | | 1 | 1 | | 1 |
| Adrenal Medulla | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Islets, Pancreatic
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland
Pars Distalis, Cyst
Pars Distalis, Hyperplasia, Focal | + | + | + | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Thyroid Gland
Follicle, Degeneration, Focal
Follicular Cell, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

GENERAL BODY SYSTEM

NONE

GENITAL 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 50

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 99007 - 06
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 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|--------------------|
| | 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 9 3 3 3 3 3 2 2 3 3 3 3 1 3 2 3 2 9 3 3 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | |
| | 1 1 1 0 0 6 1 1 1 2 0 9 9 1 0 1 1 0 0 9 0 9 7 0 0 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 | 0 | males
(cont...) |
| 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 | |
| | 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 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Epididymis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Preputial Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | X | | X | | | X | | | | | | | X | | | X | | | | | | | | X | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | | | | | | | | | | 3 | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | 2 | | | | | | 2 | | | | | | | | | | | | | | | |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | 2 | | | | | | | | 2 | |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Germinal Epithelium, Atrophy | | 2 | | | | | | | | | | | | | | | | | | | | | | | | |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | 3 | | | | | | | | | 3 | | | 2 | | 2 | | | | | 3 | | 1 | 2 | | | 1 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bronchial, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Lymph Node, Mandibular | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | Animals | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | |
|-------------------------|-------------|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|--------------------|--|
| | | 0731 | 0733 | 0734 | 0735 | 0756 | 0771 | 0777 | 0779 | 0783 | 0784 | 0792 | 0793 | 0794 | 0795 | 0796 | 0797 | 0798 | 0799 | 0800 | 0801 | 0802 | 0803 | 0804 | 0805 | 0806 | | |
| B6C3F1 MICE MALE | ANIMAL ID | 0011 | 0012 | 0013 | 0014 | 0015 | 0016 | 0017 | 0018 | 0019 | 0020 | 0021 | 0022 | 0023 | 0024 | 0025 | 0026 | 0027 | 0028 | 0029 | 0030 | 0031 | 0032 | 0033 | 0034 | 0035 | | |
| 25000 PPM | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Lymph Node, Mesenteric
 Hyperplasia, Histiocytic
 Hyperplasia, Lymphoid

+ M + + + +
 1
 3

Spleen
 Hematopoietic Cell Proliferation
 Hyperplasia
 Lymphoid Follicle, Hyperplasia

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

Thymus
 Atrophy
 Necrosis, Lymphoid

+ + + + + M + + M + M + + + + + + + + + + I + I + + I
 3
 3

INTEGUMENTARY SYSTEM

Mammary Gland

M + M M

Skin

+ +

MUSCULOSKELETAL SYSTEM

Bone

+ +

NERVOUS 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 52

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | |
| 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 0 | |
| 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 1 | 3 | 2 | 3 | 2 | 9 | 3 | 3 | 0 | |
| 1 | 1 | 1 | 0 | 0 | 6 | 1 | 1 | 1 | 2 | 0 | 9 | 9 | 1 | 0 | 1 | 1 | 0 | 0 | 9 | 0 | 9 | 7 | 0 | 0 | 0 | |
| B6C3F1 MICE MALE | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | |
| 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 | | |
| 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 | | |

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 2 |

URINARY 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 53

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

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

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | | | | | | | X | | | | | | | | | | | | | | X |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | 2 | | | | | |
| Metaplasia, Osseous | | | | | | | | | | 1 | | | | | | | | | | | | | | | |
| Nephropathy | 1 | 1 | 2 | 1 | 1 | | 2 | 2 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | | 1 | 1 | 2 | 3 |
| Renal Tubule, Pigmentation | | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | 2 | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 54

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 |
|---|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 |
| B6C3F1 MICE MALE
25000 PPM | | 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 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | |
| | | 1 | 1 | 0 | 0 | 1 | 9 | 1 | 2 | 2 | 9 | 0 | 9 | 0 | 1 | 9 | 1 | 9 | 1 | 0 | 9 | 9 | 1 | 0 | 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 | * TOTALS | | | | |
|---------------------------------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|---|---|-------|
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | 1 | | | | | | | | | 4 1.0 |
| Mixed Cell Focus | | | | X | | | | | | | | | | | | | | X | | | | | | | | 6 |
| Necrosis, Focal | | 2 | | | | | 1 | | | 2 | | | | | | | | | | | | | | | | 6 2.0 |
| Hepatocyte, Vacuolization Cytoplasmic | | | 1 | | | | | | | 2 | | | | | | | | | 2 | 1 | | | | | | 7 1.4 |
| Kupffer Cell, Pigmentation | | | | | | | | | | 2 | | | | | | | | | | | | | | | | 1 2.0 |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Fibrosis | | | | | | | | | | | 3 | | | | | | | | | | | | | | | 1 3.0 |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | 3 | | | | | | | | | | | | | | | 2 3.0 |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | 2 | | | | | | | | | 2 | 2 2.0 |
| ----- | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | X | | | | 1 |
| Erosion | | | | | | | | | | 1 | | | | | | | | | | | | | | | | 4 1.3 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--------|
| Heart | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cardiomyopathy | | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 2 | 1 | 2 | 1 | 1 | 1 | | | 1 | 1 | 1 | | 2 | 1 | 2 | 2 | 1 | 1 | 44 1.4 |

* .. 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

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TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | |
| | 1 | 1 | 0 | 0 | 1 | 9 | 1 | 2 | 2 | 9 | 0 | 9 | 0 | 1 | 9 | 1 | 9 | 1 | 0 | 9 | 9 | 1 | 0 | 1 | 1 | |
| B6C3F1 MICE MALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|--|---|---|--|---|---|---|---|--|---|---|--|---|---|---|---|---|---|---|---|----|-----|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hypertrophy, Focal | 1 | | | | | | | | | | | | | | | | | | | | | | | | 5 | 1.8 |
| Capsule, Hyperplasia | 1 | 1 | 2 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 2 | | 1 | 1 | 1 | 2 | 2 | 1 | 2 | 1 | 37 | 1.2 |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | 4 | 1.5 |
| Parathyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Pituitary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Pars Distalis, Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Pars Distalis, Hyperplasia, Focal | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Thyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Follicle, Degeneration, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |

GENERAL BODY SYSTEM

NONE

GENITAL 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 57

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 |
| | 1 | 1 | 0 | 0 | 1 | 9 | 1 | 2 | 2 | 9 | 0 | 9 | 0 | 1 | 9 | 1 | 9 | 1 | 0 | 9 | 9 | 1 | 0 | 1 | 1 | 1 |
| B6C3F1 MICE 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 | |
| | 0 | 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 | |
| | 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 | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------|
| Epididymis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Preputial Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | X | | | X | X | | X | X | X | | | | | | | | | | | | X | | | | | 13 |
| Hyperplasia | 2 | | | 2 | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Inflammation, Suppurative | 3 | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Prostate | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | 1 | | | | | | | | | | | 3 1.7 |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Testes | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Germinal Epithelium, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2 2.5 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | 2 | | | | | | | | | 2 | | | | 1 | | | | | | | | | | | | 14 2.0 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Bronchial, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 3 2 2.5 |

* .. 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 58

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 2 3 2 3 2 3 2 3 3 2 3 3 2 2 3 3 2 2 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 0 0 1 9 1 2 2 9 0 9 0 1 9 1 9 1 0 9 9 1 0 1 1 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 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 | | | | | | | | | | | | | | | | | | | | | | | |
| * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | |
|---|---|----|--------|
| Lymph Node, Mesenteric
Hyperplasia, Histiocytic
Hyperplasia, Lymphoid | + + + + + + + M + + + + + + + + + + + + + + + + + + | 48 | 1 1.0 |
| | 2 | | 2 2.5 |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia
Lymphoid Follicle, Hyperplasia | + | 50 | 20 1.9 |
| | 3 1 1 1 1 4 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | 1 1.0 |
| | 1 | | 3 2.3 |
| | 2 | | |
| Thymus
Atrophy
Necrosis, Lymphoid | + + + + + + + M + + I + + + + + + + + + + I + + + + | 41 | 2 2.5 |
| | 2 | | 1 3.0 |

INTEGUMENTARY SYSTEM

| | | |
|---------------|---|----|
| Mammary Gland | M | 1 |
| Skin | + | 50 |

MUSCULOSKELETAL SYSTEM

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

NERVOUS 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 2 3 2 3 2 3 2 3 3 2 3 3 2 2 3 3 2 2 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 1 0 0 1 9 1 2 2 9 0 9 0 1 9 1 9 1 0 9 9 1 0 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 |
| Nephropathy | 2 2 1 1 2 1 2 3 1 1 2 1 1 1 2 1 1 1 2 2 1 2 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 48 1.5 |
| Renal Tubule, Pigmentation | 3 | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Lymphocyte | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

*** END OF MALE DATA ***

* .. 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 61

TDMS No. 99007 - 06
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
Time Report Requested: 12:25:59
First Dose M/F: 05/12/03 / 05/12/03
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 | | |
| B6C3F1 MICE FEMALE
0 PPM | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | | |
| ANIMAL ID | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 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 | 0 | | |
| | 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 | | |
| | 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...) |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Ileum
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | X | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 1 | 1 | 1 | 2 | 1 | | | | | | | | | | | | | | 2 | | 1 | | | | | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | 1 | | | 1 | | | | | | | | 1 | | | | | | |
| Necrosis, Focal | | | | | | | | | | | | | | | 1 | | | | | | | | | | | |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 3 | 3 | 3 | 3 | 3 | |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | + | | | | | | + | | | | + | + | | | | + | + | + |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | 2 | | | | | 2 | | | | | 2 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

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

* .. 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 63

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 3 0 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 2 3 3 3 3 3 6 6 6 6 1 2 2 2 9 2 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 |
| 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 |
| | 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 | 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...)

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Accessory Adrenal Cortical Nodule | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | 1 | | | | | | | | | | |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | 1 | | | | | |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | |
| Capsule, Hyperplasia | 2 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 2 | 1 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | 2 | | | | | | | | | | | | | | | | | | | | 2 |
| Parathyroid Gland | + | + | + | + | + | I | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Lymphocyte | | | | 2 | | | | | | | | | | | | | | | | | | | | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia, Focal | | | | 2 | | | 2 | | | | | | | 2 | | | 2 | 1 | | 2 | | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Follicle, Degeneration, Focal | 1 | | | 2 | | | 2 | | | | | | 1 | | | 2 | 2 | | | | 1 | 1 | | 1 |

GENERAL BODY 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

| | 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 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 3 | 3 | 3 | 3 | 3 |
| B6C3F1 MICE FEMALE
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 |
| | 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 | 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...)

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | X | + | + |
| Ovary Cyst | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | 2 | | | | 2 | | | | | | | 1 | | | 2 | | | | | | | | | | | 1 |
| Corpus Luteum, Hyperplasia | 2 | | | 2 | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Uterus Hyperplasia, Cystic Inflammation, Suppurative | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 3 | 4 | 2 | 3 | 3 | 3 | 3 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone Marrow Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Lymph Node Pancreatic, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. 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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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 | | | |
|---------------------------|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------------------|
| B6C3F1 MICE FEMALE | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | | |
| | | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | | | |
| | | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 3 | 3 | 3 | | | |
| | 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 | | | |
| | | 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 | 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...) |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hyperplasia, Lymphoid Pigmentation | 3 | 3 | | | | | | | 3 | | | | | 2 | | | 3 | | | | | | | | |
| Lymph Node, Mesenteric Hyperplasia, Histiocytic Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | I | + | + | + | |
| | | | | 2 | | | | | | | | | | | 1 | | | 3 | | | 2 | | | | |
| Spleen Hematopoietic Cell Proliferation Lymphoid Follicle, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | 2 | | 3 | 2 | | 2 | | 2 | 3 | | 3 | 3 | | | 3 | 1 | | 3 | 3 | | 2 | 2 |
| Thymus Hemorrhage Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | 2 | | 3 | | | | | | | | | | | | | | | | | | | 2 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + |
| Skin Edema | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | 3 | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

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

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

Page 66

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 0 |
| 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 3 | 3 | 3 | 3 | 3 | 0 |

B6C3F1 MICE FEMALE
0 PPM

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | 2 | | | | | | 2 | | | | | | | | | | | 2 | | | |
| Inflammation, Chronic | | | | | | | | | | 2 | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | 1 | | | | | | | | | | | | | | | | | | | |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-----|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

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 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 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 0 |
| 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 1 | 2 | 2 | 2 | 9 | 2 | 3 | 3 | 3 | 3 | 3 | 0 |

B6C3F1 MICE FEMALE
0 PPM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Cornea, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Casts Protein | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Nephropathy | 1 | | | | | | | | | | | | | | 1 | 1 | 1 | | | | 1 | 1 | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Lymphocyte | 1 | | | | | | | | | | | | | | | | | | 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
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 68

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 3 | 5 | 3 | 3 | 4 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | |
| B6C3F1 MICE FEMALE
0 PPM | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|-------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Gallbladder | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Intestine Small, Ileum
Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | 1 2.0 |
| Intestine Small, Jejunum | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 24 1.2 | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | 7 1.0 | |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Tension Lipidosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |

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TDMS No. 99007 - 06
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| DAY ON TEST | 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Hepatocyte, Vacuolization Cytoplasmic | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Mesentery | + | | | | | | | | | | | | | | | | | | | | | | | | 10 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Fat, Necrosis | 2 1 | | | | | | | | | | | | | | | | | | | | | | | | 8 2.0 |
| Pancreas | + + + + + + + + A + + + + + + + + M + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 48 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Cyst | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Acinus, Cytoplasmic Alteration | 1 | | | | | | | | | | | | | | | | | | | | | | | | 4 1.5 |
| Salivary Glands | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Fibrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Lymphocyte | 1 | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Stomach, Forestomach | + + + + + + + + + + + + + + + + + + A + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Inflammation, Chronic | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Stomach, Glandular | + + + + + + + + + + X + + + + + + + + A + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | 7 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---------------|
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cardiomyopathy | 2 1 | | | | | | | | | | | | | | | | | | | | | | | | 39 1.2 |
| Mineralization | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 7 7 7 7 7 7 7 7 5 7 7 5 7 7 6 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 1 3 3 3 3 3 0 3 3 3 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 2 2 2 2 6 2 3 5 3 3 4 2 2 1 2 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 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 |
| | 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 | 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 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|--------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Capsule, Hyperplasia | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 49 2.0 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | 48 | |
| Hyperplasia | | 2 | | | | | | | | | | | | | | | | | | | | | | | 4 2.0 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | M | + | M | + | + | + | + | + | + | M | + | + | + | + | + | + | 45 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Pars Distalis, Hyperplasia, Focal | | 1 | | | | | | | | | | | | | | | | 2 | | | | | | | 8 1.8 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Follicle, Degeneration, Focal | | | | 1 | | | | | 2 | | 1 | | | | | | 2 | | | | | 1 | 2 | 2 | 1 | 18 1.4 |

GENERAL BODY 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|
| | 7 7 7 7 7 7 7 7 5 7 7 5 7 7 6 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 1 3 3 3 3 3 0 3 3 3 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 2 2 2 2 6 2 3 5 3 3 4 2 2 1 2 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 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 | |
| | 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 | 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 | |

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | X | | | | | | | | | | | | | | | | | | | 2 |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 49 |
| Cyst | | X | | X | | | | | | | | | | | | X | | X | | X | | | | | 10 |
| Hemorrhage | | | | | | | | 1 | | 1 | | | 3 | 1 | | | | | | | | | | | 10 |
| Corpus Luteum, Hyperplasia | | | | | 3 | | | | | | | | | | | | | | | | | | | | 1.6 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2.3 |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia, Cystic | 1 | 3 | 1 | 2 | 3 | 2 | 3 | 2 | | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 48 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | 2.5 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|
| Bone Marrow | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Myelofibrosis | | | | | 2 | | | 2 | | | | | | | | | | | | | | | | | 3.5 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2.0 |
| Lymph Node | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pancreatic, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 6 |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|---|---|
| | 7 7 7 7 7 7 7 7 5 7 7 5 7 7 6 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 1 3 3 3 3 3 0 3 3 3 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 2 2 2 2 6 2 3 5 3 3 4 2 2 1 2 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 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 |
| | 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 | 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 |
| | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|--|
| Hyperplasia, Lymphoid Pigmentation | 2 | | | | | | | | | | | | | | | | | | | | | | | | 3 | | | 6 2.8
1 2.0 |
| Lymph Node, Mesenteric Hyperplasia, Histiocytic Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | | | | 48
1 1.0
4 2.5 |
| Spleen Hematopoietic Cell Proliferation Lymphoid Follicle, Hyperplasia | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | | | | 48
5 3.0
24 2.4 |
| Thymus Hemorrhage Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | 2 | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | | | | 49
1 2.0
4 2.5 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|---------------------------|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | 49 |
| Skin Edema | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | 50
1 3.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|-----------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | 50 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | | 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 73

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 7 7 7 5 7 7 5 7 7 6 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 1 3 3 3 3 3 0 3 3 3 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 2 2 2 2 6 2 3 5 3 3 4 2 2 1 2 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|
| Brain | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Peripheral Nerve | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Spinal Cord | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.9 |
| Inflammation, Chronic | 1 | | | | | | | | | | | | | | | | | | | | | | | | | 2.0 |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|----|
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | A | 49 |
|-----|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|----|

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 7 | 5 | 7 | 7 | 5 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 |
| 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0 |
| 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 2 | 3 | 5 | 3 | 3 | 4 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 0 |

B6C3F1 MICE FEMALE
0 PPM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|------------|
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Cornea, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---|--|--|--|--|--|--|--|--|--|--|--|--|---|---|-----------|------------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | | | | | | | | | | | | | | |
| Casts Protein | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 | 1 | | | | | | | | | | | | | | | | | | | | | 1 | 2 | 1 | 1 | | | | | | | | | | | | | 1 | 1 | 13 | 1.1 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 75

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | | |
| 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 0 | |
| 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | 0 |
| 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 | 0 |

B6C3F1 MICE FEMALE
3000 PPM

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Gallbladder
Inflammation, Chronic | A | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Large, Cecum | A | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Large, Rectum | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Small, Duodenum | A | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Small, Ileum | A | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Small, Jejunum
Hyperplasia, Lymphoid | A | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 5 7 7 7 7 7 4 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 3 3 3 3 8 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 1 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 6 6 6 6 6 6 3 3 9 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 |
| 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 |
| | 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 | |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Necrosis, Focal
Tension Lipidosis
Hepatocyte, Vacuolization Cytoplasmic | 1 | | | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Mesentery
Fat, Necrosis | + | 3 | | | | | | | | | | | | | | | | | | | | | | | + | + | |
| Pancreas
Atrophy
Cyst
Inflammation, Granulomatous, Chronic
Acinus, Cytoplasmic Alteration | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | |
| | | | | | | | | 1 | X | | | | | | | | | | | | | | | | | | |
| Salivary Glands
Fibrosis
Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | | 2 | | | | | | | | | | | | | | | | | | | | 2 | |
| Stomach, Forestomach
Edema
Inflammation, Granulomatous, Chronic
Ulcer
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Stomach, Glandular
Cyst | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| | | | | | | | | | | | | | X | X | | | | | | | | | | | | | |

CARDIOVASCULAR 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:
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TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | |
| | 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | |
| | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 |
| B6C3F1 MICE 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 | 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 | 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 | 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 | | |

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

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Degeneration, Fatty | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Focal | | | | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hypertrophy, Focal | | | | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Granulomatous, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Capsule, Hyperplasia | 1 | 2 | 1 | 2 | 1 | 3 | 1 | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 2 | 3 | 2 | 2 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 1 | 2 | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia | 2 | | | | | | | | | | | | | | | 1 | | | | | | | | | | | | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | M | + | + | + | M | M | + | + | + | + | + | + | + | + | + | + | M | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | X | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | 1 | 2 | | | | | | | | | | | | | 2 | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

* .. 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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | Animals | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 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 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | |
| 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | Animals | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 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 | 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...)

Inflammation, Suppurative Follicle, Cyst
Follicle, Degeneration, Focal

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|---|--|---|--|--|--|---|--|--|--|--|--|--|--|---|---|--|--|--|---|---|
| X | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | 2 | | 1 | | | | 2 | | | | | | | | 2 | 1 | | | | 2 | 2 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland Cyst | + | + | + | + | + | + | + | + | X | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary Angiectasis | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary Cyst | | X | | | X | | | X | X | X | | X | | X | | | | | X | | | | | |
| Ovary Hemorrhage | | | | | | | | | | | | 2 | | | | | | | 1 | | | | | |
| Ovary Thrombosis | 4 | | | | | | | | | | | | | | | | | | | | | | | |
| Ovary Bilateral, Cyst | | | | | | | | | | | | | | | | | | | | | | X | | |
| Ovary Corpus Luteum, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Uterus Hyperplasia, Cystic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Uterus Infiltration Cellular, Histiocyte | 2 | 3 | 3 | 3 | 3 | 1 | 2 | 3 | 3 | 4 | 3 | 2 | 3 | 3 | 2 | 1 | 3 | 2 | 1 | 3 | 2 | 2 | | 3 |
| Uterus Inflammation, Granulomatous, Chronic | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | 3 |

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
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TDMS No. 99007 - 06

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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 | |
| 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | |
| 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 | |
| B6C3F1 MICE FEMALE | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | |
| 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 | 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 | 4 | 5 | | |

Bone Marrow
Hyperplasia
Myelofibrosis

+ +

3

Lymph Node

+ +

+

Lymph Node, Mandibular
Hyperplasia, Lymphoid

+ + + + + 3 + + + + + 2 + + + + + + + + + + + + + + + + + +

Lymph Node, Mesenteric
Ectasia
Hyperplasia, Histiocytic
Hyperplasia, Lymphoid
Inflammation, Granulomatous, Chronic

+ M + + + + + + + + M + + + + + + + + + 3 + + + A + +

2

Spleen
Hematopoietic Cell Proliferation
Lymphoid Follicle, Hyperplasia

+ A + +

2 3

2 2 2 2 2 3 2 2 1 2 2 1 2 2

Thymus
Atrophy
Hyperplasia, Lymphoid
Necrosis, Lymphoid

+ M +

2

3 2

INTEGUMENTARY SYSTEM

Mammary Gland

+ M + +

* .. 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) Minimal 3) Moderate
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TDMS No. 99007 - 06

Test Type: CHRONIC

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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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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 |
|--|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | | 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 1 | 3 | 3 | |
| | | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 |
| B6C3F1 MICE FEMALE
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 | |
| | | 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 | 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 | 4 | |

females (cont...)

Cyst Hyperplasia

Skin +

MUSCULOSKELETAL SYSTEM

Bone +

Skeletal Muscle +

NERVOUS SYSTEM

Brain Compression +

RESPIRATORY SYSTEM

Lung Infiltration Cellular, Lymphocyte Alveolar Epithelium, Hyperplasia + 2 2

Nose +

Trachea +

* .. 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | 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 | |
| | 5 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| | 2 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 9 | 3 | 3 |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | 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 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Eye | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |
| Harderian Gland
Hyperplasia, Focal | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 4 | |
| Hydronephrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Infarct | | | | | | | | | | | | | | | | 1 | | | | | | | | | 2 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | 1 | | | | | | | | | 1 | | 2 | 2 |
| Metaplasia, Osseous | | | | | | | 2 | | | | | | | | | | | | | | | | | | | 2 |
| Nephropathy | | | 1 | | | | 1 | 1 | 1 | 1 | | | | 1 | 1 | 1 | 1 | | | | | | | | | |
| Renal Tubule, Dilatation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Transitional Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | 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

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|----------|
| | 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 4 7 7 7 7 6 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
3000 PPM | 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 3 3 2 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 3 3 3 3 3 2 2 2 2 2 6 3 3 3 3 3 3 8 3 3 2 2 2 6 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 3000 PPM | 2 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Gallbladder Inflammation, Chronic | + | | | | | | | | | | | | | | | | | | | | | | | | 46 |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Intestine Large, Cecum | + | | | | | | | | | | | | | | | | | | | | | | | | 46 |
| Intestine Large, Colon | + | | | | | | | | | | | | | | | | | | | | | | | | 48 |
| Intestine Large, Rectum | + | | | | | | | | | | | | | | | | | | | | | | | | 47 |
| Intestine Small, Duodenum | + | | | | | | | | | | | | | | | | | | | | | | | | 46 |
| Intestine Small, Ileum | + | | | | | | | | | | | | | | | | | | | | | | | | 46 |
| Intestine Small, Jejunum Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | 46 |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Hematopoietic Cell Proliferation | X | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Infiltration Cellular, Lymphocyte | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 2 1 1 1 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | 24 1.1 |
| Infiltration Cellular, Mixed Cell | 1 | | | | | | | | | | | | | | | | | | | | | | | | 9 1.0 |
| Mixed Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|---|-------|--|--|--|
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | | | | | | | |
| B6C3F1 MICE FEMALE
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 | 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 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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
Tension Lipidosis
Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | 1 | | | | | | | | | | | | | | | | | | | 1 | 1.0 | | | |
| | | | | | | | X | | | | | | | | | | | | | | | | | | | | | 1 | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.7 | | | |
| Mesentery
Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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CARDIOVASCULAR SYSTEM

* .. 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 - 06
 Test Type: CHRONIC
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 Species/Strain: MICE/B6C3F1

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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 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | | |
| | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 2 | 6 | 2 | | |
| B6C3F1 MICE 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 | | |
| 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 | | |
| | 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 | | |
| | 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 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|---------------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cardiomyopathy | 1 | 2 | | 1 | | 1 | 1 | 1 | 1 | 1 | 2 | 1 | | 1 | 2 | 1 | 1 | | 1 | 1 | | | 1 | 2 | 1 | 38 1.1 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|---------------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | 3 | | 1 3.0 | |
| Degeneration, Fatty | | | | | 2 | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Inflammation, Granulomatous, Chronic | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 2.0 | |
| Capsule, Hyperplasia | 3 | 2 | 2 | 3 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 1 | 2 | 1 | 2 | 2 | 3 | 2 | 1 | 1 | 2 | 50 1.8 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | 1 | | | | | | | 1 | 2 1.0 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 44 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 2.0 | |
| Pituitary Gland | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Angiectasis | | | | | | | | | | | | 1 | | | | | | | | | | | | | 1 1.0 | |
| Pars Distalis, Hyperplasia, Focal | | | | | 2 | | | | | | | | | | 2 | | | | | | | | | | 5 1.8 | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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
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 1) Minimal 3) Moderate
 2) Mild 4) Marked

TDMS No. 99007 - 06
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|--------|
| | 7 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
3000 PPM | ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 2 7 7 7 7 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 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Follicle, Degeneration, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 18 1.6 |

GENERAL BODY SYSTEM
NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|--|
| Clitoral Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 3 | |
| Ovary | + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 14 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 6 1.7 | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Bilateral, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Corpus Luteum, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Uterus | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Hyperplasia, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 46 2.4 | |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Inflammation, Granulomatous, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 | |

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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 4 7 7 7 7 6 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 3 3 2 3 3 3 3 3 9 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 3 3 3 3 2 2 2 2 2 6 3 3 3 3 3 3 8 3 3 2 2 2 6 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 3000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.5 |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3.0 |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Lymph Node, Mandibular | + + + + + + + + + + M + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 2.5 |
| Lymph Node, Mesenteric | + + + M + M + + + + + + + + + + + + A + M + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 43 | |
| Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3.0 |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 2.0 |
| Inflammation, Granulomatous, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 4 | 4.0 |
| Spleen | + + + + + + + + + + + + + + + + A + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.4 |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.1 |
| Thymus | + + M + | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | 2.5 |
| Necrosis, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|

* .. 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 87

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | |
| | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 6 | 3 | 3 | 3 | 3 | 3 | 8 | 3 | 3 | 2 | 2 | 2 | 6 | 2 | |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | |
| | 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 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|-------|
| Cyst Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | X | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|-------|
| Brain Compression | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|-------|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 2.0 |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | | 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 88

TDMS No. 99007 - 06
 Test Type: CHRONIC
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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Date Report Requested: 08/14/2008
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 First Dose M/F: 05/12/03 / 05/12/03
 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | 7 | 0 | |
| 3 | 0 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 0 | 1 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 1 | 0 | 3 | 3 | 3 | 0 | |
| 3 | 8 | 3 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 3 | 3 | 9 | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 6 | 5 | 2 | 2 | 2 | 0 | |

B6C3F1 MICE FEMALE
9000 PPM

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Gallbladder | + | M | + | + | + | + | A | + | + | + | + | A | + | + | + | A | + | + | + | + | M | A | + | + | + |
| Intestine Large, Cecum | + | A | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | A | A | + | + | + |
| Intestine Large, Colon | + | A | + | + | + | + | A | + | + | + | + | A | + | + | + | A | + | + | + | + | A | A | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | A | + | + | + |
| Intestine Small, Duodenum | + | A | + | + | + | + | A | + | + | + | + | A | + | + | + | A | + | + | + | + | A | A | + | + | + |
| Intestine Small, Ileum | + | A | + | + | + | + | A | + | + | + | + | A | + | + | + | A | + | + | + | + | A | A | + | + | + |
| Intestine Small, Jejunum | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | A | + | + | + |
| Hyperplasia, Lymphoid Inflammation, Suppurative | | | | | | | | | | | | 2 | | | | | | | | | | | | | |
| | | | | | | | | | | | | 1 | | | | | | | | | | | | | |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 1 | | 1 | | 1 | 1 | | 1 | | 1 | 1 | | 1 | 1 | 1 | | 1 | 1 | | | | 1 | 1 | | |
| Infiltration Cellular, Mixed Cell | | | | 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
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | 7 |
| 3 | 0 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 0 | 1 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 1 | 0 | 3 | 3 | 3 | |
| 3 | 8 | 3 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 3 | 3 | 9 | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 6 | 5 | 2 | 2 | 2 | |
| B6C3F1 MICE FEMALE
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 | |
| | 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 | 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 | |

females (cont...)

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|--|---|---|--|---|---|---|---|--|---|---|---|--|---|---|---|---|--|---|---|---|--|
| Blood Vessel | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Heart | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cardiomyopathy | 1 | 1 | 1 | | 1 | 1 | | 1 | 1 | 1 | 1 | | 2 | 1 | 1 | | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|---|---|---|
| Adrenal Cortex | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Degeneration, Cystic Capsule, Hyperplasia | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 3 | 2 | 2 | 1 | 1 | 2 | 2 | 2 | 2 | 1 | 2 | 1 | 2 | 1 | | 2 | 2 | 2 |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Amyloid Deposition | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Parathyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Pituitary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia, Focal | 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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|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 7 7 7 7 7 7 6 7 7 7 7 7 7 7 6 7 7 7 7 5 0 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
9000 PPM | 3 0 3 3 3 3 5 3 3 3 3 0 1 3 3 5 3 3 3 1 0 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 8 3 3 3 2 7 2 2 2 3 3 9 3 3 4 2 2 2 6 5 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 9000 PPM | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 0 0 0 0 0 0 0 0 0 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 |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Thyroid Gland | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicle, Degeneration, Focal | | | | 2 | | 1 | | | | | | | | | 1 | | 1 | | | | 1 | | 1 | | |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | 1 | | | | | | | | | | | | |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | X | | | | | | | | | | | | X | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | 2 | | 2 | | 1 | | | | | | | | | | | | | | | | | | | | |
| Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Hyperplasia, Cystic | 2 | 3 | 1 | 3 | 2 | 3 | 3 | 3 | 2 | 1 | 2 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 1 | | | | | | 2 | 2 | 3 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | 7 | |
| | 3 | 0 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 0 | 1 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 1 | 0 | 3 | 3 | 3 |
| | 3 | 8 | 3 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 3 | 3 | 9 | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 6 | 5 | 2 | 2 | 2 |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | 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 | 1 | 2 | 2 | 3 | 4 | 5 |
| | | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Myelofibrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | |
| Iliac, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreatic, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | |
| Ectasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |

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

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | Animals | | | | | | | | | | | | | | | | | | | | | | | | | 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | 7 | | |
| | | 3 | 0 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 0 | 1 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 1 | 0 | 3 | 3 | 3 | |
| | | 3 | 8 | 3 | 3 | 3 | 2 | 7 | 2 | 2 | 2 | 3 | 3 | 9 | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 6 | 5 | 2 | 2 | 2 | |
| B6C3F1 MICE FEMALE | 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 | | |
| 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 | | |
| | | 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 | |

Mammary Gland

+ + + + + M +

Skin

+ +

MUSCULOSKELETAL SYSTEM

Bone
Fracture

+ +

Skeletal Muscle
Necrosis

NERVOUS SYSTEM

Brain
Hemorrhage

+ +

Peripheral Nerve

+

Spinal Cord

+

RESPIRATORY SYSTEM

Lung

+ +

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 5 | 0 | 7 | 7 | 7 | |
| ANIMAL ID | 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 | |
| B6C3F1 MICE FEMALE
9000 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 | 3 | |
| 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 | |
| 9000 PPM | 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Foreign Body | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | 2 | | | | | | | | | | 2 | | | | | | | | | | | | | | |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Foreign Body | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Glands, Degeneration, Cystic | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye | + A + + + + + + + + + A + + + A + + + + + A + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Focal | 2 1 | | | | | | | | | | 2 | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|-----|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Casts Protein | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infarct | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | 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
Page 96

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

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|---|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|---|----------------------|
| | 0
7
3
3 | 0
7
0
8 | 0
7
3
3 | 0
7
3
3 | 0
7
3
3 | 0
7
3
2 | 0
6
5
7 | 0
7
3
2 | 0
7
3
2 | 0
7
3
2 | 0
7
3
3 | 0
7
3
3 | 0
7
0
9 | 0
7
3
3 | 0
7
3
3 | 0
6
5
4 | 0
7
3
2 | 0
7
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7
3
2 | 0
5
1
6 | 0
7
0
5 | 0
7
3
2 | 0
7
3
2 | 0
7
3
2 | | |
| B6C3F1 MICE 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 | |
| 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 | |
| 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 | 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 | |
| Metaplasia, Osseous Nephropathy | | | | 1 | 1 | | | 1 | | | | 1 | | | | 1 | 1 | 1 | | | 1 | | | 2 | | |
| Urinary Bladder Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |

* .. 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 97

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 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 |
| | | 6 | 7 | 7 | 3 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 |
| | | 7 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 7 | 3 | 3 | 9 | 3 |
| | | 2 | 2 | 2 | 9 | 2 | 6 | 6 | 3 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 9 | 3 | 3 | 7 | 3 | 3 | 3 | 3 |
| B6C3F1 MICE FEMALE | 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 |
| 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 |
| | | 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 |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|------------------------------|
| Esophagus | + M + + | | | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Gallbladder | + + + + + + + M + + + A + + + + A + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 39 |
| Intestine Large, Cecum | A + + + + + + + A + + + A + + + + + + + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 41 |
| Intestine Large, Colon | A + + + + + + + A + + + A + + + + + + + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 39 |
| Intestine Large, Rectum | A + + + + + + + A + + + A + + + + + + + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 43 |
| Intestine Small, Duodenum | A + + + + + + + A + + + A + + + + A + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 38 |
| Intestine Small, Ileum | A + + + + + + + A + + + A + + + + + + + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 39 |
| Intestine Small, Jejunum | A + + + + + + + + + + + A + + + + + + + + A + + A + + | | | | | | | | | | | | | | | | | | | | | | | | | | 43 |
| Hyperplasia, Lymphoid Inflammation, Suppurative | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0
1 1.0 |
| Liver | + A + + + + + | | | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Infiltration Cellular, Lymphocyte | 1 2 1 1 1 | | | | | | | | | | | | | | | | | | | | | | | | | | 26 1.1 |
| Infiltration Cellular, Mixed Cell | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | | | 10 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:
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TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|-------|-------|-------|---|---|----|
| | 6 7 7 3 7 7 7 6 7 7 7 6 7 7 7 6 7 7 6 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | |
| ANIMAL ID | 2 2 2 2 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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 | | | | | | |
| Mixed Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | |
| Capsule, Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | | | | |
| Hepatocyte, Vacuolization Cytoplasmic | 1 | 1 | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 7 1.9 | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | 9 | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | | | | |
| Fat, Necrosis | 3 | | | 2 | | | 2 | | | 2 | | | 3 | | | | | | | | | | | | 7 2.3 | | | | | | |
| Pancreas | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | 47 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | | | | | | |
| Artery, Inflammation | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | | | | | | |
| Infiltration Cellular, Lymphocyte | 1 | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 5 1.6 | | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | 48 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | X | | | | 1 2.0 | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 3 2.0 | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | 48 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | |
| Ulcer | 2 | | | | | | | | | | | | | | | | | | | | | | | X | | | | 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 99

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
| | 6 | 7 | 7 | 3 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | | |
| | 7 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 7 | 3 | 3 | 9 | 3 | 3 | |
| | 2 | 2 | 2 | 9 | 2 | 6 | 6 | 3 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 9 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | |
| B6C3F1 MICE FEMALE
9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|----|
| Blood Vessel | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cardiomyopathy | | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | | 1 | 1 | 37 1.0 | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|--------|
| Adrenal Cortex | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 | |
| Capsule, Hyperplasia | 1 | 2 | 2 | 1 | 2 | 2 | 2 | | 2 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 2 | 1 | | 1 | 2 | 2 | 2 | 2 | 47 1.6 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Amyloid Deposition | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.0 | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | 48 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| Pars Distalis, Hyperplasia, Focal | 2 | 1 | | | | | | | | | | | | | | | | | | | | | | 1 | 6 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

| 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 |
| 6 | 7 | 7 | 3 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 6 | 7 | 6 | 7 | 7 | |
| 7 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 5 | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 7 | 3 | 3 | 9 | 3 | 3 | |
| 2 | 2 | 2 | 9 | 2 | 6 | 6 | 3 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 3 | 9 | 3 | 3 | 7 | 3 | 3 | 3 | 3 | 3 | | |
| B6C3F1 MICE FEMALE
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 | |
| | 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 | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Follicle, Cyst | | | | | | | | | | | | | X | | | | | | | | | | | | 2 |
| Follicle, Degeneration, Focal | | | | | | 1 | 2 | | | | | 1 | | | 2 | 2 | | | 1 | | 2 | 1 | | 2 | 16 1.4 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Cyst | | | | | | | | | | | | X | | | | | | X | | | | X | | | 4 |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | X | | X | | | | | | | X | | X | X | | X | X | | 10 |
| Hemorrhage | | | | | | 2 | | 1 | | | | | | | | | | | | | | | | 2 | 7 1.6 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | 3 | | | 1 3.0 |
| Pigmentation | | | | | | | | | | | | | | | | | | | | | | 4 | | | 1 4.0 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | 3 | | | 1 3.0 |
| Uterus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia, Cystic | | 2 | 2 | 2 | 2 | 1 | 2 | | 1 | 3 | 2 | | 3 | 3 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 3 | 45 2.3 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 6 7 7 3 7 7 7 6 7 7 7 6 7 7 7 6 7 7 6 7 7 6 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 7 3 3 5 3 3 3 3 3 3 3 5 3 3 3 3 7 3 3 7 3 3 9 3 3 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 2 2 2 9 2 6 6 3 6 6 2 2 2 2 2 3 9 3 3 7 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 9000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| Bone Marrow | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Myelofibrosis | 3 2 3 | | | | | | | | | | | | | | | | | | | | | | | | 5 |
| Lymph Node | + | | | | | | | | | | | | | | | | | | | | | | | | 5 |
| Iliac, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Pancreatic, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Lymph Node, Mandibular | + M + + | | | | | | | | | | | | | | | | | | | | | | | | 48 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Lymph Node, Mesenteric | + | | | | | | | | | | | | | | | | | | | | | | | | 48 |
| Ectasia | 3 | | | | | | | | | | | | | | | | | | | | | | | | 4 |
| Hyperplasia, Histiocytic | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | 47 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | A |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Lymphoid Follicle, Hyperplasia | 1 2 3 3 1 2 3 2 3 2 3 2 | | | | | | | | | | | | | | | | | | | | | | | | 18 |
| Thymus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hyperplasia, Lymphoid | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 |

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

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------------------------------|-----------------|
| | 06772 | 07733 | 07735 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | 07733 | |
| B6C3F1 MICE 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 | |
| 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 | |
| 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 | |
| | 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 | * TOTALS |
| Metaplasia, Osseous Nephropathy | 1 | | | | | | 1 | | 1 | 1 | | | | | | 1 | | 1 | | | | | 1 | 1 2.0
15 1.0 | |
| Urinary Bladder Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50
5 1.2 | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 2 2 2 6 2 3 3 3 3 3 3 3 3 3 3 2 2 9 2 8 | | | | | | | | | | | | | | | | | | | | | | | | |
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| B6C3F1 MICE FEMALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
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females
(cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Gallbladder | + A | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Cecum
Cyst | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Colon | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Large, Rectum | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Duodenum | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Ileum | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Intestine Small, Jejunum | + A + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Liver | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Hepatodiaphragmatic Nodule | X | | | | | | | | | | | | | | | | | | | | | | | | |

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 + .. Tissue examined microscopically
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 2) Mild 4) Marked

TDMS No. 99007 - 06

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First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|---------------------------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|--|----------------------|
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2
9 | | |
| B6C3F1 MICE 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 | | |
| 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 | | |
| 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 | | | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 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 | | | |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | 1 | | 1 | 1 | | 1 | | 2 | 1 | 1 | 1 | | | | | | 1 | 1 | 1 | | | 1 | | | |
| Infiltration Cellular, Mixed Cell | | | 1 | | | | 1 | | | | | | | | | | | | | | | | 1 | | | |
| Inflammation, Acute | | | | | | | | | | | | 1 | | | | | | | | | | | | | | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | X | | | |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | 1 | | | | | | | |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | + | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | X | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | 2 | | | | | | 2 | | | | | | | | | | | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Infiltration Cellular, Lymphocyte | | 1 | | | | | | | | | | | | | | | | | | | | 1 | | | | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | 2 | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Cyst | X | | X | | | | | | | | | | | | | | | | | | | | | | | |
| Glands, Ectasia | | | | | | | | | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | |
| | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 6 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 9 | 2 | 8 |
| | 3 | 3 | 3 | 3 | 3 | 9 | 9 | 9 | 3 | 9 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 9 | 9 | 2 | 9 | 4 |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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...)

CARDIOVASCULAR SYSTEM

Blood Vessel

Heart
 Cardiomyopathy

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 1 | 2 | 1 | | 1 | 1 | 1 | 2 | | 2 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | | 1 | 1 | | | | | |

ENDOCRINE SYSTEM

Adrenal Cortex
 Degeneration, Cystic
 Hypertrophy, Focal
 Vacuolization Cytoplasmic
 Capsule, Hyperplasia

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

Adrenal Medulla

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

Islets, Pancreatic
 Hyperplasia

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

Parathyroid Gland
 Cyst

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

Pituitary Gland
 Pars Distalis, Cyst
 Pars Distalis, Hyperplasia, Focal

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

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
25000 PPM | 3 3 3 3 3 2 2 2 6 2 3 3 3 3 3 3 3 3 3 3 3 2 2 9 2 8 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 3 3 3 3 9 9 9 3 9 6 6 6 6 6 6 6 6 6 6 6 9 9 2 9 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 25000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Thyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicle, Degeneration, Focal | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Clitoral Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Ovary | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Bilateral, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Corpus Luteum, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Granulosa Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Uterus | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Cystic | 2 2 2 2 3 2 2 3 3 2 3 4 3 2 2 3 2 2 2 2 2 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | |
| Myometrium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | |

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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | | |
| 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 6 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 9 | 2 | 8 | |
| 3 | 3 | 3 | 3 | 3 | 9 | 9 | 9 | 3 | 9 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 9 | 9 | 2 | 9 | 4 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
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 | |
| | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Depletion Cellular | | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | | | | | | | | 3 | | | | | | | | | | | | | | | | | | |
| Myelofibrosis | | | | | | | | | | | 2 | | | 1 | 2 | | | | | 2 | | | | 1 | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node | | | | | | | | | | | | | | | | | | | | | | | | | + | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia, Lymphoid | | | | | | | 2 | | 3 | | | | 2 | 2 | | | 2 | | 2 | | | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Ectasia | | | | | | 4 | | | 4 | | | | | | | | | | | | | | | | | |
| Hyperplasia, Histiocytic | | | | | | | | 1 | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | 3 | | | | | 3 | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | 2 | | | | |
| Lymphoid Follicle, Hyperplasia | | 3 | | | 1 | 3 | 2 | 2 | | | 3 | 2 | 2 | 3 | 3 | | 3 | 4 | 1 | 2 | 2 | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Hyperplasia, Lymphoid | | 2 | | | | | | | | | | | 2 | | | 3 | 3 | | 2 | | | | | | | |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 110

TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 2 2 2 6 2 3 3 3 3 3 3 3 3 3 3 3 2 2 9 2 8 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 3 3 3 3 9 9 9 3 9 6 6 6 6 6 6 6 6 6 6 6 9 9 2 9 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 |
| 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 |
| | 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| Glands, Degeneration, Cystic
Glands, Inflammation
Respiratory Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Trachea
Glands, Degeneration, Cystic | + | | | | | | | | | | | | | | | | | | | | | | | | | 3 |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Eye | + A + A | | | | | | | | | | | | | | | | | | | | | | | | |
| Harderian Gland
Hyperplasia, Focal | + | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney
Infiltration Cellular, Lymphocyte
Nephropathy
Renal Tubule, Accumulation, Hyaline
Droplet | + | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder
Infiltration Cellular, Lymphocyte | + | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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

| | 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 | | |
| B6C3F1 MICE FEMALE | 5 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | | |
| 25000 PPM | 2 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | | |
| | 1 | 7 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 3 | 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 | | |
| | 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 | 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 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infarct | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Infiltration Cellular, Lymphocyte | | 1 | | | 1 | | | | | | | | 2 | 1 | | | 1 | | 1 | 1 | 1 | | 1 | | 21 1.1 | |
| Infiltration Cellular, Mixed Cell | | | | 1 | | | | | | | | | 2 | | | | | | 1 | | | | | | 6 1.2 | |
| Inflammation, Acute | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 | |
| Mixed Cell Focus | | | | | | | | | | | | | | | X | | | | X | X | | | | | 4 | |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | 1 | | | | | 2 | | | | 4 | | 4 2.0 | |
| Kupffer Cell, Pigmentation | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 2.0 | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | + | | 2 | 2 2.5 | |
| Pancreas | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | 1 | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 2.0 | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | 2 | | | | | | | | | | | | | 1 | 1 2.0 | |
| Salivary Glands | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | 1 | | | | | | | | | | | | | 3 1.0 | |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | 2 | | | | | | | | | | | | 1 2.0 | |
| Ulcer | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 2 2.0 | |
| Epithelium, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 2 2.0 | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Cyst | | | X | X | | | | | X | X | | | | | | | | | | | | | | 6 | | |
| Glands, Ectasia | | | | | | | | | | | | | | | | | | | | | | | | 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 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | |
| | 2 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| | 1 | 7 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 4 | | |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | 0 |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|
| Blood Vessel | | | | | | | | | | | | | | | | | | | | | | | | | + | 1 |
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cardiomyopathy | 1 | | 1 | | 1 | | | 1 | 1 | | 1 | 2 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 33 | 1.2 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|-----|---|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | | |
| Degeneration, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 4.0 | | | | |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 | 4 | 2.0 | | |
| Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 | 1 | 2.0 | | |
| Capsule, Hyperplasia | 1 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 2 | 2 | 1 | 2 | 3 | 2 | 3 | 2 | 3 | 2 | 2 | 2 | 2 | 2 | 4 | 2 | 1 | 49 | 2.0 | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 2.0 | | | |
| Parathyroid Gland | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | M | + | + | + | + | 47 | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 | 1 | | | |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | | | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3 | 3 | | | |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 | 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
 Page 115

TDMS No. 99007 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 5 3 7 7 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 5 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 0 3 3 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 3 3 3 3 4 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 7 3 3 3 6 6 6 6 6 6 6 6 6 5 6 6 6 6 6 6 3 3 4 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 4 | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | |

* TOTALS

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Thyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Follicle, Degeneration, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 10 1.6 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Clitoral Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Ovary | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 12 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.8 |
| Bilateral, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Corpus Luteum, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Granulosa Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| Uterus | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Fibrosis | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hyperplasia, Cystic | | | | | | | | | | | | | | | | | | | | | | | | | 44 2.4 |
| Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Myometrium, Hypertrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

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 - 06

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Goldenseal root powder

CAS Number: GOLDENSEALRT

Date Report Requested: 08/14/2008

Time Report Requested: 12:25:59

First Dose M/F: 05/12/03 / 05/12/03

Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 5 3 7 7 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 5 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 0 3 3 3 3 3 3 3 3 3 3 3 9 3 3 3 3 3 3 3 3 3 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 7 3 3 3 6 6 6 6 6 6 6 6 5 6 6 6 6 6 6 3 3 3 4 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE 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 | |
| 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 | |
| | 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 | 0 |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | | |

Bone Marrow + 50
 Depletion Cellular 1 3.0
 Hyperplasia 2 3.5
 Myelofibrosis 5 1.6

Lymph Node + 4

Lymph Node, Mandibular + + + + + + + + + + + M + + + + + + + + + + + + + + 49
 Hyperplasia, Lymphoid 3 7 2.3

Lymph Node, Mesenteric + + + + + + + + + + + + + + + M + + + + + + + + + + 49
 Ectasia 2 4.0
 Hyperplasia, Histiocytic 1 1.0
 Hyperplasia, Lymphoid 4 2.8

Spleen + 49
 Hematopoietic Cell Proliferation 3 4 2.8
 Lymphoid Follicle, Hyperplasia 3 2 1 3 3 2 3 3 22 2.4

Thymus + + + + + + + M + + + + + + + + + + + + + + + + 48
 Hyperplasia, Lymphoid 2 7 2.3

INTEGUMENTARY SYSTEM

Mammary Gland + 50

Skin + 50
 Mineralization 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
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TDMS No. 99007 - 06
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

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

Date Report Requested: 08/14/2008
 Time Report Requested: 12:25:59
 First Dose M/F: 05/12/03 / 05/12/03
 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 |
| 5 | 3 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | |
| 2 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| 1 | 7 | 3 | 3 | 3 | 3 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 3 | 3 | 3 | 4 | |
| B6C3F1 MICE 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 | |
| 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 | |
| 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 | |

Pigmentation 2 **1 2.0**
 Subcutaneous Tissue, Infiltration Cellular, Lymphocyte **1 3.0**

MUSCULOSKELETAL SYSTEM

Bone + **50**
 Maxilla, Fibrosis **1 3.0**

NERVOUS SYSTEM

Brain + **50**
 Peripheral Nerve **2**
 Spinal Cord **2**

RESPIRATORY SYSTEM

Lung + **50**
 Hemorrhage **1 2.0**
 Hyperplasia, Lymphoid **1 3.0**
 Infiltration Cellular, Histiocyte **1 1.0**
 Infiltration Cellular, Lymphocyte 2 **2 2.0**
 Nose + **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
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 2) Mild 4) Marked
 Page 118

