

**TDMS No.** 20008 - 04  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

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

Milk thistle extract  
**CAS Number:** 84604-20-6

**Date Report Requested:** 09/30/2008  
**Time Report Requested:** 13:13:48  
**First Dose M/F:** 03/25/03 / 03/25/03  
**Lab:** SRI

F1\_M3

**C Number:** C20008  
**Lock Date:** 06/29/2006  
**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 7 7 7 6 7 7 7 7 7 7 7 7 7 3 7 7 7 7 7 4 7																								
ANIMAL ID	3 3 3 3 3 3 9 3 3 3 2 3 1 3 3 3 8 2 3 3 2 3 2 3																								
	2 0 1 1 0 0 9 1 0 1 9 1 2 0 1 1 0 9 9 0 1 9 2 7 1																								
<b>B6C3F1 MICE MALE</b> <b>0 PPM</b>	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...)

**ALIMENTARY SYSTEM**

Esophagus	+ +																								
Gallbladder	+ + + + + + A + M + + + + + + + + + + M + + + + + A +																								
Intestine Large, Cecum Edema	+ + + + + + A + + + + + + + + + + + + A + + + + + + + +																								
Intestine Large, Colon	+ A + + + + + + + +																								
Intestine Large, Rectum	+ A + + + + + + + +																								
Intestine Small, Duodenum	+ + + + + + A + + + + + + + + + + + + A + + + + + + + +																								
Intestine Small, Ileum	+ + + + + + A +																								
Intestine Small, Jejunum	+ A + + + + + + + +																								
Liver	+ +																								
Basophilic Focus																									
Clear Cell Focus																									
Eosinophilic Focus	X X X X X																								
Hematopoietic Cell Proliferation	4																								
Hepatodiaphragmatic Nodule	X																								
Infiltration Cellular, Mixed Cell																									
Mixed Cell Focus	X X X X																								

\* .. 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	6	7	7	7	7	7	7	7	7	7	7	3	7	7	7	7	7	4	7
3	3	3	3	3	3	9	3	3	3	2	3	1	3	3	3	3	8	2	3	3	2	3	2	3	
2	0	1	1	0	0	9	1	0	1	9	1	2	0	1	1	0	9	9	0	1	9	2	7	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	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	

**B6C3F1 MICE MALE**  
**0 PPM** **males (cont...)**

Necrosis, Focal Centrilobular, Necrosis Hepatocyte, Vacuolization Cytoplasmic						2		3								3		3						4
Mesentery Fat, Necrosis																								
Pancreas Basophilic Focus Acinus, Cytoplasmic Alteration	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	X
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Stomach, Glandular Erosion Epithelium, Hyperplasia	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	2
Tongue	+																							

**CARDIOVASCULAR SYSTEM**

Heart Cardiomyopathy Thrombosis Myocardium, Necrosis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
																			1					
																			3					
																								1

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	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	3	7	7	7	7	4
3	3	3	3	3	3	9	3	3	3	2	3	1	3	3	3	3	8	2	3	3	2	3	2	3	
2	0	1	1	0	0	9	1	0	1	9	1	2	0	1	1	0	9	9	0	1	9	2	7	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	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...)

**ENDOCRINE SYSTEM**

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

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

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	7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 3 7 7 7 7 7 4 7																								
ANIMAL ID	3 3 3 3 3 3 9 3 3 3 2 3 1 3 3 3 3 8 2 3 3 2 3 2 3																								
	2 0 1 1 0 0 9 1 0 1 9 1 2 0 1 1 0 9 9 0 1 9 2 7 1																								
<b>B6C3F1 MICE MALE</b> <b>0 PPM</b>	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...)

Epididymis	+ +																								
Preputial Gland Cyst Inflammation, Chronic	+ 3 2 2																								
Prostate	+ +																								
Seminal Vesicle Degeneration	+ 3 3																								
Testes Germinal Epithelium, Atrophy	+ 1 1																								

**HEMATOPOIETIC SYSTEM**

Bone Marrow Hyperplasia	+ + + + + + A + + + + + + + + + + + + + + + + + + 2																								
Lymph Node Mediastinal, Hematopoietic Cell Proliferation	+ 2 2																								
Mediastinal, Hyperplasia, Lymphoid	+ 4 4																								
Pancreatic, Fibrosis	+ 3 3																								
Pancreatic, Hematopoietic Cell Proliferation	+ 3 3																								
Pancreatic, Hyperplasia, Lymphoid	+ 3 3																								

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	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	3	7	7	7	7	7	4	7	
	3	3	3	3	3	3	9	3	3	3	2	3	1	3	3	3	3	8	2	3	3	2	3	2	3	
	2	0	1	1	0	0	9	1	0	1	9	1	2	0	1	1	0	9	9	0	1	9	2	7	1	
<b>B6C3F1 MICE MALE</b> <b>0 PPM</b>	ANIMAL ID																									
	0																									
	0																									
	0																									
	0																									
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	<b>males (cont...)</b>

Lymph Node, Mandibular Atrophy	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	M
Hyperplasia, Lymphoid						2												3					3		
Lymph Node, Mesenteric Atrophy	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	A	+	+	+	+	+	M	+
Hematopoietic Cell Proliferation																							2		
Hyperplasia, Lymphoid																							3		
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hematopoietic Cell Proliferation				1	4		1	2					3									1			4
Necrosis																									
Lymphoid Follicle, Atrophy																			3						
Lymphoid Follicle, Hyperplasia																	2						3		
Thymus	+	+	+	+	+	+	M	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+
Atrophy																			3						2
Cyst																3	3								

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Edema					3																				
Ulcer																									
Epidermis, Hyperplasia																									

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DAY ON TEST	0 0																								
	7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 3 7 7 7 7 7 4 7																								
B6C3F1 MICE MALE 0 PPM	3 3 3 3 3 3 9 3 3 3 2 3 1 3 3 3 8 2 3 3 2 3 2 3																								
	2 0 1 1 0 0 9 1 0 1 9 1 2 0 1 1 0 9 9 0 1 9 2 7 1																								
ANIMAL ID	0 0																								
	0 0																								
0 PPM	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																								
																									males (cont...)

**MUSCULOSKELETAL SYSTEM**

Bone	+ +																									
Fracture																										X
Skeletal Muscle																										+

**NERVOUS SYSTEM**

Brain	+ +																								
Peripheral Nerve																									
Atrophy																									
Spinal Cord																									

**RESPIRATORY SYSTEM**

Lung	+ +																									
Foreign Body																										
Hemorrhage													3													3
Infiltration Cellular, Histiocyte													4													4
Infiltration Cellular, Lymphocyte																										3
Alveolar Epithelium, Hyperplasia													3													3

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DAY ON TEST	0																									males (cont...)
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	3	7	7	7	7	7	4	7	
	3	3	3	3	3	3	9	3	3	3	2	3	1	3	3	3	3	8	2	3	3	2	3	2	3	
	2	0	1	1	0	0	9	1	0	1	9	1	2	0	1	1	0	9	9	0	1	9	2	7	1	
<b>B6C3F1 MICE MALE</b> <b>0 PPM</b>	ANIMAL ID																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	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	
	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	

Nose +

Trachea +

**SPECIAL SENSES SYSTEM**

Eye +  
 Inflammation, Chronic 2  
 Cornea, Hyperplasia 2

Harderian Gland +  
 Hyperplasia, Focal 3 2

**URINARY SYSTEM**

Kidney +  
 Cyst 3 3  
 Infarct 3  
 Infiltration Cellular, Lymphocyte 2  
 Nephropathy 1 1 1 1 1 1 1 1 1 1 1 1 1 4 1 1 1 1 1 1 1  
 Renal Tubule, Accumulation, Hyaline Droplet  
 Renal Tubule, Hyperplasia 1 1 1 1

Urinary Bladder +  
 Calculus Gross Observation X  
 Transitional Epithelium, Hyperplasia

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	7 5 7 7																							
B6C3F1 MICE MALE 0 PPM	3 3 3 2 3 3 3 3 2 3 2 3 3 3 3 2 3 3 3 3 3 3 8 3 2																							
	0 1 0 9 1 0 2 1 9 1 9 0 0 2 1 0 9 2 0 0 0 0 1 8 0 9																							
ANIMAL ID	0 0																							
	0 0																							
* TOTALS	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																							

**ALIMENTARY SYSTEM**

Esophagus	+ +																								50						
Gallbladder	+ A + +																								45						
Intestine Large, Cecum Edema	+ +																								48 2 1 2.0						
Intestine Large, Colon	+ +																								49						
Intestine Large, Rectum	+ + + + + + + + + + + + + + + + + M + + + + + + + + +																								48						
Intestine Small, Duodenum	+ A + +																								47						
Intestine Small, Ileum	+ +																								49						
Intestine Small, Jejunum	+ +																								49						
Liver	+ +																								50						
Basophilic Focus																									X	1					
Clear Cell Focus																										X	7				
Eosinophilic Focus																											X	2			
Hematopoietic Cell Proliferation																												3	X	2 3.5	
Hepatodiaphragmatic Nodule																														1	
Infiltration Cellular, Mixed Cell																														2	1 2.0
Mixed Cell Focus	X 2																									X	X	X		X	10 2.0

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	3	3	3	2	3	3	3	3	2	3	2	3	3	3	3	2	3	3	3	3	3	3	8	3	2		
	0	1	0	9	1	0	2	1	9	1	9	0	0	2	1	0	9	2	0	0	0	1	8	0	9		
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	
	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	
	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		

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst		3		3		3		3						3		3		3		3		3		3		19 3.0
Inflammation, Chronic	4		2				2				2				2		3							2		12 2.3
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Degeneration																										1 3.0
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Germinal Epithelium, Atrophy																									2	2 1.5

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Hyperplasia	2						2						2				2	1					3	3	4	13 2.2
Lymph Node	+																									2
Mediastinal, Hematopoietic Cell Proliferation																										1 2.0
Mediastinal, Hyperplasia, Lymphoid																										1 4.0
Pancreatic, Fibrosis																										1 3.0
Pancreatic, Hematopoietic Cell Proliferation																										1 3.0
Pancreatic, Hyperplasia, Lymphoid																										1 3.0

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 Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	5	7	7	
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 PPM	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	

Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

**SPECIAL SENSES SYSTEM**

Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation, Chronic																									1 2.0
Cornea, Hyperplasia																									1 2.0
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hyperplasia, Focal														2											3 2.3

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Cyst	3				3					3		3									3				8 3.0	
Infarct														1	2							4			4 2.5	
Infiltration Cellular, Lymphocyte						2												3							3 2.3	
Nephropathy	1	1	1	1	1	1	1	2	2	1	1	1	1	1	1	1	1	2	1	1	1	1	2	1	1	45 1.2
Renal Tubule, Accumulation, Hyaline																							3			1 3.0
Droplet																										
Renal Tubule, Hyperplasia				2																						5 1.2
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Calculus Gross Observation																							X			2
Transitional Epithelium, Hyperplasia																							2			1 2.0

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 16





TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	6	
3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	2	3	3	3	2	2	2	3	3	4	
2	0	1	1	0	1	1	0	0	0	0	0	0	9	0	1	9	0	0	1	9	9	9	1	0	2	
B6C3F1 MICE MALE 12500 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	
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	M	+	+	+	+	+	+	+	A
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Basophilic Focus		X																							
Clear Cell Focus						X											X								
Eosinophilic Focus																									X
Mixed Cell Focus						X				X		X							X			X			
Necrosis, Focal																									
Centrilobular, Necrosis																									
Hepatocyte, Vacuolization Cytoplasmic																									

\* .. 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																										
	7																										
ANIMAL ID	3																										
	2																										
<b>B6C3F1 MICE MALE</b> <b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	<b>males</b> <b>(cont...)</b>
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	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		

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

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Epididymis Granuloma Sperm	+ 3																								
Preputial Gland Cyst	+ 3 3																								

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





DAY ON TEST	0 0																								
	7 6																								
B6C3F1 MICE MALE 12500 PPM	3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 2 3 3 3 2 2 2 3 3 4																								
	2 0 1 1 0 1 1 0 0 0 0 0 0 9 0 1 9 0 0 1 9 9 9 1 0 2																								
ANIMAL ID	0 0																								
	0 0																								
12500 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 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...)

Peripheral Nerve Atrophy

Spinal Cord

**RESPIRATORY SYSTEM**

Lung	+ +																								
Edema																									
Hemorrhage																									
Infiltration Cellular, Histiocyte	2 4 3																								
Infiltration Cellular, Lymphocyte																									
Inflammation, Chronic	2																								
Alveolar Epithelium, Hyperplasia	2 1 1																								
Nose	+ +																								
Trachea	+ +																								

**SPECIAL SENSES SYSTEM**

Eye	+ +																								
Harderian Gland	+ +																								
Hyperplasia, Focal	3 1																								

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 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
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DAY ON TEST	0 0																								
	7 6																								
B6C3F1 MICE MALE 12500 PPM	3 3 3 3 3 3 3 3 3 3 3 3 3 2 3 3 2 3 3 3 2 2 2 3 3 4																								
	2 0 1 1 0 1 1 0 0 0 0 0 0 9 0 1 9 0 0 1 9 9 9 1 0 2																								
ANIMAL ID	0 0																								
	0 0																								
12500 PPM	5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

males  
(cont...)

**URINARY SYSTEM**

Kidney	+ +																								
Cyst	+ +																								
Infarct	2																								
Infiltration Cellular, Lymphocyte	3 3																								
Metaplasia, Osseous	2																								
Nephropathy	1 1 2 1 2 1 2 1 1 1 1 1 1 1 2 1 1 1 1 1 1 1 1 1 1																								
Renal Tubule, Hyperplasia	1																								
Renal Tubule, Necrosis	1																								
Urinary Bladder	+ +																								

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 I .. Insufficient tissue  
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 2) Mild 4) Marked  
 Page 24





TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Milk thistle extract  
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Date Report Requested: 09/30/2008  
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 First Dose M/F: 03/25/03 / 03/25/03  
 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	
<b>B6C3F1 MICE MALE</b>	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	4	7	
<b>12500 PPM</b>	3	3	2	3	3	2	2	3	3	3	1	3	3	3	3	3	3	3	3	2	3	2	3	3	
	2	0	9	2	0	9	9	0	0	3	6	0	0	1	0	0	1	1	0	9	0	9	0	7	
	.....																								
	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	1	
	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	0	

Mesentery																									
Fat, Necrosis																									3
Pancreas																									49
Acinus, Cytoplasmic Alteration																									1
Salivary Glands																									50
Stomach, Forestomach																									50
Diverticulum																									1
Ulcer																									2
Epithelium, Hyperplasia																									1
Stomach, Glandular																									50
Erosion																									1

**CARDIOVASCULAR SYSTEM**

Heart																									50
Cardiomyopathy																									1

**ENDOCRINE SYSTEM**

Adrenal Cortex																									50
Accessory Adrenal Cortical Nodule																									7
Hyperplasia, Focal																									8
Hypertrophy, Focal																									13

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 1) Minimal 3) Moderate  
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 Page 26

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																								* TOTALS
	7																								
B6C3F1 MICE MALE 12500 PPM	3																								* TOTALS
	2																								
ANIMAL ID	0																								* TOTALS
	0																								
ANIMAL ID	0																								* TOTALS
	7																								
ANIMAL ID	6																								* TOTALS
	7																								

Capsule, Hyperplasia	3																								2	2.0
Adrenal Medulla Hyperplasia	+																								50	1.0
Islets, Pancreatic Hyperplasia	+																								49	3.0
Parathyroid Gland Cyst	+																								50	3.0
Pituitary Gland Pars Distalis, Cyst	+																								48	3.0
Thyroid Gland Follicle, Degeneration, Focal	+																								49	1.1

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

Epididymis Granuloma Sperm	+																								50	1.0
Preputial Gland Cyst	+																								50	3.0

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 + .. Tissue examined microscopically  
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TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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

Milk thistle extract

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Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

DAY ON TEST	0 0																								* TOTALS
	7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 4 7																								
ANIMAL ID	3 3 2 3 3 2 2 3 3 3 1 3 3 3 3 3 3 3 2 3 2 3 3 3																								
	2 0 9 2 0 9 9 0 0 3 6 0 0 1 0 0 1 1 0 9 0 9 0 7 1																								
<b>B6C3F1 MICE MALE</b>	0 0																								
<b>12500 PPM</b>	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																								

Inflammation, Chronic	2 4 2 2 1 2 2																								<b>12 2.4</b>
Prostate	+ +																								<b>50</b>
Seminal Vesicle	+ +																								<b>50</b>
Testes	+ +																								<b>50</b>
Germinal Epithelium, Atrophy																									<b>1 1.0</b>

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+ +																								<b>49</b>
Hyperplasia	3 4 4 3 2 2 1 4 2																								<b>14 2.4</b>
Lymph Node																									<b>1</b>
Lymph Node, Mandibular	+ + + M + + + + + M + M + + + M + + + + + + + + + +																								<b>45</b>
Atrophy																									<b>3</b>
Hyperplasia, Lymphoid	3 4																								<b>2 3.5</b>
Lymph Node, Mesenteric	+ + + M + M + + + + + I M + + + + + + + + + + + + + +																								<b>44</b>
Atrophy																									<b>2</b>
Hematopoietic Cell Proliferation																									<b>3 1.7</b>
Hemorrhage	2																								<b>3 2.3</b>
Hyperplasia, Lymphoid	2																								<b>3 2.3</b>
Spleen	+ +																								<b>50</b>

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

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

Milk thistle extract  
 CAS Number: 84604-20-6

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 Lab: SRI

DAY ON TEST	0 0																								
	7 4 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 7 6 7 7 7 7 7 7																								
ANIMAL ID	2 6 2 2 3 3 3 3 3 3 3 6 1 3 3 3 3 5 2 2 3 3 3 2																								
	9 0 9 9 1 0 0 0 1 1 1 3 2 0 8 1 1 0 7 9 9 2 1 0 9																								
<b>B6C3F1 MICE MALE</b> <b>25000 PPM</b>	0 0																								
	0 0																								
	1 1																								
	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...)

**ALIMENTARY SYSTEM**

Esophagus	+ +																								
Gallbladder	+ M + + M + + + + + + + M A + + + + + A + + + + + +																								
Intestine Large, Cecum Edema	+ + + + + + + + + + + + + A + + + + + + + + + + + +																								
Intestine Large, Colon	+ +																								
Intestine Large, Rectum	+ + + + + + + + + + + + M + + + + + + + + + + + +																								
Intestine Small, Duodenum	+ + + + + + + + + + + + A A + M + + + + + + + + + +																								
Intestine Small, Ileum Epithelium, Hyperplasia	+ +																								
Intestine Small, Jejunum Hyperplasia, Lymphoid Epithelium, Hyperplasia	+ A + + + + + + + + + + A A + A + + + + + + + + + +																								
Liver	+ +																								
Basophilic Focus																									
Clear Cell Focus	X																								
Cyst																									
Eosinophilic Focus	X																								

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 1) Minimal 3) Moderate  
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TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

DAY ON TEST	0																								
	7	4	7	7	7	7	7	7	7	7	7	6	7	7	6	7	7	7	6	7	7	7	7	7	7
ANIMAL ID	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
<b>B6C3F1 MICE MALE</b>																									
<b>25000 PPM</b>																									
	9	0	9	9	1	0	0	0	1	1	1	3	2	0	8	1	1	0	7	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

males (cont...)

Infiltration Cellular, Mixed Cell Necrosis, Focal											3											3	3	
Necrosis, Diffuse																								
Thrombosis																								
Centrilobular, Necrosis																						2		
Hepatocyte, Vacuolization Cytoplasmic											3													
Mesentery																						+		
Fat, Necrosis																								
Pancreas	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																						3		
Acinus, Cytoplasmic Alteration																							3	
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration Cellular, Lymphocyte																								
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Diverticulum																								
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erosion																						2		

**CARDIOVASCULAR SYSTEM**

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
-------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

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

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

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

DAY ON TEST	0 0																								
	7 4 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 7 6 7 7 7 7 7 7																								
B6C3F1 MICE MALE 25000 PPM	2 6 2 2 3 3 3 3 3 3 3 6 1 3 3 3 3 3 5 2 2 3 3 3 2																								
	9 0 9 9 1 0 0 0 1 1 1 3 2 0 8 1 1 0 7 9 9 2 1 0 9																								
ANIMAL ID	0 0																								
	0 0																								
25000 PPM	1 1																								
	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...)

**ENDOCRINE SYSTEM**

Adrenal Cortex	+ +																								
Accessory Adrenal Cortical Nodule																									
Hyperplasia, Focal	1 3																								
Hypertrophy, Focal	1 1 3 1 1																								
Capsule, Hyperplasia	2 1																								
Adrenal Medulla	+ + + + + + + + + + + M + + + + + + + + + + + + + + +																								
Islets, Pancreatic	+ + + + + + + + + + + A + + + + + + + + + + + + + + +																								
Parathyroid Gland	+ +																								
Cyst	3																								
Pituitary Gland	+ + + + + + + + + + + M M I + + + + + + + + + + + + + + +																								
Pars Distalis, Cyst	3																								
Pars Distalis, Hyperplasia, Focal																									
Thyroid Gland	+ +																								
Follicle, Degeneration, Focal	1 2																								

**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

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																									males (cont...)
	7	4	7	7	7	7	7	7	7	7	7	6	7	7	6	7	7	7	6	7	7	7	7	7	7	
ANIMAL ID	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
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst	3		3	3	3	3							3		3		3	3		3	3			3	
Inflammation, Chronic	4				2								2	3					2	2		2			
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Inflammation, Chronic															3										
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis																									
Hyperplasia	1								2				2						1		3	2	2	2	
Lymph Node																									+
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+
Hyperplasia, Lymphoid																									
Pigmentation																									
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	M

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

DAY ON TEST	0 0																								
	7 4 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 7 6 7 7 7 7 7 7																								
ANIMAL ID	2 6 2 2 3 3 3 3 3 3 3 6 1 3 3 3 3 3 5 2 2 3 3 3 2																								
	9 0 9 9 1 0 0 0 1 1 1 3 2 0 8 1 1 0 7 9 9 2 1 0 9																								
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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	
	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 Cell Proliferation																									
Hemorrhage																									
Hyperplasia, Lymphoid																									
Spleen	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hematopoietic Cell Proliferation											3														
Lymphoid Follicle, Hyperplasia												3													
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Atrophy												3	3												
Cyst																									

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst Epithelial Inclusion											X													

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skeletal Muscle																								

**NERVOUS SYSTEM**

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 2) Mild 4) Marked

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 4 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 7 6 7 7 7 7 7 7																								
ANIMAL ID	2 6 2 2 3 3 3 3 3 3 3 6 1 3 3 3 3 3 5 2 2 3 3 3 2																								
	9 0 9 9 1 0 0 0 1 1 1 3 2 0 8 1 1 0 7 9 9 2 1 0 9																								
<b>B6C3F1 MICE MALE</b> <b>25000 PPM</b>	0 0																								
	0 0																								
	1 1																								
	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...)

Brain Infiltration Cellular, Lymphoid	+ +																								
Peripheral Nerve	+ +																								
Spinal Cord	+ +																								

**RESPIRATORY SYSTEM**

Lung	+ +																								
Foreign Body	+ +																								
Hemorrhage	2 +																								
Infiltration Cellular, Histiocyte	+ +																								
Inflammation, Chronic	+ +																								
Thrombosis	+ +																								
Alveolar Epithelium, Hyperplasia	+ +																								
Nose	+ +																								
Trachea	+ +																								

**SPECIAL SENSES SYSTEM**

Eye	+ +																								
-----	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

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 2) Mild 4) Marked  
 Page 37

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	4	7	7	7	7	7	7	7	7	7	6	7	7	6	7	7	7	6	7	7	7	7	7	7	7	0
2	6	2	2	3	3	3	3	3	3	3	6	1	3	3	3	3	3	5	2	2	3	3	3	3	2	0
9	0	9	9	1	0	0	0	0	1	1	1	3	2	0	8	1	1	0	7	9	9	2	1	0	9	0

**B6C3F1 MICE MALE**  
**25000 PPM**

Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
-----------------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	--

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Cyst					3						3															
Hydronephrosis																2										
Infiltration Cellular, Lymphocyte																										
Metaplasia, Osseous																2	1									
Nephropathy	1	1	1	1	1	1	1	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	
Renal Tubule, Hyperplasia	1																									
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	
Dilatation																										
Infiltration Cellular, Lymphocyte																										

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 Page 38

DAY ON TEST	0 0																							
	7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7																							
ANIMAL ID	2 3 3 3 2 3 5 3 3 3 2 3 3 3 2 3 9 2 2 3 3 3 2 3 2																							
	9 0 2 1 9 1 9 1 1 0 9 0 1 1 9 2 3 9 9 0 2 0 9 1 9																							
<b>B6C3F1 MICE MALE</b> <b>25000 PPM</b>	0 0																							
	0 0																							
	1 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																							
<b>* TOTALS</b>																								

**ALIMENTARY SYSTEM**

Esophagus	+ +																								50	
Gallbladder	+ +																								45	
Intestine Large, Cecum Edema	+ +																								49	1 2.0
Intestine Large, Colon	+ +																								50	
Intestine Large, Rectum	+ +																								49	
Intestine Small, Duodenum	+ +																								47	
Intestine Small, Ileum Epithelium, Hyperplasia	+ +																								50	1 2.0
Intestine Small, Jejunum Hyperplasia, Lymphoid Epithelium, Hyperplasia	+ +																								46	1 1.0 1 2.0
Liver	+ +																								50	
Basophilic Focus																										1
Clear Cell Focus																										3
Cyst	3																									1 3.0
Eosinophilic Focus	X X																									4

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	7	7	7	7	7	6	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7
ANIMAL ID	2	3	3	3	2	3	5	3	3	3	2	3	3	3	2	3	9	2	2	3	3	3	2
	9	0	2	1	9	1	9	1	1	0	9	0	1	1	9	2	3	9	9	0	2	0	9
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8
																							<b>* TOTALS</b>
Infiltration Cellular, Mixed Cell Necrosis, Focal																							2
Necrosis, Diffuse																							1
Thrombosis																							2
Centrilobular, Necrosis																							3
Hepatocyte, Vacuolization Cytoplasmic																							1
Mesentery																							3
Fat, Necrosis																							2
Pancreas																							49
Cyst																							1
Acinus, Cytoplasmic Alteration																							2
Salivary Glands																							50
Infiltration Cellular, Lymphocyte																							3
Stomach, Forestomach																							50
Diverticulum																							X
Stomach, Glandular																							50
Erosion																							1
<b>CARDIOVASCULAR SYSTEM</b>																							
Heart																							50

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 2) Mild 4) Marked  
 Page 40



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	6	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7
ANIMAL ID	2	3	3	3	2	3	5	3	3	3	2	3	3	3	2	3	9	2	2	3	3	3	2	3
	9	0	2	1	9	1	9	1	1	0	9	0	1	1	9	2	3	9	9	0	2	0	9	1
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	
	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	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	
																						* TOTALS		

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Accessory Adrenal Cortical Nodule	3		3										3											4 3.0
Hyperplasia, Focal																1					1		1	6 1.7
Hypertrophy, Focal		1		3	1	3						2	2											12 1.7
Capsule, Hyperplasia								3																3 2.0
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst								3																2 3.0
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Pars Distalis, Cyst																								2 3.0
Pars Distalis, Hyperplasia, Focal													2											1 2.0
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Follicle, Degeneration, Focal										1														3 1.3

**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  
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Page 41



	DAY ON TEST																											
	0729	0770	0772	0773	0775	0777	0778	0779	0780	0781	0782	0783	0784	0785	0786	0787	0788	0789	0790	0791	0792	0793	0794	0795		0796	0797	0798
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	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	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0			
																									<b>* TOTALS</b>			

Hematopoietic Cell Proliferation																									2	2	<b>2 2.0</b>	
Hemorrhage																											<b>1 1.0</b>	
Hyperplasia, Lymphoid																									3	2	<b>4 2.3</b>	
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hematopoietic Cell Proliferation																									2		<b>12 2.6</b>	
Lymphoid Follicle, Hyperplasia																									3	3	<b>3 2.7</b>	
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Atrophy																									3		<b>5 3.0</b>	
Cyst																									3	3	<b>4 3.0</b>	

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst Epithelial Inclusion																											<b>1</b>	

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skeletal Muscle																											<b>1</b>	

**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. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

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

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 6 7																								
B6C3F1 MICE MALE 50000 PPM	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 2 3 3																								
	1 1 1 0 3 9 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 9 1 0																								
ANIMAL ID	0 0																								
	0 0																								
50000 PPM	1 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	+ +																								
Intestine Large, Cecum	+ +																								
Intestine Large, Colon	+ +																								
Intestine Large, Rectum	+ +																								
Intestine Small, Duodenum	+ +																								
Intestine Small, Ileum	+ +																								
Intestine Small, Jejunum	+ +																								
Liver	+ +																								
Angiectasis																									
Basophilic Focus	X																								
Eosinophilic Focus	X																								
Mixed Cell Focus	X X																								
Mesentery	+ +																								
Hemorrhage	+ 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  
 Page 46

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 6 7																								
ANIMAL ID	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 2 3 3																								
	1 1 1 0 3 9 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 9 1 0																								
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	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...)

Fat, Necrosis	1																								
Pancreas	+ +																								
Cyst																									
Acinus, Cytoplasmic Alteration	4 2 3 3																								
Salivary Glands	+ +																								
Atrophy	1																								
Stomach, Forestomach	+ +																								
Epithelium, Hyperplasia																									
Stomach, Glandular	+ +																								
Ulcer	3																								

**CARDIOVASCULAR SYSTEM**

Heart	+ +																								
Cardiomyopathy	1 1																								

**ENDOCRINE SYSTEM**

Adrenal Cortex	+ +																								
Accessory Adrenal Cortical Nodule	3																								
Degeneration, Fatty	1																								
Hyperplasia, Focal	2 2																								
Hypertrophy, Focal	3 1 3 2 2																								

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

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																							
	7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7																							
ANIMAL ID	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 2 3 3																							
	1 1 1 0 3 9 1 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 1 0																							
<b>B6C3F1 MICE MALE</b>	0 0																							
<b>50000 PPM</b>	0 0																							
	1 1																							
	5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7																							
	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...)

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

**GENERAL BODY SYSTEM**

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

**GENITAL SYSTEM**

Epididymis Granuloma Sperm	+ +																							
	3																							
Preputial Gland Cyst	+ +																							
	3 3 3 3 3 3																							

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 + .. 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																								
	7 7 7 7 6 7																								
ANIMAL ID	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 2 3 3																								
	1 1 1 0 3 9 1 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 9 1 0																								
<b>B6C3F1 MICE MALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	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...)

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

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+ +																								
Hyperplasia	1 2 2 2 2 1 1 2 2 2 2 2																								
Lymph Node, Mandibular	M + + + + M + + + + + + + + + + + + + + + + + + +																								
Hyperplasia, Lymphoid	3																								
Pigmentation																									
Lymph Node, Mesenteric	M + + + + + + + + M + + + + + + + + + + + + + + + +																								
Atrophy																									
Hematopoietic Cell Proliferation	2																								
Hemorrhage																									
Hyperplasia, Lymphoid	2																								
Spleen	+ +																								
Hematopoietic Cell Proliferation	3 3 2																								
Lymphoid Follicle, Atrophy	2 2																								

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

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 6 7																								
B6C3F1 MICE MALE 50000 PPM	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 2 3 3																								
	1 1 1 0 3 9 1 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 1 0																								
ANIMAL ID	0 0																								
	0 0																								
50000 PPM	1 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...)

Lymphoid Follicle, Hyperplasia	3																										
Thymus Atrophy Cyst	I	+	M	+	+	+	+	M	+	+	+	+	+	M	+	I	+	+	+	+	+	+	I	+	+		
	3			3			3			3			3			3			3			3			3		

**INTEGUMENTARY SYSTEM**

Mammary Gland	+ +																								
Skin	+ +																								

**MUSCULOSKELETAL SYSTEM**

Bone Femur, Osteopetrosis	+ +																								
	3																								

**NERVOUS SYSTEM**

Brain	+ +																								
Peripheral Nerve Atrophy																									
	+ 1																								
Spinal Cord																									
	+																								

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 + .. 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 6 7																								
ANIMAL ID	3 3 3 3 9 2 3 3 3 3 3 3 2 3 3 3 3 3 3 2 3 2 3 2 3 3																								
	1 1 1 0 3 9 1 1 1 2 0 0 9 1 1 1 0 1 0 9 0 9 9 1 0																								
<b>B6C3F1 MICE MALE</b> <b>50000 PPM</b>	0 0																								
	0 0																								
	1 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...)

**RESPIRATORY SYSTEM**

Lung	+ +																								
Hemorrhage	1																								
Infiltration Cellular, Histiocyte	1																								
Thrombosis																									
Alveolar Epithelium, Hyperplasia	2 1 1																								
Nose	+ +																								
Trachea	+ +																								

**SPECIAL SENSES SYSTEM**

Eye	+ +																								
Cataract	3																								
Harderian Gland	+ +																								
Hyperplasia, Focal																									

**URINARY SYSTEM**

Kidney	+ +																								
Cyst	3 3 3 3																								
Infarct																									

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 1) Minimal 3) Moderate  
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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

	DAY ON TEST																									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	
<b>B6C3F1 MICE MALE</b>	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	
<b>50000 PPM</b>	3	3	3	3	9	2	3	3	3	3	3	3	2	3	3	3	3	3	3	2	3	2	2	3	3	
	1	1	1	0	3	9	1	1	1	2	0	0	9	1	1	1	0	1	0	9	0	9	9	1	0	
	-----																									
	ANIMAL ID																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	7	7	7	7	7		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4		
Nephropathy	1	1	1	1	1	1		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
Renal Tubule, Hyperplasia										1						1	1							1		
Renal Tubule, Pigmentation										2																
	-----																									
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 52



DAY ON TEST	0																								* TOTALS
	7																								
B6C3F1 MICE MALE 50000 PPM	3																								
	2																								
ANIMAL ID	0																								
	0																								
ANIMAL ID	1																								
	7																								
ANIMAL ID	6																								
	7																								
ANIMAL ID	8																								
	9																								

Fat, Necrosis 1 1.0

Pancreas + 50  
 Cyst 3 1 3.0  
 Acinus, Cytoplasmic Alteration 4 3.0

Salivary Glands + 50  
 Atrophy 1 1.0

Stomach, Forestomach + 50  
 Epithelium, Hyperplasia 1 1.0

Stomach, Glandular + 50  
 Ulcer 1 3.0

CARDIOVASCULAR SYSTEM

Heart + 50  
 Cardiomyopathy 2 1.0

ENDOCRINE SYSTEM

Adrenal Cortex + 50  
 Accessory Adrenal Cortical Nodule 3 2 3.0  
 Degeneration, Fatty 1 1.0  
 Hyperplasia, Focal 2 3 2 2 2 3 8 2.3  
 Hypertrophy, Focal 2 2 2 1 1 2 9 1.9

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
 M .. Missing tissue  
 A .. Autolysis precludes evaluation  
 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 54



TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

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	7	14	
	3	3	3	3	3	2	3	3	3	2	3	2	3	3	2	3	2	3	3	2	3	3	3	2.4	
	2	1	0	0	1	9	1	1	2	9	1	9	0	1	9	1	9	1	1	9	0	1	0		
B6C3F1 MICE MALE 50000 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	50	
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	4.0	
	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9	9	9	9	3.0	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	0	

Inflammation, Chronic	1	3	3	2	1	2	2	3	14	2.4														
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Germinal Epithelium, Atrophy																								1
Interstitial Cell, Hyperplasia																								4.0
																								1
																								3.0

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hyperplasia	2	1											2			2							2	17
																								1.8
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Hyperplasia, Lymphoid																								1
Pigmentation								3																2.0
																								3.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48
Atrophy																								1
Hematopoietic Cell Proliferation																								2.0
Hemorrhage																								1
Hyperplasia, Lymphoid																								1.0
																								2.0
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hematopoietic Cell Proliferation																								4
Lymphoid Follicle, Atrophy																								2.8
																								2
																								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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	
<b>B6C3F1 MICE MALE</b>	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
<b>50000 PPM</b>	3	3	3	3	3	2	3	3	3	2	3	2	3	3	2	3	2	3	3	2	3	3	3	3	3
<b>ANIMAL ID</b>	2	1	0	0	1	9	1	1	2	9	1	9	0	1	9	1	9	1	1	9	0	1	0	1	2
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	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
	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

Lymphoid Follicle, Hyperplasia	2																								<b>2 2.5</b>		
Thymus Atrophy Cyst	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	+	M		+	+	+	+	M	+	+	<b>40</b>
	3												3						3						<b>1 3.0</b>		
	3												3						3						<b>6 3.0</b>		

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>

**MUSCULOSKELETAL SYSTEM**

Bone Femur, Osteopetrosis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+	+	+	+	+	+	+	<b>49</b>
																									<b>1 3.0</b>		

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>
Peripheral Nerve Atrophy																									<b>1</b>	<b>1 1.0</b>	
Spinal Cord																									<b>1</b>		

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 + .. Tissue examined microscopically  
 x .. Lesion present  
 | .. 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

	DAY ON TEST																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7		
	3	3	3	3	3	2	3	3	3	2	3	2	3	3	2	3	2	3	3	2	3	3	3	3		
	2	1	0	0	1	9	1	1	2	9	1	9	0	1	9	1	9	1	1	9	0	1	0	1	2	
<b>B6C3F1 MICE MALE</b>	-----																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	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		
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9		
	-----																									
																									<b>* TOTALS</b>	
Nephropathy	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	<b>49</b>	
Renal Tubule, Hyperplasia																									<b>1.0</b>	
Renal Tubule, Pigmentation																									<b>2.0</b>	
	-----																									
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	

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

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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 59

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

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

females  
(cont...)

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Gallbladder	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	M	+	+	+	+	A	+	+	+	+
Intestine Large, Cecum Edema Hyperplasia, Lymphoid	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	A	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	A	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	A	+
Intestine Small, Jejunum Peyer's Patch, Inflammation, Suppurative	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Liver Angiectasis Basophilic Focus Hematopoietic Cell Proliferation Mixed Cell Focus Necrosis, Focal	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

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 Lab: SRI

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

  

ANIMAL ID	0																									females (cont...)
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5		

Centrilobular, Necrosis Hepatocyte, Vacuolization Cytoplasmic Kupffer Cell, Hyperplasia																					4			
Mesentery Fat, Necrosis											+	3		+	4									
Pancreas Atrophy Cyst Acinus, Cytoplasmic Alteration	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+
												4		4										
Salivary Glands Infiltration Cellular, Lymphocyte	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
											2	3		3			2				3			
Stomach, Forestomach Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
											2													
Stomach, Glandular Cyst Erosion Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
											3			3		3			3			3		
											2		1								3			

**CARDIOVASCULAR SYSTEM**

Heart 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 61

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

	DAY ON TEST																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	7	5	7	7	7	6	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	6	7
	3	6	3	3	3	1	3	1	3	3	3	3	3	8	3	3	3	3	3	3	2	3	3	4	3
	5	0	5	5	5	8	5	7	5	5	6	6	6	5	6	2	2	2	2	2	8	5	5	4	5
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>0 PPM</b>	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	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

females  
(cont...)

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule					3					3		3												
Capsule, Hyperplasia																					1			
Adrenal Medulla	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia		1																						
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+
Cyst																								
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Hyperplasia, Focal													1										1	
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Follicle, Cyst																								
Follicle, Degeneration, Focal	2	2	3							2	2	1				1	2	1	3	2		2	1	3

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

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 2) Mild 4) Marked

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	3	6	3	3	3	1	3	1	3	3	3	3	3	3	8	3	3	3	3	3	3	2	3	3	4	3
5	0	5	5	5	8	5	7	5	5	6	6	6	6	5	6	2	2	2	2	2	2	8	5	5	4	5
<b>B6C3F1 MICE FEMALE</b>																										
<b>0 PPM</b>																										
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	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	

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+
Ovary	+	+	+	+	+	I	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+
Angiectasis																									
Cyst		3	3				3					3	3					3		3			3		3
Hemorrhage	2		2						2	2			2						2		2				
Thecal Cell, Hyperplasia																									
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Angiectasis																									
Hyperplasia, Cystic	4	4	2	2	3		2	4	4	4		3	1	4	2	2	4	3	3	3	3	2	3	4	4

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Hyperplasia	2					2	3	3	2		2		2	3		2					4		2	2	3	3
Hyperplasia, Neutrophil																										
Lymph Node				+							+								+		+		+	+		
Deep Cervical, Hemorrhage																							3			
Deep Cervical, Pigmentation																						2				
Iliac, Hematopoietic Cell Proliferation																					4					
Mediastinal, Hyperplasia, Lymphoid																								3		
Lymph Node, Mandibular	+	M	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Atrophy						2																				
Ectasia																										
Hematopoietic Cell Proliferation																								3		

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																						
	7	5	7	7	7	6	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	6
ANIMAL ID	0																						
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>B6C3F1 MICE FEMALE</b>	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
<b>0 PPM</b>	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3

females  
(cont...)

Hemorrhage																							
Hyperplasia, Lymphoid							2						2										
Pigmentation																							
Lymph Node, Mesenteric	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Atrophy		2				2																	
Hematopoietic Cell Proliferation																		3			2		
Hemorrhage																							
Hyperplasia, Lymphoid				2																		3	
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hematopoietic Cell Proliferation	1			1			3	3		1	3	1				3			4		4	2	1
Hemorrhage																							4
Necrosis																							
Lymphoid Follicle, Atrophy																							
Lymphoid Follicle, Hyperplasia									3							2							
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Atrophy		3				3		3													2		
Hyperplasia, Lymphoid									3									3				3	

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia						2												3		2			
Necrosis																		4					
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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 Page 64



TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

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

females  
(cont...)

Edema

3

**MUSCULOSKELETAL SYSTEM**

Bone	+ +																								
Fibro-Osseous Lesion	1 1 1 1																								
Skeletal Muscle																									
Atrophy	2																								
Inflammation, Acute	3																								

**NERVOUS SYSTEM**

Brain	+ +																								
Compression	4																								
Hemorrhage																									
Necrosis	3																								
Peripheral Nerve																									
Atrophy	2																								
Spinal Cord																									
Hemorrhage	+																								

**RESPIRATORY 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	5	7	7	7	6	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	6	7	
	3	6	3	3	3	1	3	1	3	3	3	3	3	8	3	3	3	3	3	3	2	3	3	4	3	
	5	0	5	5	5	8	5	7	5	5	6	6	6	5	6	2	2	2	2	2	8	5	5	4	5	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>0 PPM</b>	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2		
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	<b>females (cont...)</b>

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Edema																									
Hemorrhage				1																					
Infiltration Cellular, Histiocyte																									
Infiltration Cellular, Lymphocyte														2									3		
Infiltration Cellular, Polymorphonuclear																									
Inflammation, Chronic																									
Alveolar Epithelium, Hyperplasia																						1			

Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
---------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

**SPECIAL SENSES SYSTEM**

Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cataract																									
Inflammation, Chronic																									
Cornea, Hyperplasia																									
Retina, Degeneration																									

Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
-----------------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infarct																									

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

	DAY ON TEST																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	7	5	7	7	7	6	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	
	3	6	3	3	3	1	3	1	3	3	3	3	3	8	3	3	3	3	3	3	2	3	3	4	3
	5	0	5	5	5	8	5	7	5	5	6	6	6	5	6	2	2	2	2	2	8	5	5	4	5
<b>B6C3F1 MICE FEMALE</b>	.....																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	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	
<b>0 PPM</b>	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
	.....																								
Infiltration Cellular, Lymphocyte	2									3									3						
Metaplasia, Osseous							2															1			
Nephropathy			1			1							1						3		1				
Renal Tubule, Accumulation, Hyaline Droplet																						3			
	.....																								
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Infiltration Cellular, Lymphocyte																									

females (cont...)

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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 Page 67



DAY ON TEST	0																								* TOTALS	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0
	7	7	7	5	7	7	7	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	6		
	3	3	3	8	3	3	3	3	3	3	3	3	3	3	3	4	0	3	3	3	3	3	3	2		
	2	2	2	2	2	2	2	2	2	2	5	5	5	5	5	9	5	2	2	2	2	2	2	9		
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
ANIMAL ID	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5		
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	

Centrilobular, Necrosis																										1	4.0	
Hepatocyte, Vacuolization Cytoplasmic																											1	3.0
Kupffer Cell, Hyperplasia																											1	2.0
Mesentery																												
Fat, Necrosis																											3	3.3
Pancreas																											49	
Atrophy																											2	4.0
Cyst																											2	3.5
Acinus, Cytoplasmic Alteration																											2	3.0
Salivary Glands																											50	
Infiltration Cellular, Lymphocyte																											7	2.7
Stomach, Forestomach																											50	
Epithelium, Hyperplasia																											2	2.0
Stomach, Glandular																											50	
Cyst																											4	3.0
Erosion																											2	2.0
Epithelium, Hyperplasia																											1	2.0

**CARDIOVASCULAR SYSTEM**

Heart																											50	
Mineralization																											2	1.2.0

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BLANK .. Not examined microscopically  
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DAY ON TEST	0																								* TOTALS
	7	7	7	5	7	7	7	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	6	
	3	3	3	8	3	3	3	3	3	3	3	3	3	3	3	4	0	3	3	3	3	3	3	2	
	2	2	2	2	2	2	2	2	2	2	5	5	5	5	5	9	5	2	2	2	2	2	2	9	
<b>B6C3F1 MICE FEMALE</b>	0																								* TOTALS
	0																								
	2																								
	2																								
	6																								
<b>0 PPM</b>	0																								* TOTALS
	0																								
	2																								
	2																								
	6																								

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Accessory Adrenal Cortical Nodule				3																					5
Capsule, Hyperplasia											2														2
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Hyperplasia													3												2
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48
Cyst				3																					1
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Pars Distalis, Hyperplasia, Focal											2		1			3									5
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Follicle, Cyst																									1
Follicle, Degeneration, Focal				3							1	3	1			3	1	2	1						25

**GENERAL BODY SYSTEM**

NONE

**GENITAL SYSTEM**

\* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
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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			
	7	7	7	5	7	7	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	7	6			
	3	3	3	8	3	3	3	3	3	3	3	3	3	3	4	0	3	3	3	3	3	3	3	2			
	2	2	2	2	2	2	2	2	2	2	5	5	5	5	5	9	5	2	2	2	2	2	2	9			
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	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			
Clitoral Gland	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	47	
Ovary	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	46	
Angiectasis																										1	3.0
Cyst				3			3	3			3	3			3					3						16	3.0
Hemorrhage																								3		8	2.1
Thecal Cell, Hyperplasia														2												1	2.0
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Angiectasis				2																						1	2.0
Hyperplasia, Cystic	3	4	2		2	2	3	2	4	2	4	3	4	2	3	1	1	3	4	3	4	2	2	3	4	47	2.9

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Hyperplasia										2			2				3	3			4					18	2.5
Hyperplasia, Neutrophil																										1	4.0
Lymph Node				+									+								+				+	10	
Deep Cervical, Hemorrhage																										1	3.0
Deep Cervical, Pigmentation																										1	2.0
Iliac, Hematopoietic Cell Proliferation																										1	4.0
Mediastinal, Hyperplasia, Lymphoid																										1	3.0
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48	
Atrophy																										1	2.0
Ectasia										4	2															2	3.0
Hematopoietic Cell Proliferation																										1	3.0

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BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

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2) Mild 4) Marked

DAY ON TEST	0 0																							
	7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 6																							
ANIMAL ID	3 3 3 8 3 3 3 3 3 3 3 3 3 3 3 4 0 3 3 3 3 3 3 3 2																							
	2 2 2 2 2 2 2 2 2 2 2 5 5 5 5 5 9 5 2 2 2 2 2 2 9																							
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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
																								<b>* TOTALS</b>

Hemorrhage																								1	1	1.0			
Hyperplasia, Lymphoid																								2	3	2.3			
Pigmentation	3																										3	3	3.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					
Atrophy																								49	2	2.0			
Hematopoietic Cell Proliferation																									2	2.5			
Hemorrhage																									4	4.0			
Hyperplasia, Lymphoid																		4	4	3.0									
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+						
Hematopoietic Cell Proliferation						1	2	1												1	3	2	4	1	50	20	2.1		
Hemorrhage																									1	4.0			
Necrosis																									4	4.0			
Lymphoid Follicle, Atrophy															3	1	3.0												
Lymphoid Follicle, Hyperplasia									2	2	3	3	2	6	2.3														
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+						
Atrophy															3	3	6	2.8											
Hyperplasia, Lymphoid	1											1	1	2	1	2	3	9	1.9										

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
Hyperplasia															2	2	5	2.2								
Necrosis																									2	4.0
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			
																								50		

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 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
 Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 5 7 7 7 7 7 7 7 7 7 7 7 5 7 7 7 7 7 7 7 7 6																								
ANIMAL ID	3 3 3 8 3 3 3 3 3 3 3 3 3 3 3 4 0 3 3 3 3 3 3 3 2																								
	2 2 2 2 2 2 2 2 2 2 2 5 5 5 5 5 9 5 2 2 2 2 2 2 9																								
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>0 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
																								<b>* TOTALS</b>	

Edema 2 2.5

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibro-Osseous Lesion	2									1	3	1														8 1.4
Skeletal Muscle	+			+																						3
Atrophy																										1 2.0
Inflammation, Acute																										1 3.0

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Compression																										1 4.0
Hemorrhage				3																						1 3.0
Necrosis																										1 3.0
Peripheral Nerve				+																						3
Atrophy																										1 2.0
Spinal Cord				+																						3
Hemorrhage					3																					1 3.0

**RESPIRATORY 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  
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 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
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TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

DAY ON TEST	0																								* TOTALS
	7	7	7	5	7	7	7	7	7	7	7	7	7	7	7	5	7	7	7	7	7	7	7	6	
	3	3	3	8	3	3	3	3	3	3	3	3	3	3	3	4	0	3	3	3	3	3	3	2	
	2	2	2	2	2	2	2	2	2	2	5	5	5	5	5	9	5	2	2	2	2	2	2	9	
<b>B6C3F1 MICE FEMALE</b>	0																								* TOTALS
	0																								
	2																								
	2																								
	6																								
<b>0 PPM</b>	0																								* TOTALS
	0																								
	2																								
	2																								
	6																								

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Edema															2										1 2.0
Hemorrhage													1												2 1.0
Infiltration Cellular, Histiocyte										4															1 4.0
Infiltration Cellular, Lymphocyte																						2			3 2.3
Infiltration Cellular, Polymorphonuclear																									1 3.0
Inflammation, Chronic															2		2								2 2.0
Alveolar Epithelium, Hyperplasia																									1 1.0
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

SPECIAL SENSES SYSTEM

Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cataract	3																								1 3.0
Inflammation, Chronic										1															1 1.0
Cornea, Hyperplasia										1															1 1.0
Retina, Degeneration	4																								1 4.0
Harderian Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Infarct															2										2 2.0

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+ .. 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 7 7 7 7 7 7 7 6 4 7 7 7 7 7 7 7 7 7 7 7 7 7																								
ANIMAL ID	3 3 3 3 3 3 3 3 3 3 3 7 5 3 3 3 3 3 3 3 3 3 3 3 3 3																								
	5 5 5 5 5 5 5 5 5 5 5 5 0 5 5 6 6 6 6 6 6 6 6 6 6 6																								
<b>B6C3F1 MICE FEMALE</b> <b>12500 PPM</b>	0 0																								
	0 0																								
	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 7																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

females  
(cont...)

**ALIMENTARY SYSTEM**

Esophagus	+ +																								
Gallbladder	+ A + + + + +																								
Intestine Large, Cecum Edema	+ A + + + + +																								
Intestine Large, Colon	+ A + + + + +																								
Intestine Large, Rectum	+ +																								
Intestine Small, Duodenum	+ A + + + + +																								
Intestine Small, Ileum	+ A + + + + +																								
Intestine Small, Jejunum	+ + + + + + + + + + + + A + + + + + + + + + + A + + + + +																								
Liver	+ +																								
Angiectasis	3 3																								
Clear Cell Focus	X																								
Hematopoietic Cell Proliferation	1 2																								
Infiltration Cellular, Lymphocyte	2																								
Infiltration Cellular, Mixed Cell	1 1 3																								
Mixed Cell Focus	X																								
Necrosis, Focal	1																								

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TDMS No. 20008 - 04

Test Type: CHRONIC

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Species/Strain: MICE/B6C3F1

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Milk thistle extract

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Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 7 7 7 7 7 7 7 6 4 7 7 7 7 7 7 7 7 7 7 7 7																								
B6C3F1 MICE FEMALE 12500 PPM	3 3 3 3 3 3 3 3 3 3 3 7 5 3 3 3 3 3 3 3 3 3 3 3 3																								
	5 5 5 5 5 5 5 5 5 5 5 5 0 5 5 6 6 6 6 6 6 6 6 6 6																								
ANIMAL ID	0 0																								
	0 0																								
12500 PPM	2 2																								
	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

females (cont...)

Centrilobular, Necrosis																										2
Hepatocyte, Vacuolization																										3
Cytoplasmic Kupffer Cell, Hyperplasia																										
Mesentery																										
Fat, Necrosis																										
Pancreas																										
Atrophy																										4
Acinus, Cytoplasmic Alteration																										4
Salivary Glands																										
Infiltration Cellular, Lymphocyte																										3 2 2 3 3 2
Stomach, Forestomach																										
Diverticulum																										X
Epithelium, Hyperplasia																										
Stomach, Glandular																										
Cyst																										3 3
Erosion																										2
Epithelium, Hyperplasia																										1

CARDIOVASCULAR SYSTEM

Heart																									
Cardiomyopathy																									
Mineralization																									

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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
	7	7	7	7	7	7	7	7	7	7	7	6	4	7	7	7	7	7	7	7	7	7	7	7	7
	3	3	3	3	3	3	3	3	3	3	3	7	5	3	3	3	3	3	3	3	3	3	3	3	3
	5	5	5	5	5	5	5	5	5	5	5	5	0	5	5	6	6	6	6	6	6	6	6	6	6
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	5	5	5	5	5	5	5	5	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

females (cont...)

Artery, Inflammation, Chronic Active

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Accessory Adrenal Cortical Nodule						3										3										
Cyst																							X			
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	
Hyperplasia						1								1												
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	
Parathyroid Gland	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
Cyst																										
Hyperplasia																										
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Pars Distalis, Angiectasis		2																								
Pars Distalis, Cyst										3														3		
Pars Distalis, Hyperplasia, Focal																										
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+
Ectopic Thymus																										
Follicle, Degeneration, Focal	2		2			1				3		2	2	1		1							3	2		

**GENERAL BODY SYSTEM**

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 Page 78

DAY ON TEST	0 0																								
	7 7 7 7 7 7 7 7 7 7 7 6 4 7 7 7 7 7 7 7 7 7 7 7 7																								
ANIMAL ID	3 3 3 3 3 3 3 3 3 3 3 7 5 3 3 3 3 3 3 3 3 3 3 3 3																								
	5 5 5 5 5 5 5 5 5 5 5 5 0 5 5 6 6 6 6 6 6 6 6 6 6																								
<b>B6C3F1 MICE FEMALE</b> <b>12500 PPM</b>	0 0																								
	0 0																								
	2 2																								
	5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7																								
	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...)

Tissue NOS +

**GENITAL SYSTEM**

Clitoral Gland Inflammation, Chronic	+   +																								
Ovary Angiectasis	+ +																								
Ovary Cyst	3 3 2																								
Ovary Hemorrhage	3 3 2																								
Ovary Corpus Luteum, Hyperplasia	3 3 4 1 3 3 3 3 3 2 3 3 3 4 4 4 3 3 4 3 4 3 4 1 3																								
Ovary Interstitial Cell, Hyperplasia	4 3																								
Uterus Angiectasis	+ +																								
Uterus Hyperplasia, Cystic	3 3 4 1 3 3 3 3 3 2 3 3 3 4 4 4 3 3 4 3 4 3 4 1 3																								
Uterus Inflammation, Chronic	4 3																								

**HEMATOPOIETIC SYSTEM**

Bone Marrow Hyperplasia	+ +																								
Lymph Node Iliac, Hyperplasia, Lymphoid	2 2 2 2 2 2 2 2 2 3 3 2 4 3 2 4 3 2 4 3 2 4 3 2 4																								
	+ +																								
	3																								

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DAY ON TEST	0																								
	7																								
	3										3					7					5				
	5										5					6					6				
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANIMAL ID	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	5	5	5	5	5	5	5	5	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

females (cont...)

Renal, Hyperplasia, Lymphoid																										3				
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					
Angiectasis																			2											
Hyperplasia, Lymphoid											3						3													
Pigmentation											3	3	3																	
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					
Ectasia																3						A	+	+	+	+				
Hematopoietic Cell Proliferation	2																	2												
Hyperplasia, Lymphoid	2												3	2							3									
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					
Hematopoietic Cell Proliferation				1	1	2	1	1					4	4	2				3											
Hyperplasia, Lymphoid					2																	3			3					
Lymphoid Follicle, Hyperplasia	3		3																	3		3						2		
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+					
Angiectasis												2														M	+	+	+	+
Atrophy												2																		
Hyperplasia, Lymphoid										1																				1

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																					2				
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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DAY ON TEST	0 0																								
	7 7 7 7 7 7 7 7 7 7 7 6 4 7 7 7 7 7 7 7 7 7 7 7 7																								
B6C3F1 MICE FEMALE 12500 PPM	3 3 3 3 3 3 3 3 3 3 3 7 5 3 3 3 3 3 3 3 3 3 3 3 3																								
	5 5 5 5 5 5 5 5 5 5 5 5 0 5 5 6 6 6 6 6 6 6 6 6 6																								
ANIMAL ID	0 0																								
	0 0																								
	2 2																								
	5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

females (cont...)

MUSCULOSKELETAL SYSTEM

Bone	+																								
Fibro-Osseous Lesion	1 1																								
Fibrosis	1 1																								
Skeletal Muscle	+ +																								

NERVOUS SYSTEM

Brain	+																								
-------	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

RESPIRATORY SYSTEM

Lung	+																								
Hemorrhage	1 1																								
Infiltration Cellular, Histiocyte	4 4																								
Infiltration Cellular, Lymphocyte	3 3																								
Alveolar Epithelium, Hyperplasia	1 1																								
Arteriole, Hypertrophy	2 2																								
Nose	+																								
Inflammation, Chronic	1 1																								
Trachea	+																								

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								* TOTALS
	4 6 7 7 6 7 7 7 7 7 7 3 7 7 7 7 7 7 7 7 7 7 7 7																								
B6C3F1 MICE FEMALE 12500 PPM	0 0																								* TOTALS
	0 0																								
ANIMAL ID	2 2																								* TOTALS
	7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9																								
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																								* TOTALS

**ALIMENTARY SYSTEM**

Esophagus	+ +																								50	
Gallbladder	A + + + A +																								47	
Intestine Large, Cecum Edema	+ A +																								48 2 1 2.0	
Intestine Large, Colon	+ +																								49	
Intestine Large, Rectum	+ +																								50	
Intestine Small, Duodenum	A + + + A +																								47	
Intestine Small, Ileum	+ +																								49	
Intestine Small, Jejunum	A A + + + + + + + + + + + + A + + + + + + + + + + + +																								45	
Liver	+ +																								50	
Angiectasis																									2 3.0	
Clear Cell Focus																									1	
Hematopoietic Cell Proliferation	4																								2	4 2.3
Infiltration Cellular, Lymphocyte																									2	2 2.0
Infiltration Cellular, Mixed Cell																									3	1.7
Mixed Cell Focus																									1	
Necrosis, Focal																									1	1.0

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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
	4	6	7	7	6	7	7	7	7	7	3	7	7	7	7	7	7	7	7	7	7	7	7	7	7	
	0	4	3	3	6	3	3	3	3	3	3	7	3	2	3	3	3	3	3	3	3	3	3	3	3	
	6	9	5	5	4	2	2	2	2	2	6	1	3	5	6	5	5	5	5	5	2	2	2	2	2	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	
	7	7	7	7	8	8	8	8	8	8	8	8	8	8	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	

Artery, Inflammation, Chronic Active 3 1 3.0

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Accessory Adrenal Cortical Nodule		3		3			3																3			
Cyst																										1
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	
Hyperplasia										1																3
Islets, Pancreatic	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48	
Parathyroid Gland	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48	
Cyst																							3			1
Hyperplasia																										3
Pituitary Gland	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	
Pars Distalis, Angiectasis																										1
Pars Distalis, Cyst																							3			3
Pars Distalis, Hyperplasia, Focal																							1			1
Thyroid Gland	A	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48	
Ectopic Thymus																							3			1
Follicle, Degeneration, Focal		2						3		3	1			1	3		3	2	1							19

**GENERAL BODY SYSTEM**

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DAY ON TEST	0 0																								
	4 6 7 7 6 7 7 7 7 7 7 3 7 7 7 7 7 7 7 7 7 7 7 7																								
ANIMAL ID	0 4 3 3 6 3 3 3 3 3 3 7 3 2 3 3 3 3 3 3 3 3 3 3																								
	6 9 5 5 4 2 2 2 2 2 2 6 1 3 5 6 5 5 5 5 5 2 2 2 2																								
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	<b>* TOTALS</b>
<b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	
	7	7	7	7	8	8	8	8	8	8	8	8	8	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	

Tissue NOS

1

**GENITAL SYSTEM**

Clitoral Gland Inflammation, Chronic	+	+	+	I	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	47	3	2.0	
Ovary Angiectasis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	3	2.3
Cyst				3	3			3		3													3	3		10	3.0	
Hemorrhage			3	2																							12	2.2
Corpus Luteum, Hyperplasia																											1	2.0
Interstitial Cell, Hyperplasia																											1	3.0
Uterus Angiectasis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	3	2.7
Hyperplasia, Cystic	1	3	4	3	4	3	3	2	3	3	4	1	2	3	3	2	4	2	2	2	2	2	3			46	2.8	
Inflammation, Chronic																											2	3.5

**HEMATOPOIETIC SYSTEM**

Bone Marrow Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	21	2.7	
Lymph Node Iliac, Hyperplasia, Lymphoid																											4	1	3.0

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

TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

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	
	4	6	7	7	6	7	7	7	7	7	7	3	7	7	7	7	7	7	7	7	7	7	7	7	
	0	4	3	3	6	3	3	3	3	3	3	7	3	2	3	3	3	3	3	3	3	3	3	3	
	6	9	5	5	4	2	2	2	2	2	6	1	3	5	6	5	5	5	5	5	2	2	2	2	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>12500 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	
	7	7	7	7	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9	9	9	9	0	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0
																									<b>* TOTALS</b>

Renal, Hyperplasia, Lymphoid																									<b>1 3.0</b>
Lymph Node, Mandibular	+ +																								<b>49</b>
Angiectasis																									<b>1 2.0</b>
Hyperplasia, Lymphoid																									<b>3 2.7</b>
Pigmentation	3																								<b>4 3.0</b>
Lymph Node, Mesenteric	A + + + M +																								<b>47</b>
Ectasia																									<b>1 3.0</b>
Hematopoietic Cell Proliferation																									<b>2 2.0</b>
Hyperplasia, Lymphoid	2																								<b>5 2.4</b>
Spleen	A +																								<b>48</b>
Hematopoietic Cell Proliferation	3 1 1 3 3																								<b>17 2.1</b>
Hyperplasia, Lymphoid																									<b>1 2.0</b>
Lymphoid Follicle, Hyperplasia	2 3 2 2																								<b>9 2.6</b>
Thymus	+ + + + M +																								<b>47</b>
Angiectasis																									<b>1 2.0</b>
Atrophy																									<b>1 2.0</b>
Hyperplasia, Lymphoid	3 2 1																								<b>5 1.6</b>

**INTEGUMENTARY SYSTEM**

Mammary Gland	+ +																								<b>50</b>
Hyperplasia	1 2 3 1																								<b>5 1.8</b>
Skin	+ +																								<b>50</b>

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1-4 .. Lesion qualified as:  
1) Minimal 3) Moderate  
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DAY ON TEST	0																								* TOTALS
	4 6 7 7 6 7 7 7 7 7 7 3 7 7 7 7 7 7 7 7 7 7 7 7																								
B6C3F1 MICE FEMALE 12500 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 0																								

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Fibro-Osseous Lesion			1	2								1				2	1		1	1	1				15 1.1
Fibrosis																					1				1 1.0
Skeletal Muscle																									2

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
-------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hemorrhage													2												4 1.5
Infiltration Cellular, Histiocyte							3																		4 3.8
Infiltration Cellular, Lymphocyte																									1 3.0
Alveolar Epithelium, Hyperplasia																									3 1.7
Arteriole, Hypertrophy																									1 1.0
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation, Chronic							3																		2 2.0
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

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 M .. Missing tissue  
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 2) Mild 4) Marked  
 Page 88



TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																							
	4 6 7 7 6 7 7 7 7 7 7 3 7 7 7 7 7 7 7 7 7 7 7 7																							
B6C3F1 MICE FEMALE 12500 PPM	0 0																							
	0 0																							
ANIMAL ID	2 2																							
	7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9																							
* TOTALS	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																							

**SPECIAL SENSES SYSTEM**

Eye	+																								50	
Harderian Gland	+																								50	
Hyperplasia, Focal																									1	1.0

**URINARY SYSTEM**

Kidney	+																								49	
Cyst																									1	3.0
Infiltration Cellular, Lymphocyte																									2	2.0
Mineralization																									1	2.0
Nephropathy																									3	1.3
Renal Tubule, Accumulation, Hyaline Droplet																									1	3.0
Renal Tubule, Necrosis																									2	2.5
Urinary Bladder	+																								50	
Edema																									1	3.0
Infiltration Cellular, Lymphocyte																									3	2.7

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 + .. Tissue examined microscopically  
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 Page 89

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	
7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	0
3	3	3	3	3	5	3	3	3	3	3	3	3	3	3	3	8	3	6	3	3	3	3	3	3	0
6	6	6	6	6	9	2	2	2	2	6	6	6	6	6	5	8	5	1	5	2	2	2	2	2	0
<hr/>																									
<b>B6C3F1 MICE FEMALE</b> <b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	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	1	1	1	1	1	1	1	1	1	2	2	2	2	2	0
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Duodenum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Peyer's Patch, Inflammation, Suppurative																								2
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Clear Cell Focus																								
Hematopoietic Cell Proliferation																								3
Infiltration Cellular, Lymphocyte																								
Infiltration Cellular, Mixed Cell			2	1																				
Mixed Cell Focus					X																			
Hepatocyte, Vacuolization Cytoplasmic												3												3
Kupffer Cell, Hyperplasia			3																					

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	
	3	3	3	3	3	5	3	3	3	3	3	3	3	3	3	3	8	3	6	3	3	3	3	3	3	
	6	6	6	6	6	9	2	2	2	2	6	6	6	6	6	5	8	5	1	5	2	2	2	2	2	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>25000 PPM</b>	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	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	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

females  
(cont...)

Mesentery																									
Oral Mucosa	+																								
Pancreas	+																								
Atrophy	+																								
Cyst	+																								
Acinus, Cytoplasmic Alteration	+																								
Salivary Glands	+																								
Infiltration Cellular, Lymphocyte	+																								
Stomach, Forestomach	+																								
Epithelium, Hyperplasia	+																								
Stomach, Glandular	+																								
Cyst	+																								

**CARDIOVASCULAR SYSTEM**

Heart	+																								
-------	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

**ENDOCRINE SYSTEM**

Adrenal Cortex	+																								
----------------	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

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DAY ON TEST	0 0																							
	7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 7 7 7																							
B6C3F1 MICE FEMALE 25000 PPM	3 3 3 3 3 5 3 3 3 3 3 3 3 3 3 3 8 3 6 3 3 3 3 3																							
	6 6 6 6 6 9 2 2 2 2 6 6 6 6 6 5 8 5 1 5 2 2 2 2 2																							
ANIMAL ID	0 0																							
	0 0																							
	3 3																							
	0 0 0 0 0 0 0 0 0 0 1 1 1 1 1 1 1 1 1 1 2 2 2 2																							
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																							

females (cont...)

Interstitial Cell, Hyperplasia

Uterus	+ +																							
Hyperplasia, Cystic	2 2 2 4 3 1 4 2 3 2 4 4 4 1 3 2 3 1 1 3 4 4 4 2																							
Inflammation, Chronic	2																							
Metaplasia, Squamous	3																							

HEMATOPOIETIC SYSTEM

Bone Marrow	+ +																							
Hyperplasia	4 2 4 2 3 3 3 3 4 2 2 4 3 3 3 2																							
Myelofibrosis																								

Lymph Node	+ + + + + M + + + + + + + + + + + + + + + + + + M +																							
Hematopoietic Cell Proliferation	3 3																							
Iliac, Hematopoietic Cell Proliferation	3																							
Iliac, Hyperplasia, Lymphoid	3																							
Renal, Hematopoietic Cell Proliferation	2																							
Renal, Hyperplasia, Lymphoid																								

Lymph Node, Mandibular	+ + + + + M + + + + + + + + + + + + + + + + + + M +																							
Atrophy																								
Hematopoietic Cell Proliferation	2																							
Hyperplasia, Lymphoid																								
Pigmentation	3																							

Lymph Node, Mesenteric	+ + + + + + + + + + M + + + + + + + + + + + + + +																							
Atrophy	2																							

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TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

First Dose M/F: 03/25/03 / 03/25/03

Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 7 7 7 7																								
ANIMAL ID	3 3 3 3 3 5 3 3 3 3 3 3 3 3 3 3 8 3 6 3 3 3 3 3 3																								
	6 6 6 6 6 9 2 2 2 2 6 6 6 6 6 5 8 5 1 5 2 2 2 2 2																								
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	0	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

females (cont...)

Ectasia																											
Hyperplasia, Lymphoid											3											1					
Spleen	+ +																										
Fibrosis																											
Hematopoietic Cell Proliferation	4 2 1 3 2 1 1 4 4 3																										
Lymphoid Follicle, Atrophy	3																										
Lymphoid Follicle, Hyperplasia	2																										
Thymus	+ + + + + M +																										
Atrophy	3 3 3 3 3																										
Hyperplasia, Lymphoid	1 1 3 3 2 3 3																										

INTEGUMENTARY SYSTEM

Mammary Gland	+ +																										
Hyperplasia											1											1 1					
Skin	+ +																										
Edema	3																										
Hyperkeratosis	2																										
Epidermis, Hyperplasia	3																										

MUSCULOSKELETAL SYSTEM

Bone	+ +																								
Fibro-Osseous Lesion	1 1 1 2 1 1 1																								

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

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 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7
	3	3	3	3	3	5	3	3	3	3	3	3	3	3	3	3	8	3	6	3	3	3	3	3	3
	6	6	6	6	6	9	2	2	2	2	6	6	6	6	6	5	8	5	1	5	2	2	2	2	2
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	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

females  
(cont...)

Fracture X

**NERVOUS SYSTEM**

Brain +

**RESPIRATORY SYSTEM**

Lung +  
 Hemorrhage 2  
 Infiltration Cellular, Histiocyte 2  
 Infiltration Cellular, Lymphocyte 3 3 2 2  
 Thrombosis 2  
 Alveolar Epithelium, Hyperplasia 1

Nose +

Trachea +

**SPECIAL SENSES SYSTEM**

Eye +  
 Cataract  
 Inflammation, Chronic 3  
 Cornea, Hyperplasia 3

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 Page 95

TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

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First Dose M/F: 03/25/03 / 03/25/03

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	6	7	7	7	7	7	7	7	7	7	6	7	6	7	7	7	7	7	7	7	7
	3	3	3	3	3	5	3	3	3	3	3	3	3	3	3	8	3	6	3	3	3	3	3	3	3	
	6	6	6	6	6	9	2	2	2	2	6	6	6	6	6	5	8	5	1	5	2	2	2	2	2	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ANIMAL ID	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	
	<b>females (cont...)</b>																									

Harderian Gland +

URINARY SYSTEM

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																									
Infiltration Cellular, Lymphocyte															3										
Nephropathy			1			1										1				1				3	
Renal Tubule, Dilatation, Diffuse																									2
Renal Tubule, Pigmentation							1																		
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration Cellular, Lymphocyte	2		3							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 0																							
	7 7 6 7 6 7 7 6 7 7 7 7 7 7 6 7 7 7 7 7 7 6 7 7 7																							
B6C3F1 MICE FEMALE 25000 PPM	3 3 3 3 7 3 3 9 3 3 3 3 3 3 0 3 3 3 3 3 3 6 3 3 3																							
	5 5 7 5 4 6 6 7 6 6 2 2 2 2 2 5 5 5 5 5 5 5 5 5 5																							
ANIMAL ID	0 0																							
	0 0																							
	3 3																							
	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 4 5																								
<b>* TOTALS</b>																								

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	<b>49</b>
Gallbladder	+	+	M	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	A	+	+	+	<b>47</b>
Intestine Large, Cecum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	+	+	+	+	<b>49</b>
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>49</b>
Intestine Small, Duodenum	+	+	+	+	+	+	+	A	+	+	+	+	+	+	A	+	+	+	+	+	+	A	+	+	+	<b>47</b>
Intestine Small, Ileum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	<b>48</b>
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	+	A	+	+	+	<b>48</b>
Peyer's Patch, Inflammation, Suppurative																									<b>1 2.0</b>	
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Clear Cell Focus															X										<b>1</b>	
Hematopoietic Cell Proliferation																									<b>1 3.0</b>	
Infiltration Cellular, Lymphocyte																							2		<b>1 2.0</b>	
Infiltration Cellular, Mixed Cell																									<b>2 1.5</b>	
Mixed Cell Focus																									<b>1</b>	
Hepatocyte, Vacuolization Cytoplasmic																								3	<b>3 3.0</b>	
Kupffer Cell, Hyperplasia																									<b>1 3.0</b>	

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

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	6	7	7	6	7	7	7	7	7	6	7	7	7	7	7	6	7	7	7	0	
	3	3	3	3	7	3	3	9	3	3	3	3	3	0	3	3	3	3	3	3	6	3	3	3	
	5	5	7	5	4	6	6	7	6	6	2	2	2	2	5	5	5	5	5	5	5	5	5	5	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	
																								<b>* TOTALS</b>	

Mesentery																								+	1						
Oral Mucosa																									1						
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	49		
Atrophy																									1	4.0					
Cyst																									1	3.0					
Acinus, Cytoplasmic Alteration																									1	3.0					
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	49		
Infiltration Cellular, Lymphocyte												2							3	3						3	8	2.8			
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+	+	+	+	50	
Epithelium, Hyperplasia																									3	1.3					
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+	+	+	+	50	
Cyst				3																3						50	2	3.0			

**CARDIOVASCULAR SYSTEM**

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

**ENDOCRINE SYSTEM**

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
----------------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----

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 + .. Tissue examined microscopically  
 x .. Lesion present  
 I .. Insufficient tissue  
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 BLANK .. Not examined microscopically  
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DAY ON TEST	0																								* TOTALS
	7	7	6	7	6	7	7	6	7	7	7	7	7	6	7	7	7	7	7	6	7	7	7		
	3	3	3	3	7	3	3	9	3	3	3	3	3	0	3	3	3	3	3	3	6	3	3	3	
	5	5	7	5	4	6	6	7	6	6	2	2	2	2	2	5	5	5	5	5	5	5	5		
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
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		
	2	2	2	2	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		

Interstitial Cell, Hyperplasia	3																								<b>1 3.0</b>
Uterus	+																								<b>50</b>
Hyperplasia, Cystic	3	4	4	3		2	2		2	3	2	2	2		3	4	4	2	4	2	3	3	3		
Inflammation, Chronic																							2	<b>2 2.0</b>	
Metaplasia, Squamous																							2	<b>2 2.5</b>	

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+																								<b>50</b>
Hyperplasia	2	2		2	3			4	2											2			4		
Myelofibrosis																			1	<b>1 1.0</b>					
Lymph Node																							+	<b>6</b>	
Hematopoietic Cell Proliferation																								<b>1 3.0</b>	
Iliac, Hematopoietic Cell Proliferation																								<b>1 3.0</b>	
Iliac, Hyperplasia, Lymphoid																							2	<b>3 2.7</b>	
Renal, Hematopoietic Cell Proliferation																								<b>1 3.0</b>	
Renal, Hyperplasia, Lymphoid																							1	<b>3 1.7</b>	
Lymph Node, Mandibular	+																								<b>46</b>
Atrophy																							3	<b>1 3.0</b>	
Hematopoietic Cell Proliferation																								<b>1 2.0</b>	
Hyperplasia, Lymphoid																							3	<b>1 3.0</b>	
Pigmentation																								<b>1 3.0</b>	
Lymph Node, Mesenteric	+																								<b>49</b>
Atrophy																								<b>1 2.0</b>	

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 BLANK .. Not examined microscopically  
 1-4 .. Lesion qualified as:  
 1) Minimal 3) Moderate  
 2) Mild 4) Marked  
 Page 100

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	6	7	7	6	7	7	7	7	7	6	7	7	7	7	7	7	6	7	7	7	0	
	3	3	3	3	7	3	3	9	3	3	3	3	3	0	3	3	3	3	3	3	6	3	3	3	3	
	5	5	7	5	4	6	6	7	6	6	2	2	2	2	2	5	5	5	5	5	5	5	5	5	5	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	2	2	2	2	3	3	3	3	3	3	3	3	3	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	
																										<b>* TOTALS</b>

Ectasia	3																											<b>1 3.0</b>	
Hyperplasia, Lymphoid																													<b>2 2.0</b>
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	A	+	+	+	+	+	<b>49</b>	
Fibrosis																													<b>1 3.0</b>
Hematopoietic Cell Proliferation	3					1		4	2	2										1		1						<b>17 2.3</b>	
Lymphoid Follicle, Atrophy																													<b>1 3.0</b>
Lymphoid Follicle, Hyperplasia	2			2			2						2		3	3	2												<b>8 2.3</b>
Thymus	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>46</b>	
Atrophy															3														<b>5 3.0</b>
Hyperplasia, Lymphoid												1																	<b>6 1.8</b>

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Hyperplasia					1			2																						<b>5 1.2</b>
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Edema																														<b>1 3.0</b>
Hyperkeratosis																														<b>1 2.0</b>
Epidermis, Hyperplasia																														<b>1 3.0</b>

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>
Fibro-Osseous Lesion	1		2	2					1		1	1		1	2			1		2	3		1	2					<b>19 1.4</b>

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	6	7	7	6	7	7	7	7	7	7	6	7	7	7	7	7	7	6	7	7	7	7	0
3	3	3	3	7	3	3	9	3	3	3	3	3	3	0	3	3	3	3	3	3	6	3	3	3	3	0
5	5	7	5	4	6	6	7	6	6	2	2	2	2	2	5	5	5	5	5	5	5	5	5	5	5	0
<hr/>																										
<b>B6C3F1 MICE FEMALE</b> <b>25000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	4	5
6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	<b>50</b>	

Harderian Gland + **50**

**URINARY SYSTEM**

Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Cyst																											<b>1 3.0</b>
Infiltration Cellular, Lymphocyte																											<b>2 3.0</b>
Nephropathy																											<b>13 1.2</b>
Renal Tubule, Dilatation, Diffuse																											<b>1 2.0</b>
Renal Tubule, Pigmentation																											<b>1 1.0</b>
<hr/>																											
Urinary Bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	<b>50</b>	
Infiltration Cellular, Lymphocyte																											<b>5 2.4</b>

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 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	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	6	7	6	7	7	1	7	7	
3	3	3	3	2	2	2	2	2	2	3	3	3	3	3	3	3	3	8	3	5	2	2	9	2	2	
5	5	5	2	1	9	9	9	9	9	6	6	6	6	6	6	6	6	8	6	9	9	9	6	9	9	
<hr/>																										
<b>B6C3F1 MICE FEMALE</b> <b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	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	3

Kupffer Cell, Pigmentation																										3
Mesentery																										
Fat, Necrosis																										
Pancreas																										
Atrophy																										
Cyst																										2
Acinus, Cytoplasmic Alteration																										
Duct, Hyperplasia																										3 3
Salivary Glands																										
Atrophy																										
Infiltration Cellular, Lymphocyte																										3 2 1
Stomach, Forestomach																										
Erosion																										2
Stomach, Glandular																										
Cyst																										3 3 3 3
Erosion																										3

**CARDIOVASCULAR SYSTEM**

Heart																										

**ENDOCRINE SYSTEM**

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 + .. Tissue examined microscopically  
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 Page 105

TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 1 7 7																								
ANIMAL ID	3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2																								
	5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9																								
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	5	5	5	5	5	5	5	5	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

females  
(cont...)

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule					3	3								3										
Hypertrophy, Focal																						1		
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia							2																	
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Parathyroid Gland	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																								
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	M	+	+	+	+	+	+	+	+
Pars Distalis, Angiectasis									2															
Pars Distalis, Hyperplasia, Focal		2	1						2	3												1		
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ultimobranchial Cyst																								
Follicle, Cyst																								
Follicle, Degeneration, Focal	3		3	2			2	3			1		2									1		
Follicular Cell, Hyperplasia																								

**GENERAL BODY SYSTEM**

Tissue NOS

\* .. 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. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
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 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 1 7 7																								
B6C3F1 MICE FEMALE 50000 PPM	3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2																								
	5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9																								
ANIMAL ID	0 0																								
	0 0																								
	3 3																								
	5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

females  
(cont...)

**GENITAL SYSTEM**

Clitoral Gland	+ + + + + + + + + + M + + + + + + + + + + M + +																								
Cyst																									
Inflammation, Chronic	2 2																								
Ovary	+ +																								
Angiectasis	3 3																								
Cyst	1 3																								
Hemorrhage	2 2																								
Corpus Luteum, Hyperplasia																									
Interstitial Cell, Hyperplasia																									
Thecal Cell, Hyperplasia																									
Uterus	+ +																								
Angiectasis	2 2 3 3 1 4 4 3 2 4 4 2 2 1 2 2 2 3 1 4																								
Hyperplasia, Cyst																									
Inflammation, Chronic																									
Metaplasia, Squamous																									

**HEMATOPOIETIC SYSTEM**

Bone Marrow	+ +																								
Hyperplasia	4 4 2 3 2																								
Lymph Node																									
Iliac, Hematopoietic Cell Proliferation																									

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DAY ON TEST	0 0																								
	7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 1 7 7																								
ANIMAL ID	3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2																								
	5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9																								
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
	5	5	5	5	5	5	5	5	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

females (cont...)

Iliac, Hyperplasia, Lymphoid																																					
Lymph Node, Mandibular	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	M	+	+	+	+												
Hematopoietic Cell Proliferation																																					
Hyperplasia, Lymphoid	3			2																																	
Pigmentation																																					
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+												
Atrophy					3																																
Hyperplasia, Lymphoid																																					
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+												
Hematopoietic Cell Proliferation					4		4																														
Lymphoid Follicle, Hyperplasia									2		2																										
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+												
Atrophy					3		2																														

**INTEGUMENTARY SYSTEM**

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+																				
Hyperplasia													1		3		1		2																										
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+																				
Edema					2																																								
Inflammation, Chronic																																													

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

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
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 Lab: SRI

DAY ON TEST	0 0																								
	7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 1 7 7																								
B6C3F1 MICE FEMALE 50000 PPM	3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2																								
	5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9																								
ANIMAL ID	0 0																								
	0 0																								
50000 PPM	3 3																								
	5 5 5 5 5 5 5 5 5 5 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

females (cont...)

**SPECIAL SENSES SYSTEM**

Eye	+ +																								
Harderian Gland	+ +																								

**URINARY SYSTEM**

Kidney	+ +																								
Cyst																									
Hyperplasia, Lymphoid	2																								
Infiltration Cellular, Lymphocyte	3 2 3 3 3																								
Metaplasia, Osseous	1 1																								
Nephropathy	1 1 1 1																								
Renal Tubule, Accumulation, Hyaline Droplet	3																								
Urinary Bladder	+ +																								
Infiltration Cellular, Lymphocyte	3																								

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 Lab: SRI

	DAY ON TEST																									* TOTALS	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
<b>B6C3F1 MICE FEMALE</b>	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	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
<b>50000 PPM</b>	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	5	5	5	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>ANIMAL ID</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	7	7	7	7	8	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	0	

**ALIMENTARY SYSTEM**

Esophagus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Gallbladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	
Intestine Large, Cecum Edema	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	1 2.0
Intestine Large, Colon	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Intestine Large, Rectum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Intestine Small, Duodenum Epithelium, Hyperplasia	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	1 3.0
Intestine Small, Ileum Peyer's Patch, Necrosis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	1 2.0
Intestine Small, Jejunum	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49	
Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Clear Cell Focus																												1
Hematopoietic Cell Proliferation																												6 2.3
Necrosis, Diffuse																												1 2.0
Centrilobular, Necrosis																												1 3.0
Kupffer Cell, Hyperplasia																												1 3.0

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TDMS No. 20008 - 04  
 Test Type: CHRONIC  
 Route: DOSED FEED  
 Species/Strain: MICE/B6C3F1

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

Milk thistle extract  
 CAS Number: 84604-20-6

Date Report Requested: 09/30/2008  
 Time Report Requested: 13:13:48  
 First Dose M/F: 03/25/03 / 03/25/03  
 Lab: SRI

DAY ON TEST	0																								* TOTALS
	7																								
B6C3F1 MICE FEMALE 50000 PPM	3																								* TOTALS
	6																								
ANIMAL ID	0																								* TOTALS
	0																								
ANIMAL ID	3																								* TOTALS
	7																								
ANIMAL ID	8																								* TOTALS
	9																								

Kupffer Cell, Pigmentation																									1	3.0
Mesentery																										3
Fat, Necrosis																									3	3.0
Pancreas																									50	
Atrophy																									1	2.0
Cyst																									4	4.0
Acinus, Cytoplasmic Alteration																									2	3.0
Duct, Hyperplasia																									4	4.0
Salivary Glands																									50	
Atrophy																									2	1.5
Infiltration Cellular, Lymphocyte																									3	2.8
Stomach, Forestomach																									50	
Erosion																									1	2.0
Stomach, Glandular																									50	
Cyst																									4	3.0
Erosion																									1	3.0

**CARDIOVASCULAR SYSTEM**

Heart																									50	
-------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	----	--

**ENDOCRINE SYSTEM**

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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 FEMALE	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	
50000 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	
	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	5	5	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	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

GENITAL SYSTEM

Clitoral Gland	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+	+	47
Cyst				3																					1 3.0
Inflammation, Chronic																									2 2.0
Ovary	+	+	+	+	+	I	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Angiectasis	2												2									3			4 2.5
Cyst		3		3			3				4	3	3				3	3				3		3	19 3.1
Hemorrhage		3											2	3	2	3						2			10 2.3
Corpus Luteum, Hyperplasia																3									1 3.0
Interstitial Cell, Hyperplasia														2								2			2 2.0
Thecal Cell, Hyperplasia											3														1 3.0
Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Angiectasis		2											4			3									6 2.7
Hyperplasia, Cystic	4	4	3	3	3	3	3	4		3	1	2	2	3	2	3	2	3	3	4	1	3	1	3	44 2.7
Inflammation, Chronic														3											1 3.0
Metaplasia, Squamous												3	3												2 3.0

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Hyperplasia		2	2		2		2	4		2			2	4		3	2	2	2				2		18 2.6
Lymph Node									+		+														4
Iliac, Hematopoietic Cell Proliferation																2									1 2.0

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Species/Strain: MICE/B6C3F1

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

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DAY ON TEST	0																								* TOTALS
	7																								
	3																								
	6																								
<b>B6C3F1 MICE FEMALE</b>	0																								
	0																								
	3																								
	7																								
	6																								
<b>50000 PPM</b>	0																								
	0																								
	3																								
	7																								
	6																								

Iliac, Hyperplasia, Lymphoid	3																								<b>1 3.0</b>
Lymph Node, Mandibular	+																								<b>47</b>
Hematopoietic Cell Proliferation	2																								<b>1 2.0</b>
Hyperplasia, Lymphoid	2																								<b>3 2.3</b>
Pigmentation	3																								<b>7 3.0</b>
Lymph Node, Mesenteric	+																								<b>50</b>
Atrophy	+																								<b>2 2.5</b>
Hyperplasia, Lymphoid	3																								<b>1 3.0</b>
Spleen	+																								<b>50</b>
Hematopoietic Cell Proliferation	3																								<b>11 2.7</b>
Lymphoid Follicle, Hyperplasia	2																								<b>6 2.2</b>
Thymus	+																								<b>49</b>
Atrophy	+																								<b>3 2.7</b>

**INTEGUMENTARY SYSTEM**

Mammary Gland	+																								<b>50</b>
Hyperplasia	+																								<b>4 1.8</b>
Skin	+																								<b>50</b>
Edema	+																								<b>1 2.0</b>
Inflammation, Chronic	+																								<b>1 1.0</b>

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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	
	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	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	5	5	5	5	
<b>B6C3F1 MICE FEMALE</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
<b>50000 PPM</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
	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	<b>* TOTALS</b>

**MUSCULOSKELETAL SYSTEM**

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50			
Fibro-Osseous Lesion				1	4						2					1									1	2		17	1.7	
Fracture																													1	
Skeletal Muscle																													3	

**NERVOUS SYSTEM**

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50			
Compression																2													1	2.0

**RESPIRATORY SYSTEM**

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Hemorrhage							1	2							1	3		2										7	1.7
Infiltration Cellular, Histiocyte																	2											1	2.0
Infiltration Cellular, Lymphocyte				2																				3				5	2.2
Alveolar Epithelium, Hyperplasia			1																									1	1.0
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Inflammation, Chronic																									1			1	1.0
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

