

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 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	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...)

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 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
 + .. 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	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
B6C3F1 MICE MALE																								
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	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
0 PPM	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5

males (cont...)

Necrosis, Focal 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	+	+	+	+	+	+	+	+	+	+	+	2
Tongue	+																								

CARDIOVASCULAR SYSTEM

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

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

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																									
3																									3	
2																									1	
B6C3F1 MICE MALE	0																									0
	0																									0
	0																									0
	0																									0
	0																									0
	0																									0
0 PPM	1																									2
ANIMAL ID	2																									3
	3																									4
	4																									5
	5																									6
	6																									7
	7																									8
	8																									9
	9																									0
	0																									1
	1																									2
	2																									3
	3																									4
	4																									5
	5																									6
	6																									7
	7																									8
	8																									9
	9																									0
	0																									1
	1																									2
	2																									3
	3																									4
	4																									5
	5																									6
	6																									7
	7																									8
	8																									9
	9																									0
	0																									1
	1																									2
	2																									3
	3																									4
	4																									5
	5																									6
	6																									7
	7																									8
	8																									9
	9																									0
	0																									1
	1																									2
	2																									3
	3																									4
	4																									5
	5																									6
	6																									7
	7																									8
	8																									9
	9																									0

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		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

Page 4

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 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	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 2 2 2 3 4 5																								

males (cont...)

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

HEMATOPOIETIC SYSTEM

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

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

TDMS No. 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	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	
B6C3F1 MICE MALE 0 PPM	ANIMAL ID																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	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	

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																									

* .. 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

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

males (cont...)

MUSCULOSKELETAL SYSTEM

Bone Fracture +

Skeletal Muscle +

NERVOUS SYSTEM

Brain +

Peripheral Nerve Atrophy

Spinal Cord

RESPIRATORY SYSTEM

Lung Foreign Body +

Lung Hemorrhage +

Lung Infiltration Cellular, Histiocyte 4 3 4 4

Lung Infiltration Cellular, Lymphocyte 3 3 3

Lung Alveolar Epithelium, Hyperplasia 3 3

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

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

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

DAY ON TEST	0																									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	
B6C3F1 MICE MALE 0 PPM	ANIMAL ID																									
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	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

* .. 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	0	
		7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	3	7	7	7	7	7	4	7			
		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	

B6C3F1 MICE MALE 0 PPM	ANIMAL ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	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...)																									

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

+ .. Tissue examined microscopically

x .. Lesion present

l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 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																							
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 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																							
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 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 10 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	0 0																							
	7 5 7 7																							
ANIMAL ID	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																							
B6C3F1 MICE MALE	0 0																							
0 PPM	0 0																							
	2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5																							
	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																							
																								* TOTALS

Necrosis, Focal																								1	3	2 2.0
Centrilobular, Necrosis																										1 4.0
Hepatocyte, Vacuolization Cytoplasmic																3	3								3	7 2.9
Mesentery																										
Fat, Necrosis																									+	2 1 2.0
Pancreas																										
Basophilic Focus																										49 1
Acinus, Cytoplasmic Alteration																	3									1 3.0
Salivary Glands																										50
Stomach, Forestomach																										50
Stomach, Glandular																										49
Erosion																										2 2.0
Epithelium, Hyperplasia																										1 3.0
Tongue																										1

CARDIOVASCULAR SYSTEM

Heart																											
Cardiomyopathy																											50
Thrombosis																											4 1.5
Myocardium, Necrosis																											2 3.0
																											1 1.0

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

TDMS No. 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	0
		7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	5	7	7		
		3	3	3	2	3	3	3	3	2	3	2	3	3	3	3	2	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	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 PPM		2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	* TOTALS

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule											3	3					3					3				
Hyperplasia, Focal																			1			1		1		
Hypertrophy, Focal																				2		1				
Capsule, Hyperplasia		2	1	2	1		3					2							2							
																										50
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+
																										49
Islets, Pancreatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Hyperplasia																										
																										49
																										1
																										2.0
Parathyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
																										50
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Pars Distalis, Cyst																										
																										48
Pars Distalis, Hyperplasia, Focal																										
																										2
																										3.0
																										2
																										2.0
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Follicle, Degeneration, Focal																										
																										48
																										6
																										1.5

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

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

M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 Page 12

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																								* TOTALS
	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																								* TOTALS
	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																								* TOTALS
	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 4 5																								* 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																								

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

HEMATOPOIETIC SYSTEM

Bone Marrow Hyperplasia	+ +																								49
	2 2																								13 2.2
Lymph Node Mediastinal, Hematopoietic Cell Proliferation	+																								2
																									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

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

Lymph Node, Mandibular Atrophy	+ +																								48	1	3.0
Hyperplasia, Lymphoid	2																									3	2.3
Lymph Node, Mesenteric Atrophy	+ + + + + + + + 3 + + + + + + + + + + + + + + + + + +																								47	1	3.0
Hematopoietic Cell Proliferation	3																									2	2.5
Hyperplasia, Lymphoid	3																									2	3.0
Spleen	+ +																								50	16	2.7
Hematopoietic Cell Proliferation	3 2																									1	2.0
Necrosis	3																									1	3.0
Lymphoid Follicle, Atrophy	2																									2	2.5
Lymphoid Follicle, Hyperplasia																											
Thymus	+ + + + + + + + 2 + + + + + + + + + + + + M M + M																								45	4	2.5
Atrophy	3																									2	3.0
Cyst	3																									3	3.0

INTEGUMENTARY SYSTEM

Mammary Gland	+ +																								50		
Skin	+ +																								50		
Edema																											
Ulcer																										3	3.0
Epidermis, Hyperplasia																										3	3.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 14

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
	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																								* TOTALS
	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																								* TOTALS
	0 0																								
ANIMAL ID	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																								* 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																								

MUSCULOSKELETAL SYSTEM

Bone	+																								50
Fracture																									1
Skeletal Muscle																									1

NERVOUS SYSTEM

Brain	+																								50	
Peripheral Nerve Atrophy																									1	1 2.0
Spinal Cord																									1	

RESPIRATORY SYSTEM

Lung	+																								50
Foreign Body																									2
Hemorrhage																									3 2.3
Infiltration Cellular, Histiocyte																									6 3.5
Infiltration Cellular, Lymphocyte																									1 3.0
Alveolar Epithelium, Hyperplasia																									2 3.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 15

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

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
 Infarct 1 2 4
 Infiltration Cellular, Lymphocyte 2 3 4
 Nephropathy 1 1 1 1 1 1 2 2 1 1 1 1 1 1 1 1 2 1 1 1 1 2 1 1 1 1 1 1 1 1
 Renal Tubule, Accumulation, Hyaline Droplet 3
 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	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	5	7	7		
		3	3	3	2	3	3	3	3	2	3	2	3	3	3	3	2	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	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 PPM		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	
																											* TOTALS

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

Page 17

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 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...)

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

DAY ON TEST	0 0																								
	7 7																								
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...)

Mesentery	+																								
Fat, Necrosis	3																								
Pancreas	+ A																								
Acinus, Cytoplasmic Alteration																									
Salivary Glands	+ +																								
Stomach, Forestomach	+ +																								
Diverticulum																									
Ulcer																									
Epithelium, Hyperplasia	X																								
Stomach, Glandular	+ +																								
Erosion																									

CARDIOVASCULAR SYSTEM

Heart	+ +																								
Cardiomyopathy	2																								

ENDOCRINE SYSTEM

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

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

TDMS No. 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																								
B6C3F1 MICE MALE 12500 PPM	3																								
	2																								
ANIMAL ID	0																								
	0																								
12500 PPM	5																								
	1																								

males
(cont...)

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 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1																								

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

Epididymis Granuloma Sperm	+ 3																								
Preputial Gland Cyst	+ 3 3																								

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

TDMS No. 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 6																								
ANIMAL ID	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																								
	5 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 7 7 7 7																								
	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5																								

males
(cont...)

Inflammation, Chronic																										3	3	2			3	3
Prostate	+ +																															
Seminal Vesicle	+ +																															
Testes	+ +																															
Germinal Epithelium, Atrophy																												1				

HEMATOPOIETIC SYSTEM

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

* .. 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 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	ANIMAL ID																									males (cont...)
	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																									

Hematopoietic Cell Proliferation Lymphoid Follicle, Atrophy Red Pulp, Atrophy																										3	2	4	2	1				
Thymus Atrophy Cyst	+	+	+	+	+	+	+	+	I	+	+	+	+	+	+	+	+	+	I	+	+	+	+	+	M	+	+	3						

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

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

* .. 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 22

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																								

* .. 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 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																									
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	+ +																								

* .. 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 24

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																								
B6C3F1 MICE MALE 12500 PPM	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																								
ANIMAL ID	0 0																								
	0 0																								
12500 PPM	0 1																								
	7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 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																									

Mesentery																											3			
Fat, Necrosis																												2	2 2.5	
Pancreas	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49		
Acinus, Cytoplasmic Alteration																												3	1 3.0	
Salivary Glands	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Stomach, Forestomach	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Diverticulum																													1	
Ulcer																													2	1 2.0
Epithelium, Hyperplasia																												1	1 1.0	
Stomach, Glandular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Erosion																													1	1 1.0

CARDIOVASCULAR SYSTEM

Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Cardiomyopathy																														1 2.0

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50			
Accessory Adrenal Cortical Nodule																														3 3	
Hyperplasia, Focal																													1	1 3	
Hypertrophy, Focal																													1	2 3 1 3 1 1	8 1.5
																														2	13 1.5

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

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
	7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 4 7																								
B6C3F1 MICE MALE 12500 PPM	3 3 2 3 3 2 2 3 3 3 1 3 3 3 3 3 3 3 2 3 2 3 3 3																								* TOTALS
	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																								
ANIMAL ID	0 0																								* TOTALS
	0 0																								
ANIMAL ID	0 0																								* TOTALS
	7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 0																								
ANIMAL ID	6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0																								* TOTALS

Capsule, Hyperplasia	3																								2	2.0
Adrenal Medulla Hyperplasia	+ +																								50	1.0
Islets, Pancreatic Hyperplasia	+ + + + + + + + + + + + 3 + + + + + + + + + + + +																								49	3.0
Parathyroid Gland Cyst	+ + + + + + + + + + + + 3 + + + + + + + 3 + + + + + +																								50	3.0
Pituitary Gland Pars Distalis, Cyst	+ + + + + + + + + + M + + + + + + + + + + + + + + +																								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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 27

TDMS No. 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																								
	2																								
ANIMAL ID	0																								
	0																								
7																									
6																									

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

HEMATOPOIETIC SYSTEM

Bone Marrow	+																																																49																		
Hyperplasia	+																								3	4	4	3	2															2	1			4	2	14	2.4																
Lymph Node																																																	1																		
Lymph Node, Mandibular	+																																																45																		
Atrophy	+																																																3																		
Hyperplasia, Lymphoid	+																																																3	4															2	1	3.0
Lymph Node, Mesenteric	+																																																44																		
Atrophy	+																																																2																		
Hematopoietic Cell Proliferation	+																																																3	1.7																	
Hemorrhage	+																																																2	3	2.3																
Hyperplasia, Lymphoid	+																																																2	3	2.3																
Spleen	+																																																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

DAY ON TEST	0																								* TOTALS
	7	7	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7	7	7	7	4	
3	3	2	3	3	2	2	3	3	3	1	3	3	3	3	3	3	3	3	2	3	2	3	3	3	10.3
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	2.5
B6C3F1 MICE MALE 12500 PPM	0																								* TOTALS
	0																								
	0																								
	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8	9	9	9	9	9	9	9	9	9	
6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1.0

URINARY SYSTEM

Kidney	+																								50
Cyst																									10
Infarct																									3.0
Infiltration Cellular, Lymphocyte																									2
Metaplasia, Osseous																									2.5
Nephropathy																									3
Renal Tubule, Hyperplasia																									1.7
Renal Tubule, Necrosis																									3
Urinary Bladder	+																								49
																									1.3
																									1
																									1.0
																									1
																									1.0

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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																								
B6C3F1 MICE MALE 25000 PPM	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
 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																								
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
	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

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	
25000 PPM	2																									males (cont...)
	6	2	2	3	3	3	3	3	3	3	3	6	1	3	3	3	3	3	5	2	2	3	3	3	2	
B6C3F1 MICE MALE	9																									males (cont...)
	0	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																									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	
25000 PPM	1																									males (cont...)
	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	
ANIMAL ID	0																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
25000 PPM	1																									males (cont...)
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Accessory Adrenal Cortical Nodule																									3
Hyperplasia, Focal				1	3									3											
Hypertrophy, Focal	1		1						1										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
 Page 34

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																								
B6C3F1 MICE MALE 25000 PPM	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 2 3 4 5																								

males
(cont...)

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

HEMATOPOIETIC SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 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	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	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																									males (cont...)
ANIMAL ID																									
Hematopoietic Cell Proliferation																									
Hemorrhage																									1
Hyperplasia, Lymphoid																									2
Spleen																									
Hematopoietic Cell Proliferation																									3
Lymphoid Follicle, Hyperplasia																									3
Thymus																									
Atrophy																									3
Cyst																									3

INTEGUMENTARY SYSTEM

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

MUSCULOSKELETAL SYSTEM

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

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	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	7	6	7	7	6	7	7	7	6	7	7	7	7	7	7	0
2	6	2	2	3	3	3	3	3	3	3	3	6	1	3	3	3	3	3	5	2	2	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

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

RESPIRATORY SYSTEM

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

SPECIAL SENSES SYSTEM

Eye																										
	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 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	2	0	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									3						
Hydronephrosis															2											
Infiltration Cellular, Lymphocyte																										
Metaplasia, Osseous																2	1								2 3	
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																										

* .. 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 38

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 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																							
B6C3F1 MICE MALE 25000 PPM	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																							
																								* TOTALS

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

* .. 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 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																							
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25000 PPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
																								* TOTALS

Infiltration Cellular, Mixed Cell																								2	1	2.0																			
Necrosis, Focal																								1	1	2.2																			
Necrosis, Diffuse																								2		2.0																			
Thrombosis																								3		3.0																			
Centrilobular, Necrosis																										2.0																			
Hepatocyte, Vacuolization Cytoplasmic																										3.0																			
Mesentery																								+	+	3																			
Fat, Necrosis																								2	3	2.5																			
Pancreas																								+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Cyst																										49																			
Acinus, Cytoplasmic Alteration																								4		3.5																			
Salivary Glands																								+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Infiltration Cellular, Lymphocyte																									3	3.0																			
Stomach, Forestomach																								+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Diverticulum																									X	1																			
Stomach, Glandular																								+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Erosion																										50																			
																										2.0																			

CARDIOVASCULAR SYSTEM

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

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

TDMS No. 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	6	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7
	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	9
B6C3F1 MICE MALE 25000 PPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	5
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
* TOTALS																								

ENDOCRINE SYSTEM

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50		
Accessory Adrenal Cortical Nodule	3		3												3											4	3.0
Hyperplasia, Focal																								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																3										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
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 41

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

Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Preputial Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Cyst	3			3	3		3	3	3	3	3	3						3				3	3	3	3	26 3.0
Inflammation, Chronic		2				3		2		3		2					4	1					1	2	2	17 2.3
Prostate	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Inflammation, Chronic																										1 3.0
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

HEMATOPOIETIC SYSTEM

Bone Marrow	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Angiectasis																										1 3.0
Hyperplasia							2										2		3	2	2					13 2.0
Lymph Node								+																		2
Lymph Node, Mandibular	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	49
Hyperplasia, Lymphoid																										1 2.0
Pigmentation																										1 3.0
Lymph Node, Mesenteric	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	48

* .. 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	7	7	7	7	6	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7		
	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	
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
25000 PPM	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	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	

Hematopoietic Cell Proliferation																											2		2		2 2.0	
Hemorrhage																																1 1.0
Hyperplasia, Lymphoid									3																			2		2		4 2.3
Spleen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			49		12 2.6
Hematopoietic Cell Proliferation							2																							2		3 2.7
Lymphoid Follicle, Hyperplasia				3					3													2										3 2.7
Thymus	+	+	+	+	+	+	+	+	+	+	+	+	+	+	M	+	+	+	+	+	+	+	+	+	+	+	+			49		5 3.0
Atrophy							3																							3		4 3.0
Cyst									3															3		3						4 3.0

INTEGUMENTARY SYSTEM

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			50			
Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			50		
Cyst Epithelial Inclusion																																	1

MUSCULOSKELETAL SYSTEM

Bone	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+			50			
Skeletal Muscle																																		1

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																								* TOTALS	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
B6C3F1 MICE MALE 25000 PPM	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7		
	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	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	5	
	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	

Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Infiltration Cellular, Lymphoid																		1								1 1.0
Peripheral Nerve																										1
Spinal Cord																										1

RESPIRATORY SYSTEM

Lung	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Foreign Body																		X								1
Hemorrhage																						1				3 1.3
Infiltration Cellular, Histiocyte	3														2									3	4 2.8	
Inflammation, Chronic															2											1 2.0
Thrombosis																										1 2.0
Alveolar Epithelium, Hyperplasia															1	1										3 1.0
Nose	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	
Trachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50	

SPECIAL SENSES SYSTEM

Eye	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
-----	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	----

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

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

		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
DAY ON TEST		7	7	7	7	7	6	7	7	7	7	7	7	7	7	6	7	7	7	7	7	7	7	7	7					
		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				
B6C3F1 MICE MALE		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
25000 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				
		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1				
		2	2	2	2	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4	4	4	4	4	5			
		6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	* TOTALS			
Harderian Gland		+																								50				
URINARY SYSTEM																														
Kidney		+																								50				
Cyst																					3	3	5 3.0							
Hydronephrosis																										1 2.0				
Infiltration Cellular, Lymphocyte																					4		3	2	3 3.0					
Metaplasia, Osseous																										1				5 1.8
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	1				
Renal Tubule, Hyperplasia																														47 1.0
Urinary Bladder		+																								49				
Dilatation																														1
Infiltration Cellular, Lymphocyte																					2				1 2.0					

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

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

Page 45

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

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	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	0	
3	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	0	
1	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	0
<hr/>																											
B6C3F1 MICE MALE 50000 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
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	5	5	5	5	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	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	0	

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																							
B6C3F1 MICE MALE	0 0																							
50000 PPM	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																							

* .. 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 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																								
B6C3F1 MICE MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50000 PPM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	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																								
Lymph Node, Mesenteric	M + + + + + + + + M + + + + + + + + + + + + + + + +																								
Atrophy	2																								
Hematopoietic Cell Proliferation	2																								
Hemorrhage																									
Hyperplasia, Lymphoid																									
Spleen	+ +																								
Hematopoietic Cell Proliferation	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 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																								
																									males (cont...)
																									1 1
																									1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5

Lymphoid Follicle, Hyperplasia

3

Thymus
 Atrophy
 Cyst

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

INTEGUMENTARY SYSTEM

Mammary Gland

+ +

Skin

+ +

MUSCULOSKELETAL SYSTEM

Bone
 Femur, Osteopetrosis

+
 3

NERVOUS SYSTEM

Brain

+ +

Peripheral Nerve
 Atrophy

+
 1

Spinal Cord

+

* .. 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |

males
(cont...)

RESPIRATORY 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | | 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 | |
| B6C3F1 MICE MALE | 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 | |
| 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 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 | 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 | |
| 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

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

| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
|--|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
| | | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 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 | 3 | 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 | 0 | 1 | 2 | 2 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| | | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 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 | 0 | 0 | 0 | 0 | * TOTALS | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Angiectasis | | | | | | | 4 | | | | | | | | | | | | | | | | | | 1 | | | | | | 2 2.5 |
| Basophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Mixed Cell Focus | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |

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

Page 53

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 | |
|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----|
| | 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 | 50 |
| | 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 |
| | 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 |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 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 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 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 |

B6C3F1 MICE MALE
50000 PPM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| 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 | 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 | 8 | 2.3 |
| Hypertrophy, Focal | 2 | | | | | | | | | | | | | | | | | | | | | | | | 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 | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 2 3 3 3 2 3 2 3 3 2 3 3 2 3 3 2 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 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------|
| Capsule, Hyperplasia | 2 3 | | | | | | | | | | | | | | | | | | | | | | | | 5 1.8 |
| Adrenal Medulla | + + + + + + + + M + + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Parathyroid Gland Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | 50 1 3.0 |
| Pituitary Gland Pars Distalis, Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | 50 3 3.0 |
| Thyroid Gland Follicle, Degeneration, Focal | + | | | | | | | | | | | | | | | | | | | | | | | | 50 6 1.3 |

GENERAL BODY SYSTEM

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

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|------------------|
| Epididymis Granuloma Sperm | + | | | | | | | | | | | | | | | | | | | | | | | | 50 1 3.0 |
| Preputial Gland Cyst | M + | | | | | | | | | | | | | | | | | | | | | | | | 49 20 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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
50000 PPM | 3 3 3 3 3 2 3 3 3 2 3 2 3 3 2 3 3 2 3 3 2 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | 1 | 3 | 3 | 2 | 1 | 2 | 2 | 3 | 14 | 2.4 | |
| Prostate | + | + | + | + | + | + | + | + | + | + | 50 |
| Seminal Vesicle | + | + | + | + | + | + | + | + | + | + | 50 |
| Testes | + | + | + | + | + | + | + | + | + | + | 50 |
| Germinal Epithelium, Atrophy | | | | | | | | | | | 1 4.0 |
| Interstitial Cell, Hyperplasia | | | | | | | | | | | 1 3.0 |

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Bone Marrow | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | 2 | 1 | | | | | | | | | | | 2 | | 2 | | | | | | | | 2 | 17 1.8 |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | 47 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | 2 | | | | | | | 1 2.0 |
| Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Lymph Node, Mesenteric | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Spleen | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | 3 | 4 2.8 |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 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 | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.3 |
| Infiltration Cellular, Histiocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | | 4 | 2.8 |
| Thrombosis | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |
| Alveolar Epithelium, Hyperplasia | 1 | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.6 |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Eye | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Cataract | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Harderian Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Hyperplasia, Focal | 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 |
| Infarct | 1 | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1.5 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 58

TDMS No. 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 | |
| B6C3F1 MICE MALE | ----- | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | | |
| 50000 PPM | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | * TOTALS | |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 1 | 49 1.0 |
| Renal Tubule, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.0 |
| Renal Tubule, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |

*** END OF MALE DATA ***

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

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 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 | 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|---|--|--|--|--|--|---|
| Centrilobular, Necrosis
Hepatocyte, Vacuolization Cytoplasmic
Kupffer Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | 4 | | | | | | | | | | | |
| Mesentery
Fat, Necrosis | | | | | | | | | | | + | | | | | | | | | | | + | | | | | | | | | | |
| | | | | | | | | | | | 3 | | | | | | | | | | | 4 | | | | | | | | | | |
| Pancreas
Atrophy
Cyst
Acinus, Cytoplasmic Alteration | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | | | | | | | | |
| | | | | | | | | | | | 4 | | | | | | | | | | | 4 | | | | | | | | | | |
| | 4 | | | | 2 | | | | | | | | | | | | | | 4 | | | | | | | | | | | | | |
| Salivary Glands
Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| | | | | | | | | | | | 2 | 3 | | | | | | | | | | | 3 | | | | | | | | | |
| Stomach, Forestomach
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | |
| Stomach, Glandular
Cyst
Erosion
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | | | | | | |
| | 3 | | | | | | | | | | | | | | 3 | | | | | | | | | | | 3 | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | 1 | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | 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 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 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 | 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

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 62

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

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

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | |

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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 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 | 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...) |

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

* .. 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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

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 | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 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...) | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

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

* .. 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 67

| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
0 PPM | 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 2 2 2 2 2 5 5 5 5 5 9 5 2 2 2 2 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | | 0 | | | | | | | | | | | | | | | | | | | | | | | | 0 |
| 0 PPM | | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| | | 2 2 2 2 3 3 3 3 3 3 3 3 3 3 4 4 4 4 4 4 4 4 4 4 5 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

ALIMENTARY SYSTEM

| | | | |
|--|---|----|-------|
| Esophagus | + | 49 | |
| Gallbladder | + + + M + I + A | 44 | |
| Intestine Large, Cecum | + | 48 | |
| Edema | | 2 | 1 2.0 |
| Hyperplasia, Lymphoid | | | 1 3.0 |
| Intestine Large, Colon | + | 50 | |
| Intestine Large, Rectum | + | 50 | |
| Intestine Small, Duodenum | + | 49 | |
| Intestine Small, Ileum | + A + + + + + + + + + | 46 | |
| Intestine Small, Jejunum | + A + + + + + + + + + | 49 | |
| Peyer's Patch, Inflammation, Suppurative | | 2 | 1 2.0 |
| Liver | + | 50 | |
| Angiectasis | | | 1 3.0 |
| Basophilic Focus | | | 1 |
| Hematopoietic Cell Proliferation | | | 1 3.0 |
| Mixed Cell Focus | | | 1 |
| Necrosis, Focal | 1 | | 3 2.3 |

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

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

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

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 | 6 | | |
| | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 0 | 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 | 9 | | |
| B6C3F1 MICE FEMALE
0 PPM | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accessory Adrenal Cortical Nodule | | | | 3 | | | | | | | | | | | | | | | | | | | | 5 |
| Capsule, Hyperplasia | | | | | | | | | | | 2 | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| | | | | | | | | | | | | | | | | | | | | | | | | 1.5 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia | | | | | | | | | | | | | 3 | | | | | | | | | | | 2 |
| | | | | | | | | | | | | | | | | | | | | | | | | 2.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Cyst | | | | 3 | | | | | | | | | | | | | | | | | | | | 1 |
| | | | | | | | | | | | | | | | | | | | | | | | | 3.0 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | 2 | | 1 | | | 3 | | | | | | | | 5 |
| | | | | | | | | | | | | | | | | | | | | | | | | 1.6 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Follicle, Degeneration, Focal | | | | 3 | | | | | | 1 | 3 | 1 | | | | 3 | 1 | 2 | 1 | | | | | 25 |
| | | | | | | | | | | | | | | | | | | | | | | | | 1.9 |

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

| | 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 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | | | |
| 0 PPM | 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 | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | | |
| | 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 |

* .. 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 | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---------------------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 7 | 7 | 7 | 5 | 7 | 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 | 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 | |
| B6C3F1 MICE FEMALE | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 PPM | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

Edema 2 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
 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 | | | | | | | | | | | | | | | | | | | | | | | | * 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 | |
| B6C3F1 MICE FEMALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 PPM | 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 |

* .. 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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Date Report Requested: 09/30/2008

Test Type: CHRONIC

Milk thistle extract

Time Report Requested: 13:13:48

Route: DOSED FEED

CAS Number: 84604-20-6

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

Species/Strain: MICE/B6C3F1

Lab: SRI

| DAY ON TEST | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|----------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 7 | 7 | 7 | 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 | 3 | 3 | 4 | 0 | 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 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 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 | 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 | 9 | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 2 | 4 2.5 |
| Metaplasia, Osseous | | | | | | | | | | | 1 | | | | | | | | | | | | | 1 | 4 1.3 |
| Nephropathy | | | | | | | | | | | 1 | | | | | | 1 | | | | 1 | 2 | | 1 | 10 1.3 |
| Renal Tubule, Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | 1 | | | | | | 2 2.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Infiltration Cellular, Lymphocyte | 3 | | | | | | | | | | | | | | | | 3 | | | | | | | | 2 3.0 |

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 75

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 7 7 7 7 7 7 7 7 7 7 7 6 4 7 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 12500 PPM | 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 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 |

females (cont...)

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 12500 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 7 7 7 7 7 7 6 4 7 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 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...)

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

* .. 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 78

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-----------|--|--|--|--|---|--|--|--|--|---|--|--|--|--|---|--|--|--|--|---|--|--|--|--|---|--|--|--|--|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | 3 | | | | | 3 | | | | | 7 | | | | | 5 | | | | | 3 | | | | |
| | 5 | | | | | 5 | | | | | 5 | | | | | 5 | | | | | 0 | | | | | 6 | | | | |
| B6C3F1 MICE FEMALE
12500 PPM | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| females (cont...) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Tissue NOS

+

GENITAL SYSTEM

Clitoral Gland
Inflammation, Chronic

+ | +
2 2

Ovary
Angiectasis
Cyst
Hemorrhage
Corpus Luteum, Hyperplasia
Interstitial Cell, Hyperplasia

+
3 3 2
3 3

Uterus
Angiectasis
Hyperplasia, Cystic
Inflammation, Chronic

+
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
4 3

HEMATOPOIETIC SYSTEM

Bone Marrow
Hyperplasia

+
2 2 2 2 2 2 2 2 2 3 3 2 4 3 2 4

Lymph Node
Iliac, Hyperplasia, Lymphoid

+ +
3

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 5 0 5 5 6 6 6 6 6 6 6 6 6 6 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
12500 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 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...)

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

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | | |

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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 4 | 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 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 0 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 12500 PPM | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | 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...)

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

RESPIRATORY SYSTEM

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

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

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 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...)

SPECIAL SENSES SYSTEM

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

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + A + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | | |
| Renal Tubule, Necrosis | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Edema | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 3 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

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 | | 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 | 7 | 7 | 0 | |
| 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 | 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 | 2 | 0 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 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 | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 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 | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-------|
| Esophagus | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Gallbladder | A + + + A + | | | | | | | | | | | | | | | | | | | | | | | | | 47 | |
| Intestine Large, Cecum
Edema | + A + | | | | | | | | | | | | | | | | | | | | | | | | | 48 | 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 | 2.3 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1.7 |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Necrosis, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1.0 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 83

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----|-----|-----|-----|-----|
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 | | | | |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 | | | |
| Kupffer Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 1 | 3.0 | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2 | 2.5 | | |
| Pancreas | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | 1 | 4.0 | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 | 3 | 3.3 | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 | 50 | 8 | 2.5 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Diverticulum | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 50 | 2 | 1.5 |
| Stomach, Glandular | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | 4 | 3.0 | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|----|---|-----|
| Heart | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 | 50 | 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 84

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 |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 4 6 7 7 6 7 7 7 7 7 3 7 7 7 7 7 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
12500 PPM
ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 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 | 6 3.0
1 |
| Accessory Adrenal Cortical Nodule | | 3 | | 3 | | | 3 | | | | | | | | | | | | | | | | 3 | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 3 1.0 |
| Hyperplasia | | | | | | | | | 1 | | | | | | | | | | | | | | | | | |
| Islets, Pancreatic | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Parathyroid Gland | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | 1 3.0
1 3.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 3 | | |
| Pituitary Gland | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | 1 2.0
3 3.0
1 1.0 |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | 1 | | | |
| Thyroid Gland | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | 1 3.0
19 2.0 |
| Ectopic Thymus | | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Follicle, Degeneration, Focal | | 2 | | | | | | | 3 | | 3 | 1 | | | | 1 | 3 | | 3 | 2 | 1 | | | | | |

GENERAL BODY SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 85

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

Tissue NOS

1

GENITAL SYSTEM

Clitoral Gland
Inflammation, Chronic

+ + + | + M + 47
2 3 2.0

Ovary
Angiectasis
Cyst
Hemorrhage
Corpus Luteum, Hyperplasia
Interstitial Cell, Hyperplasia

+ 50
2 3 2.3
3 3 10 3.0
3 2 12 2.2
2 2 2 2 2 1 2.0
2 3 1 3.0

Uterus
Angiectasis
Hyperplasia, Cystic
Inflammation, Chronic

+ 50
1 3 4 3 4 3 3 2 3 3 4 1 2 3 3 2 4 2 2 2 2 3 2 3 2.7
46 2.8
2 3.5

HEMATOPOIETIC SYSTEM

Bone Marrow
Hyperplasia

+ 50
2 4 4 2 3 4 2 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 | 3 | 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 | | |
| | 6 | 9 | 5 | 5 | 4 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 3 | 5 | 6 | 5 | 5 | 5 | 5 | 5 | 2 | 2 | 2 | 2 | | |
| B6C3F1 MICE FEMALE
12500 PPM | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | |
| Renal, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Lymph Node, Mandibular
Angiectasis
Hyperplasia, Lymphoid
Pigmentation | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 3 2.7 |
| | | | | | 3 | | | | | | | | | | | | | | | | | | | | | 4 3.0 |
| Lymph Node, Mesenteric
Ectasia
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid | A | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 2 2.0 |
| | | | | | | | | | | | | | | | 2 | | | | | | | | | | | 5 2.4 |
| Spleen
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Lymphoid Follicle, Hyperplasia | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | | |
| | | | | | 3 | | | | | 1 | | | | 1 | 3 | 3 | | | | | | | | | | 17 2.1 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | | | | | | | 2 | | | | | 3 | 2 | | | | | | 2 | | | | | | | 9 2.6 |
| Thymus
Angiectasis
Atrophy
Hyperplasia, Lymphoid | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 47 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | | | | | | 3 | | | | | | | | | | 2 | | | | | | | | | | 5 1.6 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|--|-------|
| Mammary Gland
Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 5 1.8 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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

| 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 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 |

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

TDMS No. 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 | 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 | 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 | 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 | 2 | 2 | |
| B6C3F1 MICE FEMALE | ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 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 | |
| | | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | |
| | | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | | * TOTALS | |

SPECIAL SENSES SYSTEM

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

URINARY SYSTEM

| | | | |
|---|---|-----------|--------------|
| Kidney | + | 49 | |
| Cyst | | | 1 3.0 |
| Infiltration Cellular, Lymphocyte | | 2 | 2 2.0 |
| Mineralization | | 2 | 1 2.0 |
| Nephropathy | | | 7 1.3 |
| Renal Tubule, Accumulation, Hyaline Droplet | 3 1 | | 1 3.0 |
| Renal Tubule, Necrosis | 3 | | 2 2.5 |
| Urinary Bladder | + | 50 | |
| Edema | | | 1 3.0 |
| Infiltration Cellular, Lymphocyte | | | 3 2.7 |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 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 | 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 |
| | 3 | 3 | 3 | 3 | 3 | 5 | 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 |
| B6C3F1 MICE FEMALE
25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 |

females (cont...)

ALIMENTARY SYSTEM

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

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

TDMS No. 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 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 |
| | 6 | 6 | 6 | 6 | 6 | 9 | 2 | 2 | 2 | 2 | 6 | 6 | 6 | 6 | 6 | 5 | 8 | 5 | 1 | 5 | 2 | 2 | 2 | 2 |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25000 PPM | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 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 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | |

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

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

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Accessory Adrenal Cortical Nodule | 3 | 3 | 3 | 3 | | | | | | | | | | | | | | | | | | | | | |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Pars Distalis, Cyst | | 3 | | | | | | | | | | | | | | | | | | | | | | | |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | 1 | | | | | | | | | | | | | | | | |
| Pars Intermedia, Hyperplasia | | | | | | | | | | | | | | | | | 3 | | | | | | | | |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Follicle, Degeneration, Focal | | | 1 | | | 2 | 2 | | | | 1 | | | 1 | 2 | 1 | | | | 1 | | | 1 | 1 | |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clitoral Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Ovary | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Angiectasis | | | | | | | | | | | | | | 3 | | | | | | | | | | | |
| Cyst | | | 3 | 3 | | | | | | | | 3 | | | 3 | | | | | 3 | 3 | 3 | | | 3 |
| Hemorrhage | | | | | | | 2 | | | | 2 | | | | | | | | | | 2 | | 2 | | 1 |

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

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| 25000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |

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

B6C3F1 MICE FEMALE
25000 PPM

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

* .. 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 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|---|
| | 0736 | 0736 | 0736 | 0736 | 0736 | 0765 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | 0777 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| ANIMAL ID | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 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

* .. 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 | ANIMAL ID | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|-------------|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 6 | 7 | 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 | 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 | 2 | 0 |

B6C3F1 MICE FEMALE
25000 PPM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| 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
 Page 96

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 | 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 | | |
| | 5 | 5 | 7 | 5 | 4 | 6 | 6 | 7 | 6 | 6 | 2 | 2 | 2 | 2 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 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 | | |
| | 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 | * TOTALS | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | 8 2.8 |
| Stomach, Forestomach | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 98

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

Interstitial Cell, Hyperplasia 3 1 3.0

Uterus 50
 Hyperplasia, Cystic 3 4 4 3 2 2 2 3 2 2 2 3 4 4 2 4 2 3 3 3 2 3 46 2.8
 Inflammation, Chronic 2 2 2.0
 Metaplasia, Squamous 2 2 2.5

HEMATOPOIETIC SYSTEM

Bone Marrow 50
 Hyperplasia 2 2 2 3 4 2 24 2.8
 Myelofibrosis 1 1 1.0

Lymph Node 6
 Hematopoietic Cell Proliferation + 1 3.0
 Iliac, Hematopoietic Cell Proliferation + 1 3.0
 Iliac, Hyperplasia, Lymphoid 2 3 2.7
 Renal, Hematopoietic Cell Proliferation + 1 3.0
 Renal, Hyperplasia, Lymphoid 1 3 1.7

Lymph Node, Mandibular 46
 Atrophy + + + + M + + + + + + + + + + + + + + + M + + + 1 3.0
 Hematopoietic Cell Proliferation 3 1 2.0
 Hyperplasia, Lymphoid 3 1 3.0
 Pigmentation 3 1 3.0

Lymph Node, Mesenteric 49
 Atrophy + 1 2.0

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

TDMS No. 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 |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 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 | 2 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | |
| B6C3F1 MICE FEMALE
25000 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 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | |

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

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hyperplasia | | | | 1 | | | 2 | | | | | | | | | | | | | | | | | 5 1.2 |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Edema | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Hyperkeratosis | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epidermis, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Fibro-Osseous Lesion | 1 | | 2 | 2 | | | | | 1 | | 1 | 1 | | 1 | 2 | | | 1 | | 2 | 3 | | 1 | 2 | 19 1.4 |

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

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 7 6 7 6 7 7 6 7 7 7 7 7 7 6 7 7 7 7 7 7 6 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |

Fracture

1

NERVOUS SYSTEM

Brain + 50

RESPIRATORY SYSTEM

Lung + 50
 Hemorrhage 3 2.5
 Infiltration Cellular, Histiocyte 1 2.0
 Infiltration Cellular, Lymphocyte 2 3 6 2.5
 Thrombosis 1 2.0
 Alveolar Epithelium, Hyperplasia 2 2 3 1.7

Nose + 50

Trachea + M + + + 49

SPECIAL SENSES SYSTEM

Eye + 50
 Cataract 3 3.0
 Inflammation, Chronic 3 3.0
 Cornea, Hyperplasia 3 3.0

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 102

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| females (cont...) | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Gallbladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Large, Cecum
Edema | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Duodenum
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Intestine Small, Ileum
Peyer's Patch, Necrosis | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Clear Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | 3 | 3 | | | | | | | | | | | | | | | | | 3 | | |
| Necrosis, Diffuse | | | | | | | | | | | | | | | | | | | | | | 2 | | |
| Centrilobular, Necrosis | | | | 3 | | | | | | | | | | | | | | | | | | | | |
| Kupffer Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | 3 | | |

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 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 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
50000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pancreas | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Duct, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Stomach, Glandular | | | | | | | | | | | | | | | | | | | | | | | | | | + |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | 3 |

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 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 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Cell, Hyperplasia | 3 | | 3 | 2 | | | | 2 | 3 | | | 1 | 2 | | | | | | | | | 1 | | | |

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
 Time Report Requested: 13:13:48
 First Dose M/F: 03/25/03 / 03/25/03
 Lab: SRI

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | 1 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Corpus Luteum, Hyperplasia | 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

* .. 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 | 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 | 2 | 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 | 9 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 8 | 6 | 9 | 9 | 9 | 6 | 9 | 9 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
50000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|
| Iliac, Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular
Hematopoietic Cell Proliferation
Hyperplasia, Lymphoid
Pigmentation | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | M | + | + | + | + | + | | |
| | | | 3 | | | 2 | | | | | | | | | | | | | | | | | | 3 | 3 | | |
| Lymph Node, Mesenteric
Atrophy
Hyperplasia, Lymphoid | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | | 3 | | | | | | | | | | | | | | | 2 | | | | | | | |
| Spleen
Hematopoietic Cell Proliferation
Lymphoid Follicle, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | 4 | 4 | | | | | 2 | 2 | | | | | 2 | | | 3 | 1 | 3 | 1 | | | 3 | | |
| Thymus
Atrophy | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| | | | | 3 | 2 | | | | | | | | | | | | | | | 3 | | | | | | | |

INTEGUMENTARY SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ .. Tissue examined microscopically
x .. Lesion present
I .. Insufficient tissue
M .. Missing tissue
A .. Autolysis precludes evaluation
BLANK .. Not examined microscopically
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked
Page 108

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 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 50000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 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 | |

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 | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked
 Page 110

TDMS No. 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 | 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 | |
| | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 5 | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 50000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Accessory Adrenal Cortical Nodule | 3 | | | 3 | 3 | | | | | | | | | | | | | 3 | | | | | | | 7 | 3.0 | |
| Hypertrophy, Focal | | | | | | | | | | | | 1 | | | | | | | | | | | | | | 2 | 1.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 | |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 5 | 1.8 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Ultimobranchial Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Follicle, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Follicle, Degeneration, Focal | | | | | 1 | 1 | 2 | | | | | 2 | | | 2 | | | | | | | | | | | 13 | 1.9 |
| Follicular Cell, Hyperplasia | | | | | | | | | | | | 1 | | | | | | 3 | | | | | | | | 3 | 1.7 |

GENERAL BODY SYSTEM

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

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * 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 | 7 | 47 |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 11 |
| | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 6 |

B6C3F1 MICE FEMALE

50000 PPM

ANIMAL ID

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

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-------|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 4 1.8 |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Edema | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

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

+ .. Tissue examined microscopically

x .. Lesion present

I .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
50000 PPM
ANIMAL ID | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 5 5 5 5 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fracture | 1 4 2 1 X | | | | | | | | | | | | | | | | | | | | | | | | 17 1.7 |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | 3 |

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-------|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Histiocyte | 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 7 1.7 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | 2 1 3 2 2 | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | 5 2.2 |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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

