

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

B6C3F1 MICE MALE

0 PPM

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									X	X	X				X	X						X			
Eosinophilic Focus																									
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

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DAY ON TEST	ANIMAL ID																									males (cont...)
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7	7	7	7	7	7	6	7	7	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	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

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

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 Lab: SRI

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

males
(cont...)

ENDOCRINE SYSTEM

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

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 3 7 7 7 7 7 4 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 3 9 3 3 3 2 3 1 3 3 3 8 2 3 3 2 3 2 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 0 1 1 0 0 9 1 0 1 9 1 2 0 1 1 0 9 9 0 1 9 2 7 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0 PPM | 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...) | | | | | | | | | | | | | | | | | | | | | | | | |

Epididymis

+ +

Preputial Gland

+ +

Cyst

3 3

Inflammation, Chronic

3 2

Prostate

+ +

Seminal Vesicle

+ +

Degeneration

3 3

Testes

+ +

Germinal Epithelium, Atrophy

1 1

HEMATOPOIETIC SYSTEM

Bone Marrow

+ + + + + + A + + + + + + + + + + + + + + + + + +

Hyperplasia

2 2

Lymph Node

+ +

Mediastinal, Hematopoietic Cell

2 2

Proliferation

4 4

Mediastinal, Hyperplasia, Lymphoid

3 3

Pancreatic, Fibrosis

3 3

Pancreatic, Hematopoietic Cell

3 3

Proliferation

3 3

Pancreatic, Hyperplasia, Lymphoid

3 3

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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 3 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 9 | 3 | 3 | 3 | 2 | 3 | 1 | 3 | 3 | 3 | 3 | 8 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | |
| | 2 | 0 | 1 | 1 | 0 | 0 | 9 | 1 | 0 | 1 | 9 | 1 | 2 | 0 | 1 | 1 | 0 | 9 | 9 | 0 | 1 | 9 | 2 | 7 | 1 | |
| 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
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| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|--------------------|
| B6C3F1 MICE MALE
0 PPM | DAY ON TEST | 0
7
3
2 | 0
7
3
0 | 0
7
3
1 | 0
7
3
1 | 0
7
3
0 | 0
6
9
9 | 0
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9 | 0
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2 | 0
7
3
7 | 0
4
2
1 | 0
7
3
1 | males
(cont...) |
| | ANIMAL ID | 0
0
0
0
1 | 0
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0
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3 | 0
0
0
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4 | 0
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4 | 0
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5 | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Fracture | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | X |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | + |

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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 Page 7

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) | |
|---|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|---|
| | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 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 | 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 | | |

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 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 | 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 | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |

males
(cont...)

* .. Total animals with tissue examined microscopically; Total animals with lesion 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 9

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 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

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 | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Clear Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | 7 |
| Eosinophilic Focus | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hematopoietic Cell Proliferation | X | | | | | | | | | | | | | | | | | | | | | | | | 2 3.5 |
| Hepatodiaphragmatic Nodule | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | 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

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

*** TOTALS**

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|---|---|---|--------------|
| Necrosis, Focal
Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | 1 | 3 | 2 2.0 |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | 3 | 3 | | | | | | | | | 3 | | | 1 4.0 |
| Mesentery
Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 7 2.9 |
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CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|--|--|--|--|--|--|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|---|--|-------|
| Heart | | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cardiomyopathy | | | | | | | | | | | 1 | | | | | | | | | | | | | | 4 1.5 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | 3 | | 2 3.0 |
| Myocardium, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | | 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 11

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | | 7 | 7 | 7 | 7 | 7 | 7 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accessory Adrenal Cortical Nodule | | | | | | | | | 3 | 3 | | | | | 3 | | | | 3 | | | | | | | 7 3.0 |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | 1 | | 1 | 1 | | | | | | 4 1.0 |
| Hypertrophy, Focal | | 2 | 1 | 2 | 1 | | 3 | | | | 2 | | | | 1 | | | 2 | 1 | | | | | | | 13 1.5 |
| Capsule, Hyperplasia | | | | | | | | | | | | | | | | | 2 | | | | | | | | | 2 2.0 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | + | + | + | + | + | 49 |
| Islets, Pancreatic | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia | | | 2 | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Parathyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Pituitary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Pars Distalis, Cyst | | 3 | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Pars Distalis, Hyperplasia, Focal | | | 2 | | | | | | | 2 | | | | | | | | | | | | | | | | 2 2.0 |
| Thyroid Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Follicle, Degeneration, Focal | | | | | | | | 1 | | | | | 2 | | | | | | | 1 | | | | | | 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
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Milk thistle extract
 CAS Number: 84604-20-6

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

| | | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|-----------|---|-----------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | 7 5 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
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| | | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | ANIMAL ID | 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 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 | | | | | | | | | | | | | | | | | | | | | | | |

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

INTEGUMENTARY SYSTEM

| | | |
|--|---|-------------------------------|
| Mammary Gland | + | 50 |
| Skin
Edema
Ulcer
Epidermis, Hyperplasia | +
3
3 | 50
1 3.0
1 3.0
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
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 Lab: SRI

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-------|
| Brain | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | |
| Peripheral Nerve | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 1 2.0 |
| Spinal Cord | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-------|---|---|-------|
| Lung | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | | | | |
| Foreign Body | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3 2.3 | | | |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 4 | 3 | 4 | 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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| B6C3F1 MICE MALE | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | | |
| 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 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 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 |

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

SPECIAL SENSES SYSTEM

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

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------|---------------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cyst | 3 | | | | 3 | | | | | 3 | | | 3 | | | | | | | | | | | 3 | | | 8 3.0 |
| Infarct | | | | | | | | | | | | | | | 1 | 2 | | | | | | | 4 | | | | 4 2.5 |
| Infiltration Cellular, Lymphocyte | | | | | | 2 | | | | | | | | | | | | | | | 3 | | | | | | 3 2.3 |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | | 45 1.2 |
| Renal Tubule, Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | 1 3.0 |
| 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

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 | 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 | 5 | 7 | 7 | | | | | | | | | | | | | | | |
| 3 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 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 | 0 | 0 | 1 | 8 | 0 | 9 | | | | | | | | | | | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
0 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 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 | | | | | | | | | | | | | | | | | | | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion 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 17

1-4 .. Lesion qualified as:

1) Minimal 3) Moderate

2) Mild 4) Marked

TDMS No. 20008 - 04
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 Route: DOSED FEED
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 Lab: SRI

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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...)

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 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 12500 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 5 5 5 5 5 5 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 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 |

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

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

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

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Epididymis Granuloma Sperm | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Preputial Gland Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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 x .. Lesion present
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Milk thistle extract
 CAS Number: 84604-20-6

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 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
Atrophy
Hyperplasia, Lymphoid | + M + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric
Atrophy
Hematopoietic Cell Proliferation
Hemorrhage
Hyperplasia, Lymphoid | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 2 | | | | | | | | | | | 1 | | | | | | | | | | | 2 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | | | | | | | | | | | 2 | | | | | | | | | | | 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

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 Milk thistle extract
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|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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...)

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|---|---|---|--|--|--|--|--|---|--|---|---|---|---|---|--|--|--|--|--|
| Hematopoietic Cell Proliferation
Lymphoid Follicle, Atrophy
Red Pulp, Atrophy | | | | | | | | | | | 3 | 2 | 4 | | | | | | 2 | | | | | | 1 | | | | | |
| Thymus
Atrophy
Cyst | + + + + + + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | M | + | + | 3 | | | | | | |
| | | | | | | | | | | | 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
 Page 22
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

| DAY ON TEST | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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
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|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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...)

URINARY SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
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|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|--|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 4 | 7 | | |
| | 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 | |
| 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 | 1 | |
| 12500 PPM | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|-------|
| 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 | |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 1.0 | |
| Stomach, Glandular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | | |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------|
| Heart | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-------------|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 | |
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 3 |
| Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 1 |
| Hypertrophy, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2 3 1 3 1 1 |

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|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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 1.0 |
| Islets, Pancreatic
Hyperplasia | + + + + + + + + + + + + 3 + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 49 | 1 3.0 |
| Parathyroid Gland
Cyst | + + + + + + + + + + + + 3 + + + + + + + 3 + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 2 3.0 |
| Pituitary Gland
Pars Distalis, Cyst | + + + + + + + + + + M + + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 48 | 3 3.0 |
| Thyroid Gland
Follicle, Degeneration, Focal | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | 11 1.1 |

GENERAL BODY SYSTEM
 NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|--------|
| Epididymis
Granuloma Sperm | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 1 3.0 |
| Preputial Gland
Cyst | + | | | | | | | | | | | | | | | | | | | | | | | | 50 | 28 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 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 7 7 4 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 2 3 3 2 2 3 3 3 1 3 3 3 3 3 3 3 2 3 2 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 0 9 2 0 9 9 0 0 3 6 0 0 1 0 0 1 1 0 9 0 9 0 7 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| 12500 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 7 7 7 8 8 8 8 8 8 8 8 8 8 9 9 9 9 9 9 9 9 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---------------|
| 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 | + + + M + + + + + M + M + + + M + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 45 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Hyperplasia, Lymphoid | 3 4 | | | | | | | | | | | | | | | | | | | | | | | | 2 3.5 |
| Lymph Node, Mesenteric | + + + M + M + + + + + I M + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | 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

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
12500 PPM | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|----------------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | 7 |
| | 3 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| | | | | | 3 | 1 | | | | 1 | 4 | 2 | | | 2 | | | 1 | | | | | | | | |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymphoid Follicle, Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Red Pulp, Atrophy | | | | | | | | | | | | | | | | | | | | | | | 3 | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | + | |
| Atrophy | | | | | | | | | | | 3 | 4 | 3 | | | | | | | | | | 3 | | | |
| Cyst | | | | | | | | | | | | | | 3 | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 46 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 5 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3.2 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 2 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | 3.0 | |

INTEGUMENTARY SYSTEM

Mammary Gland

+ 50

Skin

+ 50

MUSCULOSKELETAL SYSTEM

Bone Necrosis

+ 50
2 1 2.0

Skeletal Muscle

+ 2

NERVOUS SYSTEM

Brain

+ 50

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

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

males
(cont...)

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 4 7 7 7 7 7 7 7 7 7 6 7 7 6 7 7 7 6 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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
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 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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

TDMS No. 20008 - 04
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 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 | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | | | | | |

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

HEMATOPOIETIC SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|
| Bone Marrow Angiectasis Hyperplasia | 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 | 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 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 | 2 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 |

males (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Hematopoietic Cell Proliferation | | | | | | | | | | 3 | | 3 | | 2 | | | 2 | 2 | | | | 4 | | 3 | 3 |
| Lymphoid Follicle, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | |
| Thymus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | |
| Atrophy | | | | | | | | | | | | 3 | 3 | | | | | | 3 | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |

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

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

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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| B6C3F1 MICE MALE | 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 | 6 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 1 | 3 | 3 | 3 | 3 | 3 | 5 | 2 | 2 | 3 | 3 | 3 | 2 | |
| ANIMAL ID | 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 3 | 2 | 0 | 8 | 1 | 1 | 0 | 7 | 9 | 9 | 2 | 1 | 0 | 9 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | |

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

RESPIRATORY SYSTEM

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

SPECIAL SENSES SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 Page 37
 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 | 3 | 2 | 0 |
| 9 | 0 | 9 | 9 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 3 | 2 | 0 | 8 | 1 | 1 | 0 | 7 | 9 | 9 | 2 | 1 | 0 | 9 | 0 |

B6C3F1 MICE MALE
25000 PPM

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

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Cyst | | | | | 3 | | | | | | 3 | | | | | | | | | 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 | |
| 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

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| | 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 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 |
| 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 |
| 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 | 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 |

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
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 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 6 7 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 3 3 3 2 3 5 3 3 3 2 3 3 3 2 3 9 2 2 3 3 3 2 3 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 | | | | | | | | | | | | | | | | | | | | | | | | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| | | | | | | | | | | | | | | | | | | | | | | | | | | 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

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 | |
| B6C3F1 MICE MALE
25000 PPM | ANIMAL ID | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 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 | 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 | | |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 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 | | | |
| | | 2 | 2 | 2 | 2 | 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 | | | |
| | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | |

ENDOCRINE SYSTEM

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

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 | | 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 | 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 | 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 | 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 | 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 | |

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|-----|-----|
| 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 | | | | | | | | | | | | | | 3 | | | | | | | | | | | | 1 | 3.0 |
| Hyperplasia | | | | | | 2 | | | | | | | | 2 | | 3 | 2 | 2 | | | | | | | | 13 | 2.0 |
| Lymph Node | | | | | | | + | | | | | | | | | | | | | | | | | | | 2 | |
| Lymph Node, Mandibular | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 | |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | 2 | | | 1 | 2.0 |
| Pigmentation | | | | | | | | | | 3 | | | | | | | | | | | | | | | | 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
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 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 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | |
| 25000 PPM | 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 | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 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 | |

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

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|----------|
| Mammary Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| Cyst Epithelial Inclusion | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|--|----------|
| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | | |
| 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
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TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

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

Lab: SRI

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|---|---|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 | 7 | 7 | 7 | 7 | 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
25000 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | |

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|-------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 6 7 7 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
25000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 2 2 2 2 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 | | | | | | | | | | | | | | | | | | | | | | | | |

Harderian Gland + **50**

URINARY SYSTEM

| | | |
|-----------------------------------|---|---------------|
| Kidney | + | 50 |
| Cyst | | 3 3 |
| Hydronephrosis | | |
| Infiltration Cellular, Lymphocyte | | 4 |
| Metaplasia, Osseous | | 3 2 |
| Nephropathy | 1 | 5 1.8 |
| 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
 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 45

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 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 | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eosinophilic Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Mixed Cell Focus | X | | | | | | | | | | | | | | | | | | | | | | | | |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | + + | | | | | | | | | | | | | | | | | | | | | | | | |

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
 + .. Tissue examined microscopically
 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
 A .. Autolysis precludes evaluation
 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
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TDMS No. 20008 - 04
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 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 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 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
| | 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 | 0 | | | | | | | | | | | | | | | | | | | | | | | | | males
(cont...) |
| 50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 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 | 3 1 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
 Page 47

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mandibular | M + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lymph Node, Mesenteric | M + + + + + + + + M + + + + + + + + + + + + + + + + | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Spleen | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Hematopoietic Cell Proliferation | 3 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
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|-------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 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...)

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

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone Femur, Osteopetrosis | + | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 7 7 7 7 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infarct | 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 | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | |
| | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 7 | 7 | 7 | 7 | 7 | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | | |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | |
| Renal Tubule, Hyperplasia | | | | | | | | | | 1 | | | | | | 1 | 1 | | | | | | | 1 | | |
| Renal Tubule, Pigmentation | | | | | | | | | | 2 | | | | | | | | | | | | | | | | |
| | ----- | | | | | | | | | | | | | | | | | | | | | | | | | |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | | |

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

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 | 7 |
| | | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 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 | 2 |
| 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 | |
| | | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| 50000 PPM | | 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 | + | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | 2 |
| 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
 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 | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| 50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

Fat, Necrosis 1 1.0

Pancreas 50
 Cyst 1 3.0
 Acinus, Cytoplasmic Alteration 4 3.0

Salivary Glands 50
 Atrophy 1 1.0

Stomach, Forestomach 50
 Epithelium, Hyperplasia 1 1.0

Stomach, Glandular 50
 Ulcer 1 3.0

CARDIOVASCULAR SYSTEM

Heart 50
 Cardiomyopathy 2 1.0

ENDOCRINE SYSTEM

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

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2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | 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
50000 PPM | 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 | | | | | | | | | | | | | | | | | | | | | | | |
| | * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | |
|--------------------------------|---|---|---|---|---|---|---|---|----|-------|
| 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
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| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE MALE
50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 | | | | | | | | | | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Lymphoid Follicle, Hyperplasia | 2 | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Thymus | + | | | | | | | | | | | | | | | | | | | | | | | | 40 |
| Atrophy | + | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Cyst | 3 | | | | | | | | | | | | | | | | | | | | | | | | 6 3.0 |

INTEGUMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------|
| Mammary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Skin | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Bone | + | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Femur, Osteopetrosis | + | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |

NERVOUS SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Brain | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Peripheral Nerve | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Spinal Cord | | | | | | | | | | | | | | | | | | | | | | | | | 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 57

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|
| 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 |
| B6C3F1 MICE MALE
50000 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 |
| | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 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 |

RESPIRATORY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | 3 1.3 |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | 4 2.8 |
| Thrombosis | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Alveolar Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 5 1.6 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

SPECIAL SENSES SYSTEM

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

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | 7 3.0 |
| Infarct | | | | | | | | | | | | | | | | | | | | | | | | 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
Page 58
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
2) Mild 4) Marked

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

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 3 | 3 | 3 | 3 | 3 | 2 | 3 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 2 | 3 | 3 | 2 | 3 | 3 | 3 | 3 | | |
| | 2 | 1 | 0 | 0 | 1 | 9 | 1 | 1 | 2 | 9 | 1 | 9 | 0 | 1 | 9 | 1 | 9 | 1 | 1 | 9 | 0 | 1 | 0 | 1 | 2 | |
| 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 | 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 | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| 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 | 49 | |
| Renal Tubule, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 1.0 | |
| Renal Tubule, Pigmentation | | | | | | | | | | | | | | | | | | | | | | | | | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 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...)

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
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
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| | DAY ON TEST | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| | 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 | 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 | 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 | | | | | | | | |
| Salivary Glands
Infiltration Cellular, Lymphocyte | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 | 3 | 3 | 2 | 3 | | | | |
| Stomach, Forestomach
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 2 | | | | | |
| Stomach, Glandular
Cyst
Erosion
Epithelium, Hyperplasia | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 3 | 3 | 3 | 1 | 3 | 3 |

CARDIOVASCULAR SYSTEM

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

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

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

0 PPM **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
1-4 .. Lesion qualified as:
1) Minimal 3) Moderate
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| 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| Skeletal Muscle | | | | | | | | | | | | | | | | | | | | | | | | | |
| Atrophy | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Inflammation, Acute | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| B6C3F1 MICE FEMALE | 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 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 | |

females (cont...)

| | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Edema | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhage | | | 1 | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Histiocyte | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | 2 | | | | | | | | | 3 | | |
| Infiltration Cellular, Polymorphonuclear | | | | | | | | | 3 | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | 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
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TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

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

ENDOCRINE SYSTEM

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

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 | | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|-------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-----------------|--------|
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 5 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 6 | | |
| | 3 | 3 | 3 | 8 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 2 | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 5 | 5 | 5 | 5 | 5 | 9 | 5 | 2 | 2 | 2 | 2 | 2 | 2 | 9 | | |
| B6C3F1 MICE FEMALE | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 0 PPM | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | |
| | | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
| 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
Page 74

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 | 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 | 3 | 4 | 0 | 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 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | 4 2.5 |
| Metaplasia, Osseous | | | | | | | | | | 1 | | | | | | | | | | | | | | 4 1.3 | |
| Nephropathy | | | | | | | | | | 1 | | | | | | 1 | | | 1 | 2 | 1 | | | 10 1.3 | |
| Renal Tubule, Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | 1 | | | | | 2 2.0 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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

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

Page 75

| 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...)

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
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TDMS No. 20008 - 04
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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 | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
|---------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----------------------|
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | ANIMAL ID |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | females
(cont...) |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 | | | | | | | | | | | | | | | | | | | | | | | | | |

Centrilobular, Necrosis 2
 Hepatocyte, Vacuolization Cytoplasmic 3
 Kupffer Cell, Hyperplasia

Mesentery
 Fat, Necrosis

Pancreas + + + + + + + + + + + + + + + + + + + A + + + +
 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 + + + + + + + + + + + + + + + + + + + A + + + +
 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 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 77

TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

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| 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 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...)

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 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 | + | | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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

TDMS No. 20008 - 04

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract

CAS Number: 84604-20-6

Date Report Requested: 09/30/2008

Time Report Requested: 13:13:48

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

Lab: SRI

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

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 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

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

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------------|
| Centrilobular, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Kupffer Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Mesentery | | | | | | | | | | | | | | | | | | | | | | | | 2 |
| Fat, Necrosis | | | | | | | | | | | | | | | | | | | | | | | | 2 2.5 |
| Pancreas | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Atrophy | | | | | | | | | | | | | | | | | | | | | | | | 1 4.0 |
| Acinus, Cytoplasmic Alteration | | | | | | | | | | | | | | | | | | | | | | | | 3 3.3 |
| Salivary Glands | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | 8 2.5 |
| Stomach, Forestomach | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Diverticulum | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Stomach, Glandular | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | 4 3.0 |
| Erosion | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Epithelium, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |

CARDIOVASCULAR SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------------|
| Heart | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Cardiomyopathy | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | 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 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 | 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 |
| 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 |
| B6C3F1 MICE FEMALE | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 | |
| 12500 PPM | 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 | |

Artery, Inflammation, Chronic Active 3 1 3.0

ENDOCRINE SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Adrenal Cortex | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Accessory Adrenal Cortical Nodule | | 3 | | 3 | | | 3 | | | | | | | | | | | | | | | | | | 6 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Adrenal Medulla | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Hyperplasia | | | | | | | | | | 1 | | | | | | | | | | | | | | | 3 |
| Islets, Pancreatic | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Parathyroid Gland | + | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Pituitary Gland | + | + | + | M | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Pars Distalis, Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Thyroid Gland | A | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 48 |
| Ectopic Thymus | | | | | | | | | | | | | | | | | | | | | | | | | 3 |
| Follicle, Degeneration, Focal | | | 2 | | | | | | | 3 | | 3 | 1 | | | | | 1 | 3 | | | | | | 19 |

GENERAL BODY SYSTEM

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

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

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

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

Renal, Hyperplasia, Lymphoid 1 3.0

Lymph Node, Mandibular 49

Angiectasis 1 2.0

Hyperplasia, Lymphoid 3 2.7

Pigmentation 3 4 3.0

Lymph Node, Mesenteric 47

Ectasia 1 3.0

Hematopoietic Cell Proliferation 2 2.0

Hyperplasia, Lymphoid 2 5 2.4

Spleen 48

Hematopoietic Cell Proliferation 3 1 1 3 3 17 2.1

Hyperplasia, Lymphoid 1 2.0

Lymphoid Follicle, Hyperplasia 2 3 2 2 9 2.6

Thymus 47

Angiectasis 1 2.0

Atrophy 1 2.0

Hyperplasia, Lymphoid 3 2 1 5 1.6

INTEGUMENTARY SYSTEM

Mammary Gland 50

Hyperplasia 1 2 3 1 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

Page 87

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 | |
| 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 |
| 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 | 0 |
| 6 | 9 | 5 | 5 | 4 | 2 | 2 | 2 | 2 | 2 | 2 | 6 | 1 | 3 | 5 | 6 | 5 | 5 | 5 | 5 | 5 | 5 | 2 | 2 | 2 | 0 |
| B6C3F1 MICE FEMALE | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12500 PPM | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 3 |
| 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 0 |
| 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 |

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

| 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 6 1 3 5 6 5 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 * TOTALS | | | | | | | | | | | | | | | | | | | | | | | |

SPECIAL SENSES SYSTEM

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

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|----|-----|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | 2 | 2.0 |
| Mineralization | | | | | | | | | | | | | | | | | | | | | | | | | 1 | 2.0 |
| Nephropathy | 3 1 | | | | | | | | | | | | | | | | | | | | | | | | 7 | 1.3 |
| Renal Tubule, Accumulation, Hyaline Droplet | 3 | | | | | | | | | | | | | | | | | | | | | | | | 1 | 3.0 |
| Renal Tubule, Necrosis | 2 | | | | | | | | | | | | | | | | | | | | | | | | 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 | 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
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 x .. Lesion present
 I .. Insufficient tissue
 M .. Missing tissue
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 BLANK .. Not examined microscopically
 1-4 .. Lesion qualified as:
 1) Minimal 3) Moderate
 2) Mild 4) Marked

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

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 | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
|---------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 7 7 7 7 7 6 7 7 7 7 7 7 7 7 7 7 6 7 6 7 7 7 7 7 7 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 3 5 3 3 3 3 3 3 3 3 3 3 8 3 6 3 3 3 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 6 6 6 6 6 9 2 2 2 2 6 6 6 6 6 5 8 5 1 5 2 2 2 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 |
| | 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...)

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

INTEGUMENTARY SYSTEM

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

MUSCULOSKELETAL SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion 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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|
| | 7 | 7 | 6 | 7 | 6 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | 7 | 7 | 6 | 7 | 7 | 7 | | |
| | 3 | 3 | 3 | 3 | 7 | 3 | 3 | 9 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 6 | 3 | 3 | 3 | |
| | 5 | 5 | 7 | 5 | 4 | 6 | 6 | 7 | 6 | 6 | 2 | 2 | 2 | 2 | 2 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | | |
| B6C3F1 MICE FEMALE
25000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | | | | | | | |

ALIMENTARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Esophagus | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | M | + | + | + | 49 |
| Gallbladder | + | + | M | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | A | + | + | + | 47 |
| Intestine Large, Cecum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Large, Colon | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Intestine Large, Rectum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 49 |
| Intestine Small, Duodenum | + | + | + | + | + | + | + | A | + | + | + | + | + | + | A | + | + | + | + | + | + | A | + | + | + | 47 |
| Intestine Small, Ileum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | 48 |
| Intestine Small, Jejunum | + | + | + | + | + | + | + | + | + | + | + | + | + | + | A | + | + | + | + | + | + | A | + | + | + | 48 |
| Peyer's Patch, Inflammation, Suppurative | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Liver | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Clear Cell Focus | | | | | | | | | | | | | | | X | | | | | | | | | | | 1 |
| Hematopoietic Cell Proliferation | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Mixed Cell | | | | | | | | | | | | | | | | | | | | | | | | | | 2 1.5 |
| Mixed Cell Focus | | | | | | | | | | | | | | | | | | | | | | | | | | 1 |
| Hepatocyte, Vacuolization Cytoplasmic | | | | | | | | | | | | | | | | | | | | | | | | | | 3 3.0 |
| Kupffer Cell, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | 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
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TDMS No. 20008 - 04
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: MICE/B6C3F1

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Milk thistle extract
 CAS Number: 84604-20-6

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

| DAY ON TEST | 0 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | |
|--|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----------|----|
| | 7 | | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
25000 PPM
ANIMAL ID | 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | 3 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6 | 7 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 8 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 49 |
| | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 49 |
| | 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 | 50 |
| | 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 | 50 |
| | 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 | 50 |

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

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

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--------------|-----------|-----------|---------------|
| Accessory Adrenal Cortical Nodule | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | 3 | 7 3.0 | | | |
| Adrenal Medulla | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 50 | | |
| Islets, Pancreatic | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Parathyroid Gland | + + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Pituitary Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Pars Distalis, Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 2 3.0 |
| Pars Distalis, Hyperplasia, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Pars Intermedia, Hyperplasia | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Thyroid Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 49 |
| Follicle, Degeneration, Focal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 20 1.5 |

GENERAL BODY SYSTEM

NONE

GENITAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------|---------------|
| Clitoral Gland | + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 49 | |
| Ovary | + + + + + + + M + | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 48 | |
| Angiectasis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 3 3.0 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 19 3.0 |
| Hemorrhage | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | 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
Page 99

| 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 2.0
 Metaplasia, Squamous 2 2.5

HEMATOPOIETIC SYSTEM

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

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

Lymph Node, Mandibular + + + + M + + + + + + + + + + + + + + + M + + + 46
 Atrophy 3 1 3.0
 Hematopoietic Cell Proliferation 1 2.0
 Hyperplasia, Lymphoid 3 1 3.0
 Pigmentation 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 | | | | | | | | | | | | | | | | | | | | | | | | * TOTALS | | | | | |
|----------------------------------|-------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|----------|------|------|-----|-----|-----|
| | 0735 | 0736 | 0737 | 0738 | 0739 | 0740 | 0741 | 0742 | 0743 | 0744 | 0745 | 0746 | 0747 | 0748 | 0749 | 0750 | 0751 | 0752 | 0753 | 0754 | 0755 | 0756 | 0757 | 0758 | | 0759 | 0760 | | | |
| 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 | | | | |
| 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 | | | | |
| ANIMAL ID | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | | | | |
| | 2 | 2 | 2 | 2 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | | | |
| | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | | | | | |
| 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 | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

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 | |
| <hr/> | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | |

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

CARDIOVASCULAR SYSTEM

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

ENDOCRINE SYSTEM

* .. Total animals with tissue examined microscopically; Total animals with lesion 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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| B6C3F1 MICE FEMALE
50000 PPM | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

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

females
(cont...)

GENITAL SYSTEM

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

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

females (cont...)

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

INTEGUMENTARY SYSTEM

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

* .. Total animals with tissue examined microscopically; Total animals with lesion 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 6 7 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 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 8 6 9 9 9 6 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 0 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | | | | | | | | | | | | |

females (cont...)

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Bone | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Fibro-Osseous Lesion | 2 2 1 2 1 1 3 2 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Fracture | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skeletal Muscle | + + | | | | | | | | | | | | | | | | | | | | | | | | |

NERVOUS SYSTEM

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

RESPIRATORY SYSTEM

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

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 | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 3 3 3 3 2 2 2 2 2 2 3 3 3 3 3 3 8 3 5 2 2 9 2 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| | 5 5 5 2 1 9 9 9 9 9 6 6 6 6 6 6 8 6 9 9 9 6 9 9 | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 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 | + | | | | | | | | | | | | | | | | | | | | | | | | |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Kidney | + | | | | | | | | | | | | | | | | | | | | | | | | |
| Cyst | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hyperplasia, Lymphoid | 2 | | | | | | | | | | | | | | | | | | | | | | | | |
| Infiltration Cellular, Lymphocyte | 3 2 3 3 3 | | | | | | | | | | | | | | | | | | | | | | | | |
| Metaplasia, Osseous | 1 1 | | | | | | | | | | | | | | | | | | | | | | | | |
| Nephropathy | 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

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 | 0 | | |
| | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | 7 | | |
| | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 5 | 5 | 5 | 5 | 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 | 0 | |
| 50000 PPM | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | |
| | 7 | 7 | 7 | 7 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 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 | |

ALIMENTARY SYSTEM

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

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

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

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

MUSCULOSKELETAL SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------------|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--------|
| Bone | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Fibro-Osseous Lesion | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fracture | 1 4 2 1 X 1 2 | | | | | | | | | | | | | | | | | | | | | | | | 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 1 3 2 | | | | | | | | | | | | | | | | | | | | | | | | 7 1.7 |
| Infiltration Cellular, Lymphocyte | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alveolar Epithelium, Hyperplasia | 2 3 1 | | | | | | | | | | | | | | | | | | | | | | | | 5 2.2 |
| Nose | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |
| Inflammation, Chronic | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1 | | | | | | | | | | | | | | | | | | | | | | | | 1 1.0 |
| Trachea | + | | | | | | | | | | | | | | | | | | | | | | | | 50 |

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

SPECIAL SENSES SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|-----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|----|
| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |

URINARY SYSTEM

| | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--------|
| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Cyst | | | | | | | | | | | | | | | | | | | | | | 3 | | 1 3.0 |
| Hyperplasia, Lymphoid | | | | | | | | | | | | | | | | | | | | | | | | 1 2.0 |
| Infiltration Cellular, Lymphocyte | | | | | | 3 | 3 | | 3 | 3 | | | | | 3 | | | | | | 3 | | | 11 2.9 |
| Metaplasia, Osseous | | | | 1 | | | | | | | | | | | | | | | | | | | | 3 1.0 |
| Nephropathy | | | | 1 | | 1 | | 1 | | | | | | | | 1 | | 1 | | | | | 1 | 10 1.0 |
| Renal Tubule, Accumulation, Hyaline Droplet | | | | | | | | | | | | | | | | | | | | | | | | 1 3.0 |
| Urinary Bladder | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | 50 |
| Infiltration Cellular, Lymphocyte | | | | 3 | | | | | | | | | | | | | | | | | | 3 | | 3 3.0 |

*** END OF REPORT ***

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

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l .. Insufficient tissue

M .. Missing tissue

A .. Autolysis precludes evaluation

BLANK .. Not examined microscopically

Page 117

1-4 .. Lesion qualified as:

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