

TDMS No. 20008 - 04

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 09/30/2008

Test Type: CHRONIC

Milk thistle extract

Time Report Requested: 13:13:48

Route: DOSED FEED

CAS Number: 84604-20-6

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

Species/Strain: MICE/B6C3F1

Lab: SRI

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

Test Type: CHRONIC

Milk thistle extract

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CAS Number: 84604-20-6

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice		1	1	1
Natural Death	5	3	6	
Survivors				
Terminal Sacrifice	45	46	43	49
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(48)	(47)	(49)	(50)
Edema	1 [2.0]		1 [2.0]	
Intestine Small, Ileum	(49)	(48)	(50)	(50)
Epithelium, Hyperplasia			1 [2.0]	
Intestine Small, Jejunum	(49)	(49)	(46)	(50)
Hyperplasia, Lymphoid			1 [1.0]	
Epithelium, Hyperplasia			1 [2.0]	
Liver	(50)	(50)	(50)	(50)
Angiectasis				2 [2.5]
Basophilic Focus	1	1	1	1
Clear Cell Focus	7	3	3	
Cyst			1 [3.0]	
Eosinophilic Focus	2	1	4	1
Hematopoietic Cell Proliferation	2 [3.5]			
Hepatodiaphragmatic Nodule	1			
Infiltration Cellular, Mixed Cell	1 [2.0]		1 [2.0]	
Mixed Cell Focus	10 [2.0]			3
Necrosis, Focal	2 [2.0]	3 [2.3]	5 [2.2]	
Necrosis, Diffuse			1 [2.0]	
Thrombosis			1 [3.0]	
Centrilobular, Necrosis	1 [4.0]	2 [1.5]	1 [2.0]	
Hepatocyte, Vacuolization Cytoplasmic	7 [2.9]	4 [2.5]	1 [3.0]	
Mesentery	(2)	(3)	(3)	(3)
Hemorrhage				1 [4.0]
Fat, Necrosis	1 [2.0]	2 [2.5]	2 [2.5]	1 [1.0]
Pancreas	(49)	(49)	(49)	(50)

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Basophilic Focus	1			
Cyst			1 [3.0]	1 [3.0]
Acinus, Cytoplasmic Alteration	1 [3.0]	1 [3.0]	2 [3.5]	4 [3.0]
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy				1 [1.0]
Infiltration Cellular, Lymphocyte			1 [3.0]	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Diverticulum		1	1	
Ulcer		1 [2.0]		
Epithelium, Hyperplasia		1 [1.0]		1 [1.0]
Stomach, Glandular	(49)	(50)	(50)	(50)
Erosion	2 [2.0]	1 [1.0]	1 [2.0]	
Ulcer				1 [3.0]
Epithelium, Hyperplasia	1 [3.0]			
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	4 [1.5]	1 [2.0]		2 [1.0]
Thrombosis	2 [3.0]			
Myocardium, Necrosis	1 [1.0]			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	7 [3.0]	7 [3.0]	4 [3.0]	2 [3.0]
Degeneration, Fatty				1 [1.0]
Hyperplasia, Focal	4 [1.0]	8 [1.5]	6 [1.7]	8 [2.3]
Hypertrophy, Focal	13 [1.5]	13 [1.5]	12 [1.7]	9 [1.9]
Capsule, Hyperplasia	2 [2.0]	2 [2.0]	3 [2.0]	5 [1.8]
Adrenal Medulla	(49)	(50)	(49)	(49)
Hyperplasia		1 [1.0]		
Islets, Pancreatic	(49)	(49)	(49)	(50)
Hyperplasia	1 [2.0]	1 [3.0]		
Parathyroid Gland	(50)	(50)	(50)	(50)
Cyst		2 [3.0]	2 [3.0]	1 [3.0]
Pituitary Gland	(48)	(48)	(47)	(50)
Pars Distalis, Cyst	2 [3.0]	3 [3.0]	2 [3.0]	3 [3.0]
Pars Distalis, Hyperplasia, Focal	2 [2.0]		1 [2.0]	

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Test Type: CHRONIC

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Thyroid Gland Follicle, Degeneration, Focal	(48) 6 [1.5]	(49) 11 [1.1]	(50) 3 [1.3]	(50) 6 [1.3]
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(0)	(0)	(1)
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 [3.0]		1 [3.0]
Preputial Gland	(50)	(50)	(50)	(49)
Cyst	19 [3.0]	28 [3.0]	26 [3.0]	20 [3.0]
Inflammation, Chronic	12 [2.3]	12 [2.4]	17 [2.3]	14 [2.4]
Prostate	(50)	(50)	(50)	(50)
Inflammation, Chronic			1 [3.0]	
Seminal Vesicle	(50)	(50)	(50)	(50)
Degeneration	1 [3.0]			
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	2 [1.5]	1 [1.0]		1 [4.0]
Interstitial Cell, Hyperplasia				1 [3.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(49)	(49)	(50)
Angiectasis			1 [3.0]	
Hyperplasia	13 [2.2]	14 [2.4]	13 [2.0]	17 [1.8]
Lymph Node	(2)	(1)	(2)	(0)
Mediastinal, Hematopoietic Cell Proliferation	1 [2.0]			
Mediastinal, Hyperplasia, Lymphoid	1 [4.0]			
Pancreatic, Fibrosis	1 [3.0]			
Pancreatic, Hematopoietic Cell Proliferation	1 [3.0]			
Pancreatic, Hyperplasia, Lymphoid	1 [3.0]			
Lymph Node, Mandibular	(48)	(45)	(49)	(47)
Atrophy	1 [3.0]	1 [3.0]		
Hyperplasia, Lymphoid	3 [2.3]	2 [3.5]	1 [2.0]	1 [2.0]

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Pigmentation			1 [3.0]	2 [3.0]
Lymph Node, Mesenteric	(47)	(44)	(48)	(48)
Atrophy	1 [3.0]	1 [2.0]		1 [2.0]
Hematopoietic Cell Proliferation	2 [2.5]	3 [1.7]	2 [2.0]	1 [2.0]
Hemorrhage		3 [2.3]	1 [1.0]	1 [1.0]
Hyperplasia, Lymphoid	2 [3.0]	3 [2.3]	4 [2.3]	1 [2.0]
Spleen	(50)	(50)	(49)	(50)
Hematopoietic Cell Proliferation	16 [2.7]	11 [2.2]	12 [2.6]	4 [2.8]
Necrosis	1 [2.0]			
Lymphoid Follicle, Atrophy	1 [3.0]	1 [2.0]		2 [2.0]
Lymphoid Follicle, Hyperplasia	2 [2.5]		3 [2.7]	2 [2.5]
Red Pulp, Atrophy		1 [3.0]		
Thymus	(45)	(46)	(49)	(40)
Atrophy	4 [2.5]	5 [3.2]	5 [3.0]	1 [3.0]
Cyst	4 [3.0]	2 [3.0]	4 [3.0]	6 [3.0]
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion			1	
Edema	1 [3.0]			
Ulcer	1 [3.0]			
Epidermis, Hyperplasia	1 [3.0]			
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(49)
Fracture	1			
Necrosis		1 [2.0]		
Femur, Osteopetrosis				1 [3.0]
Skeletal Muscle	(1)	(2)	(1)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid			1 [1.0]	
Peripheral Nerve	(1)	(1)	(1)	(1)
Atrophy	1 [2.0]	1 [1.0]		1 [1.0]

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Edema		1 [3.0]		
Foreign Body	2		1	
Hemorrhage	3 [2.3]	3 [1.3]	3 [1.3]	3 [1.3]
Infiltration Cellular, Histiocyte	6 [3.5]	6 [3.3]	4 [2.8]	4 [2.8]
Infiltration Cellular, Lymphocyte	1 [3.0]	2 [3.0]		
Inflammation, Chronic		1 [2.0]	1 [2.0]	
Thrombosis			1 [2.0]	1 [1.0]
Alveolar Epithelium, Hyperplasia	2 [3.0]	7 [1.4]	3 [1.0]	5 [1.6]
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract				1 [3.0]
Inflammation, Chronic	1 [2.0]			
Cornea, Hyperplasia	1 [2.0]			
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	3 [2.3]	2 [2.0]		1 [2.0]
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Cyst	8 [3.0]	10 [3.0]	5 [3.0]	7 [3.0]
Hydronephrosis			1 [2.0]	
Infarct	4 [2.5]	3 [2.0]		2 [1.5]
Infiltration Cellular, Lymphocyte	3 [2.3]	2 [2.5]	3 [3.0]	
Metaplasia, Osseous		3 [1.7]	5 [1.8]	
Nephropathy	45 [1.2]	49 [1.3]	47 [1.0]	49 [1.0]
Renal Tubule, Accumulation, Hyaline Droplet	1 [3.0]			
Renal Tubule, Hyperplasia	5 [1.2]	1 [1.0]	1 [1.0]	4 [1.0]
Renal Tubule, Necrosis		1 [1.0]		
Renal Tubule, Pigmentation				1 [2.0]
Urinary Bladder	(50)	(50)	(49)	(50)
Calculus Gross Observation	2			

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B6C3F1 MICE MALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Dilatation			1	
Infiltration Cellular, Lymphocyte			1 [2.0]	
Transitional Epithelium, Hyperplasia	1 [2.0]			

*** END OF MALE ***

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Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed				1
Moribund Sacrifice	3	2	2	3
Natural Death	7	5	6	1
Survivors				
Natural Death		1		
Terminal Sacrifice	40	42	42	45
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(48)	(48)	(49)	(50)
Edema	1 [2.0]	1 [2.0]		1 [2.0]
Hyperplasia, Lymphoid	1 [3.0]			
Intestine Small, Duodenum	(49)	(47)	(47)	(49)
Epithelium, Hyperplasia				1 [3.0]
Intestine Small, Ileum	(46)	(49)	(48)	(49)
Peyer's Patch, Necrosis				1 [2.0]
Intestine Small, Jejunum	(49)	(45)	(48)	(49)
Peyer's Patch, Inflammation, Suppurative	1 [2.0]		1 [2.0]	
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [3.0]	2 [3.0]		
Basophilic Focus	1			
Clear Cell Focus		1	1	1
Hematopoietic Cell Proliferation	1 [3.0]	4 [2.3]	1 [3.0]	6 [2.3]
Infiltration Cellular, Lymphocyte		2 [2.0]	1 [2.0]	
Infiltration Cellular, Mixed Cell		3 [1.7]	2 [1.5]	
Mixed Cell Focus	1	1	1	
Necrosis, Focal	3 [2.3]	1 [1.0]		
Necrosis, Diffuse				1 [2.0]
Centrilobular, Necrosis	1 [4.0]	1 [2.0]		1 [3.0]
Hepatocyte, Vacuolization Cytoplasmic	1 [3.0]	1 [3.0]	3 [3.0]	
Kupffer Cell, Hyperplasia	1 [2.0]	1 [3.0]	1 [3.0]	1 [3.0]
Kupffer Cell, Pigmentation				1 [3.0]
Mesentery	(5)	(2)	(1)	(3)

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Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Fat, Necrosis	3 [3.3]	2 [2.5]		3 [3.0]
Oral Mucosa	(0)	(0)	(1)	(0)
Pancreas	(49)	(48)	(49)	(50)
Atrophy	2 [4.0]	1 [4.0]	1 [4.0]	1 [2.0]
Cyst	2 [3.5]		1 [3.0]	1 [4.0]
Acinus, Cytoplasmic Alteration	2 [3.0]	3 [3.3]	1 [3.0]	2 [3.0]
Duct, Hyperplasia				1 [4.0]
Salivary Glands	(50)	(50)	(49)	(50)
Atrophy				2 [1.5]
Infiltration Cellular, Lymphocyte	7 [2.7]	8 [2.5]	8 [2.8]	4 [2.8]
Stomach, Forestomach	(50)	(50)	(50)	(50)
Diverticulum		1		
Erosion				1 [2.0]
Epithelium, Hyperplasia	2 [2.0]	2 [1.5]	3 [1.3]	
Stomach, Glandular	(50)	(48)	(50)	(50)
Cyst	4 [3.0]	4 [3.0]	2 [3.0]	4 [3.0]
Erosion	2 [2.0]	1 [2.0]		1 [3.0]
Epithelium, Hyperplasia	1 [2.0]	1 [1.0]		
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy		1 [2.0]		
Mineralization	1 [2.0]	2 [1.5]		
Artery, Inflammation, Chronic Active		1 [3.0]		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	5 [3.0]	6 [3.0]	7 [3.0]	7 [3.0]
Cyst		1		
Hypertrophy, Focal				2 [1.0]
Capsule, Hyperplasia	2 [1.5]			
Adrenal Medulla	(49)	(49)	(50)	(50)
Hyperplasia	2 [2.0]	3 [1.0]		1 [2.0]
Islets, Pancreatic	(49)	(48)	(49)	(50)
Parathyroid Gland	(48)	(48)	(48)	(48)
Cyst	1 [3.0]	1 [3.0]		1 [3.0]
Hyperplasia		1 [3.0]		

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Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Pituitary Gland	(49)	(49)	(48)	(48)
Pars Distalis, Angiectasis		1 [2.0]		1 [2.0]
Pars Distalis, Cyst		3 [3.0]	2 [3.0]	
Pars Distalis, Hyperplasia, Focal	5 [1.6]	1 [1.0]	1 [1.0]	5 [1.8]
Pars Intermedia, Hyperplasia			1 [3.0]	
Thyroid Gland	(50)	(48)	(49)	(50)
Ectopic Thymus		1 [3.0]		
Ultimobranchial Cyst				1 [3.0]
Follicle, Cyst	1 [3.0]			1 [3.0]
Follicle, Degeneration, Focal	25 [1.9]	19 [2.0]	20 [1.5]	13 [1.9]
Follicular Cell, Hyperplasia				3 [1.7]
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(0)	(1)
GENITAL SYSTEM				
Clitoral Gland	(47)	(47)	(49)	(47)
Cyst				1 [3.0]
Inflammation, Chronic		3 [2.0]		2 [2.0]
Ovary	(46)	(50)	(48)	(49)
Angiectasis	1 [3.0]	3 [2.3]	3 [3.0]	4 [2.5]
Cyst	16 [3.0]	10 [3.0]	19 [3.0]	19 [3.1]
Hemorrhage	8 [2.1]	12 [2.2]	10 [2.0]	10 [2.3]
Corpus Luteum, Hyperplasia		1 [2.0]		1 [3.0]
Interstitial Cell, Hyperplasia		1 [3.0]	1 [3.0]	2 [2.0]
Thecal Cell, Hyperplasia	1 [2.0]			1 [3.0]
Uterus	(50)	(50)	(50)	(50)
Angiectasis	1 [2.0]	3 [2.7]		6 [2.7]
Hyperplasia, Cystic	47 [2.9]	46 [2.8]	46 [2.8]	44 [2.7]
Inflammation, Chronic		2 [3.5]	2 [2.0]	1 [3.0]
Metaplasia, Squamous			2 [2.5]	2 [3.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	18 [2.5]	21 [2.7]	24 [2.8]	18 [2.6]

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B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Hyperplasia, Neutrophil	1 [4.0]			
Myelofibrosis			1 [1.0]	
Lymph Node	(10)	(4)	(6)	(4)
Hematopoietic Cell Proliferation			1 [3.0]	
Deep Cervical, Hemorrhage	1 [3.0]			
Deep Cervical, Pigmentation	1 [2.0]			
Iliac, Hematopoietic Cell Proliferation	1 [4.0]		1 [3.0]	1 [2.0]
Iliac, Hyperplasia, Lymphoid		1 [3.0]	3 [2.7]	1 [3.0]
Mediastinal, Hyperplasia, Lymphoid	1 [3.0]			
Renal, Hematopoietic Cell Proliferation			1 [3.0]	
Renal, Hyperplasia, Lymphoid		1 [3.0]	3 [1.7]	
Lymph Node, Mandibular	(48)	(49)	(46)	(47)
Angiectasis		1 [2.0]		
Atrophy	1 [2.0]		1 [3.0]	
Ectasia	2 [3.0]			
Hematopoietic Cell Proliferation	1 [3.0]		1 [2.0]	1 [2.0]
Hemorrhage	1 [1.0]			
Hyperplasia, Lymphoid	4 [2.3]	3 [2.7]	1 [3.0]	3 [2.3]
Pigmentation	2 [3.0]	4 [3.0]	1 [3.0]	7 [3.0]
Lymph Node, Mesenteric	(49)	(47)	(49)	(50)
Atrophy	2 [2.0]		1 [2.0]	2 [2.5]
Ectasia		1 [3.0]	1 [3.0]	
Hematopoietic Cell Proliferation	2 [2.5]	2 [2.0]		
Hemorrhage	1 [4.0]			
Hyperplasia, Lymphoid	3 [3.0]	5 [2.4]	2 [2.0]	1 [3.0]
Spleen	(50)	(48)	(49)	(50)
Fibrosis			1 [3.0]	
Hematopoietic Cell Proliferation	20 [2.1]	17 [2.1]	17 [2.3]	11 [2.7]
Hemorrhage	1 [4.0]			
Hyperplasia, Lymphoid		1 [2.0]		
Necrosis	1 [4.0]			
Lymphoid Follicle, Atrophy	1 [3.0]		1 [3.0]	
Lymphoid Follicle, Hyperplasia	6 [2.3]	9 [2.6]	8 [2.3]	6 [2.2]
Thymus	(49)	(47)	(46)	(49)
Angiectasis		1 [2.0]		
Atrophy	6 [2.8]	1 [2.0]	5 [3.0]	3 [2.7]
Hyperplasia, Lymphoid	9 [1.9]	5 [1.6]	6 [1.8]	

INTEGUMENTARY SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

Milk thistle extract

Time Report Requested: 13:13:48

Route: DOSED FEED

CAS Number: 84604-20-6

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

Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Mammary Gland	(50)	(50)	(50)	(50)
Hyperplasia	5 [2.2]	5 [1.8]	5 [1.2]	4 [1.8]
Necrosis	1 [4.0]			
Skin	(50)	(50)	(50)	(50)
Edema	2 [2.5]		1 [3.0]	1 [2.0]
Hyperkeratosis			1 [2.0]	
Inflammation, Chronic				1 [1.0]
Epidermis, Hyperplasia			1 [3.0]	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibro-Osseous Lesion	8 [1.4]	15 [1.1]	19 [1.4]	17 [1.7]
Fibrosis		1 [1.0]		
Fracture			1	1
Skeletal Muscle	(3)	(2)	(0)	(3)
Atrophy	1 [2.0]			
Inflammation, Acute	1 [3.0]			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression	1 [4.0]			1 [2.0]
Hemorrhage	1 [3.0]			
Necrosis	1 [3.0]			
Peripheral Nerve	(3)	(0)	(0)	(0)
Atrophy	1 [2.0]			
Spinal Cord	(3)	(0)	(0)	(0)
Hemorrhage	1 [3.0]			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Edema	1 [2.0]			
Hemorrhage	2 [1.0]	4 [1.5]	2 [2.5]	7 [1.7]
Infiltration Cellular, Histiocyte	1 [4.0]	4 [3.8]	1 [2.0]	1 [2.0]
Infiltration Cellular, Lymphocyte	3 [2.3]	1 [3.0]	6 [2.5]	5 [2.2]
Infiltration Cellular, Polymorphonuclear	1 [3.0]			

a - Number of animals examined microscopically at site and number of animals with lesion

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Test Type: CHRONIC

Milk thistle extract

Time Report Requested: 13:13:48

Route: DOSED FEED

CAS Number: 84604-20-6

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

Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
Inflammation, Chronic Thrombosis	2 [2.0]		1 [2.0]	
Alveolar Epithelium, Hyperplasia	1 [1.0]	3 [1.7]	3 [1.7]	1 [1.0]
Arteriole, Hypertrophy		1 [1.0]		
Nose	(50)	(50)	(50)	(50)
Inflammation, Chronic		2 [2.0]		1 [1.0]
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Cataract	1 [3.0]		1 [3.0]	
Inflammation, Chronic	1 [1.0]		2 [3.0]	
Cornea, Hyperplasia	1 [1.0]		2 [3.0]	
Retina, Degeneration	1 [4.0]			
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal		1 [1.0]		
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Cyst		1 [3.0]	1 [3.0]	1 [3.0]
Hyperplasia, Lymphoid				1 [2.0]
Infarct	2 [2.0]			
Infiltration Cellular, Lymphocyte	4 [2.5]	2 [2.0]	2 [3.0]	11 [2.9]
Metaplasia, Osseous	4 [1.3]			3 [1.0]
Mineralization		1 [2.0]		
Nephropathy	10 [1.3]	7 [1.3]	13 [1.2]	10 [1.0]
Renal Tubule, Accumulation, Hyaline Droplet	2 [2.0]	1 [3.0]		1 [3.0]
Renal Tubule, Dilatation, Diffuse			1 [2.0]	
Renal Tubule, Necrosis		2 [2.5]		
Renal Tubule, Pigmentation			1 [1.0]	
Urinary Bladder	(50)	(50)	(50)	(50)
Edema		1 [3.0]		
Infiltration Cellular, Lymphocyte	2 [3.0]	3 [2.7]	5 [2.4]	3 [3.0]

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

TDMS No. 20008 - 04

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 09/30/2008

Test Type: CHRONIC

Milk thistle extract

Time Report Requested: 13:13:48

Route: DOSED FEED

CAS Number: 84604-20-6

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

Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	12500 PPM	25000 PPM	50000 PPM
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*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion
b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)