

**Experiment Number:** 20008-01

**Test Type:** 90-DAY

**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Milk thistle extract

**CAS Number:** 84604-20-6

**Date Report Requested:** 10/21/2014

**Time Report Requested:** 09:04:03

**First Dose M/F:** NA / NA

**Lab:** SRI

<b>C Number:</b>	C20008
<b>Lock Date:</b>	11/08/2002
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intussusception						1 [3.0]
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intussusception						1 [3.0]
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(1)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule		1 [2.0]	1 [2.0]	1 [2.0]		1 [2.0]
Inflammation, Chronic, Focal	6 [1.0]		9 [1.0]	10 [1.0]	2 [1.0]	3 [1.0]
Vacuolization Cytoplasmic, Focal	2 [1.0]					1 [1.0]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Basophilic Focus	1 [1.0]					
Basophilic Focus						1 [1.0]
Fibrosis	1 [1.0]					
Interstitial, Fibrosis, Focal	1 [1.0]					
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Parotid GI, Basophilic Focus	3 [1.0]					
Parotid GI, Basophilic Focus, Multiple	5 [1.2]					8 [1.1]

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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F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy, Focal	10 [1.1]	10 [1.3]	10 [1.4]	10 [1.3]	9 [1.1]	10 [1.2]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule	2					2 [1.0]
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst	1 [1.0]					
Pars Nervosa, Cyst						1 [1.0]
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst						1 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Myeloid Cell, Hyperplasia, Focal						1 [1.0]
Lymph Node	(1)	(0)	(0)	(0)	(0)	(1)

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F 344/N Rat MALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Pancreatic, Hemorrhage	1 [2.0]					1 [2.0]
Lymph Node, Mandibular	(1)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Histiocytic, Focal	1 [1.0]					1 [1.0]
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage						1 [1.0]
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(1)	(0)	(0)	(10)
Lip, Hemorrhage, Focal			1 [2.0]			
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic, Focal	2 [1.0]					2 [1.0]
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Lacrimal Gland	(1)	(0)	(0)	(0)	(0)	(1)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(10)	(10)	(10)	(10)
Nephropathy	4 [1.0]		3 [1.0]	3 [1.0]	5 [1.0]	5 [1.0]

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<b>F 344/N Rat MALE</b>	<b>0 PPM</b>	<b>3125 PPM</b>	<b>6250 PPM</b>	<b>12500 PPM</b>	<b>25000 PPM</b>	<b>50000 PPM</b>
Nephropathy, Focal						1 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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

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F 344/N Rat FEMALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
<b>Disposition Summary</b>						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Esophagus	(10)	(0)	(0)	(0)	(0)	(9)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intussusception						1 [3.0]
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intussusception						1 [3.0]
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule	1 [2.0]	2 [2.0]	2 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]
Inflammation, Chronic, Focal	7 [1.0]	10 [1.0]	8 [1.1]	9 [1.2]	10 [1.0]	9 [1.1]
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Acinus, Atrophy, Focal	1 [1.0]					
Interstitial, Fibrosis, Focal						1 [1.0]
Salivary Glands	(10)	(10)	(10)	(10)	(7)	(10)
Duct, Parotid GI, Inflammation, Chronic, Focal				1 [1.0]		
Duct, Parotid GI, Proliferation, Focal						1 [1.0]
Interstitial, Fibrosis, Focal						1 [1.0]
Parotid GI, Basophilic Focus	1 [1.0]	3 [1.0]	4 [1.0]	3 [1.0]	5 [1.0]	1 [1.0]
Parotid GI, Basophilic Focus, Multiple	1 [1.0]	4 [1.0]		1 [1.0]	1 [1.0]	6 [1.0]

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F 344/N Rat FEMALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Tooth	(1)	(0)	(0)	(0)	(0)	(0)
Pulp, Dysplasia	1 [2.0]					
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy, Focal	2 [1.0]					2 [1.0]
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Accessory Adrenal Cortical Nodule	1 [1.0]					
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(9)
Pars Distalis, Cyst						2 [1.0]
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	1 [1.0]					1 [1.0]
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland	(10)	(1)	(1)	(1)	(0)	(10)
Cyst				1 [2.0]		
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Uterus	(10)	(1)	(0)	(2)	(0)	(10)
Hydrometra	1 [2.0]	1 [1.0]		2 [2.0]		1 [2.0]
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(1)	(0)	(2)	(1)	(0)	(0)

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F 344/N Rat FEMALE	0 PPM	3125 PPM	6250 PPM	12500 PPM	25000 PPM	50000 PPM
Mediastinal, Hemorrhage	1 [2.0]					
Pancreatic, Hyperplasia, Lymphoid			2 [2.5]	1 [2.0]		
Lymph Node, Mandibular	(2)	(0)	(0)	(0)	(0)	(1)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Hyperplasia, Histiocytic	2 [1.5]					5 [1.0]
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic, Focal	1 [1.0]					
Nose	(10)	(0)	(0)	(0)	(0)	(10)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(0)	(0)	(0)	(0)	(10)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Nephropathy	2 [1.0]					2 [1.0]
Pelvis, Inflammation						1 [2.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

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**F 344/N Rat FEMALE**

**0 PPM**

**3125 PPM**

**6250 PPM**

**12500 PPM**

**25000 PPM**

**50000 PPM**

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**\*\* END OF REPORT \*\***

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