

**TDMS No.** 20203 - 01

**Test Type:** 90-DAY

**Route:** GAVAGE

**Species/Strain:** RATS/F344/N Tac

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Green tea extract

**CAS Number:** GREENTEAEXTR

**Date Report Requested:** 04/15/2009

**Time Report Requested:** 08:55:05

**First Dose M/F:** 04/17/06 / 04/18/06

**Lab:** BAT

F\_RD

**C Number:** C20203  
**Lock Date:** 11/14/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.1.0

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<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>						
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Clear Cell Focus		1 (10%)				
Hepatodiaphragmatic Nodule	1 (10%)	1 (10%)				
Infiltration Cellular, Mononuclear Cell	7 (70%)	9 (90%)	7 (70%)	5 (50%)	8 (80%)	4 (40%)
Bile Duct, Hyperplasia		1 (10%)				
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation						1 (10%)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	9 (90%)					8 (80%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Vacuolization Cytoplasmic	3 (30%)					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	1 (10%)					
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Inflammation	9 (90%)					9 (90%)
Testes	(10)	(10)	(10)	(10)	(10)	(10)
Seminiferous Tubule, Degeneration	3 (30%)	1 (10%)	2 (20%)	3 (30%)	3 (30%)	7 (70%)
<b>HEMATOPOIETIC SYSTEM</b>						
Lymph Node, Mandibular	(10)	(10)	(10)	(10)	(10)	(10)
Ectasia			1 (10%)			
Hyperplasia, Lymphoid	3 (30%)		2 (20%)		1 (10%)	2 (20%)
Hyperplasia, Plasma Cell	5 (50%)	10 (100%)	7 (70%)	9 (90%)	8 (80%)	8 (80%)
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Lymphoid		1 (10%)				
Infiltration Cellular, Histiocyte		2 (20%)	6 (60%)	7 (70%)	7 (70%)	7 (70%)
Thymus	(10)	(10)	(10)	(10)	(10)	(8)
Atrophy				1 (10%)		5 (63%)
<b>INTEGUMENTARY SYSTEM</b>						
None						
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage	6 (60%)					
Inflammation	9 (90%)					7 (70%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation	2 (20%)	3 (30%)	1 (10%)	2 (20%)	3 (30%)	5 (50%)
Glands, Olfactory Epithelium, Hyperplasia					3 (30%)	7 (70%)
Lamina Propria, Pigmentation, Histiocyte						2 (20%)
Nasopharyngeal Duct, Degeneration					3 (30%)	3 (30%)
Nasopharyngeal Duct, Inflammation					2 (20%)	3 (30%)
Nerve, Atrophy					5 (50%)	10 (100%)
Olfactory Epithelium, Atrophy			2 (20%)	1 (10%)	3 (30%)	9 (90%)

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Olfactory Epithelium, Hyperplasia, Basal Cell					1 (10%)	1 (10%)
Olfactory Epithelium, Metaplasia			1 (10%)		6 (60%)	10 (100%)
Olfactory Epithelium, Necrosis					1 (10%)	3 (30%)
Olfactory Epithelium, Pigmentation					4 (40%)	5 (50%)
Respiratory Epithelium, Atrophy						1 (10%)
Respiratory Epithelium, Hyperplasia	1 (10%)				2 (20%)	4 (40%)
Respiratory Epithelium, Metaplasia, Squamous						1 (10%)
Respiratory Epithelium, Necrosis						1 (10%)
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 (10%)					
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization						2 (20%)
Nephropathy	8 (80%)					5 (50%)

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

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>Disposition Summary</b>						
Animals Initially in Study	10	10	10	10	10	10
Early Deaths						
Natural Death			1			
Survivors						
Terminal Sacrifice	10	10	9	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
<b>ALIMENTARY SYSTEM</b>						
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule	1 (10%)		1 (10%)	2 (20%)	1 (10%)	2 (20%)
Infiltration Cellular, Mononuclear Cell	9 (90%)	8 (80%)	6 (60%)	7 (70%)	8 (80%)	7 (70%)
Inflammation, Chronic						1 (10%)
Mitosis						2 (20%)
Mixed Cell Focus						1 (10%)
Pigmentation						2 (20%)
Bile Duct, Hyperplasia						3 (30%)
Hepatocyte, Necrosis						1 (10%)
Oval Cell, Hyperplasia						3 (30%)
Periportal, Hypertrophy						2 (20%)
Pancreas	(10)	(0)	(1)	(0)	(0)	(10)
Atrophy						1 (10%)
Inflammation, Chronic Active	1 (10%)					1 (10%)
Acinus, Atrophy	1 (10%)					
Stomach, Glandular	(10)	(0)	(1)	(0)	(0)	(10)
Hyperplasia						1 (10%)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart	(10)	(0)	(1)	(0)	(0)	(10)
Cardiomyopathy	9 (90%)		1 (100%)			6 (60%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex	(10)	(0)	(1)	(0)	(0)	(10)
Vacuolization Cytoplasmic						1 (10%)
Pituitary Gland	(10)	(0)	(1)	(0)	(0)	(10)
Cyst						1 (10%)

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Clitoral Gland Inflammation	(10) 5 (50%)	(0)	(1) 1 (100%)	(0)	(0)	(10) 2 (20%)
<b>HEMATOPOIETIC SYSTEM</b>						
Lymph Node, Mandibular Hyperplasia, Lymphoid	(10) 3 (30%)	(10) 4 (40%)	(10) 1 (10%)	(10) 1 (10%)	(10)	(10) 2 (20%)
Hyperplasia, Plasma Cell	4 (40%)	5 (50%)	7 (70%)	7 (70%)	7 (70%)	8 (80%)
Lymph Node, Mesenteric Atrophy	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	8 (80%)	10 (100%)	9 (90%)	7 (70%)	7 (70%)	6 (60%)
Thymus Atrophy	(10)	(10)	(10)	(10)	(10)	(10) 6 (60%)
<b>INTEGUMENTARY SYSTEM</b>						
None						
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
Lung Hemorrhage	(10) 1 (10%)	(0)	(1)	(0)	(0)	(10) 2 (20%)
Inflammation	8 (80%)		1 (100%)			9 (90%)
Metaplasia, Osseous						1 (10%)
Nose Infiltration Cellular, Mononuclear Cell	(10)	(10)	(10)	(10)	(10)	(10) 1 (10%)

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Inflammation	2 (20%)	1 (10%)	1 (10%)	4 (40%)	10 (100%)	8 (80%)
Glands, Olfactory Epithelium, Hyperplasia				2 (20%)	1 (10%)	4 (40%)
Lamina Propria, Pigmentation, Histiocyte						1 (10%)
Nasopharyngeal Duct, Degeneration					2 (20%)	
Nerve, Atrophy				1 (10%)	4 (40%)	5 (50%)
Olfactory Epithelium, Atrophy		1 (10%)	1 (10%)			7 (70%)
Olfactory Epithelium, Hyperplasia, Basal Cell				1 (10%)		
Olfactory Epithelium, Metaplasia					5 (50%)	4 (40%)
Olfactory Epithelium, Pigmentation				2 (20%)	3 (30%)	5 (50%)
Respiratory Epithelium, Hyperplasia				1 (10%)	1 (10%)	
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(1)	(1)	(0)	(0)	(10)
Atrophy						1 (10%)
Cornea, Degeneration		1 (100%)				
Harderian Gland	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation	1 (10%)					1 (10%)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(0)	(1)	(0)	(0)	(10)
Mineralization	5 (50%)					5 (50%)
Nephropathy						1 (10%)

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