

TDMS No. 20203 - 01

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

Date Report Requested: 04/15/2009

Test Type: 90-DAY

Green tea extract

Time Report Requested: 08:55:05

Route: GAVAGE

CAS Number: GREENTEAEXTR

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

Species/Strain: RATS/F344/N Tac

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

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Species/Strain: RATS/F344/N Tac

Lab: BAT

Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Disposition Summary						
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
ALIMENTARY SYSTEM						
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Clear Cell Focus		1				
Hepatodiaphragmatic Nodule	1	1			1	2
Infiltration Cellular, Mononuclear Cell	7 [1.0]	9 [1.1]	7 [1.0]	5 [1.0]	8 [1.0]	4 [1.0]
Bile Duct, Hyperplasia		1 [1.0]				
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation						1 [1.0]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	9 [1.3]					8 [1.1]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Vacuolization Cytoplasmic	3 [1.0]					
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)
Ultimobranchial Cyst	1					
GENERAL BODY SYSTEM						
None						
GENITAL 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)

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Fischer 344-Taconic RATS MALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 [1.0]					
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	9 [1.7]					9 [1.7]
Testes	(10)	(10)	(10)	(10)	(10)	(10)
Seminiferous Tubule, Degeneration	3 [1.0]	1 [1.0]	2 [1.0]	3 [1.0]	3 [1.0]	7 [1.0]
HEMATOPOIETIC SYSTEM						
Lymph Node, Mandibular	(10)	(10)	(10)	(10)	(10)	(10)
Ectasia			1 [3.0]			
Hyperplasia, Lymphoid	3 [2.3]		2 [2.5]		1 [1.0]	2 [1.5]
Hyperplasia, Plasma Cell	5 [1.4]	10 [1.4]	7 [1.6]	9 [1.2]	8 [1.4]	8 [1.8]
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Lymphoid		1 [2.0]				
Infiltration Cellular, Histiocyte		2 [2.0]	6 [1.5]	7 [1.9]	7 [1.7]	7 [1.7]
Thymus	(10)	(10)	(10)	(10)	(10)	(8)
Atrophy				1 [1.0]		5 [1.0]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(0)	(0)	(0)	(10)
Hemorrhage	6 [1.2]					
Inflammation	9 [1.9]					7 [1.0]
Nose	(10)	(10)	(10)	(10)	(10)	(10)

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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	2 [1.0]	3 [1.0]	1 [1.0]	2 [1.0]	3 [1.3]	5 [2.0]
Glands, Olfactory Epithelium, Hyperplasia					3 [1.3]	7 [1.1]
Lamina Propria, Pigmentation, Histiocyte						2 [2.0]
Nasopharyngeal Duct, Degeneration					3 [2.0]	3 [2.0]
Nasopharyngeal Duct, Inflammation					2 [1.0]	3 [2.0]
Nerve, Atrophy					5 [1.8]	10 [1.7]
Olfactory Epithelium, Atrophy			2 [1.0]	1 [1.0]	3 [1.0]	9 [1.1]
Olfactory Epithelium, Hyperplasia, Basal Cell					1 [1.0]	1 [1.0]
Olfactory Epithelium, Metaplasia			1 [1.0]		6 [1.5]	10 [1.0]
Olfactory Epithelium, Necrosis					1 [1.0]	3 [1.7]
Olfactory Epithelium, Pigmentation					4 [1.0]	5 [1.0]
Respiratory Epithelium, Atrophy						1 [2.0]
Respiratory Epithelium, Hyperplasia	1 [2.0]				2 [1.0]	4 [1.0]
Respiratory Epithelium, Metaplasia, Squamous						1 [1.0]
Respiratory Epithelium, Necrosis						1 [2.0]
Trachea	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 [1.0]					
SPECIAL SENSES SYSTEM						
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation	1 [2.0]					
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Mineralization						2 [1.0]
Nephropathy	8 [1.0]					5 [1.0]

*** END OF MALE ***

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Lab: BAT

Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
Disposition Summary						
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
ALIMENTARY SYSTEM						
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hepatodiaphragmatic Nodule	1		1	2	1	2
Infiltration Cellular, Mononuclear Cell	9 [1.4]	8 [1.1]	6 [1.2]	7 [1.4]	8 [1.1]	7 [1.1]
Inflammation, Chronic						1 [2.0]
Mitosis						2 [1.5]
Mixed Cell Focus						1
Pigmentation						2 [2.0]
Bile Duct, Hyperplasia						3 [1.0]
Hepatocyte, Necrosis						1 [3.0]
Oval Cell, Hyperplasia						3 [1.7]
Periportal, Hypertrophy						2 [1.5]
Pancreas	(10)	(0)	(1)	(0)	(0)	(10)
Atrophy						1 [1.0]
Inflammation, Chronic Active	1 [1.0]					1 [1.0]
Acinus, Atrophy	1 [1.0]					
Stomach, Glandular	(10)	(0)	(1)	(0)	(0)	(10)
Hyperplasia						1 [2.0]
CARDIOVASCULAR SYSTEM						
Heart	(10)	(0)	(1)	(0)	(0)	(10)
Cardiomyopathy	9 [1.0]		1 [1.0]			6 [1.0]
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(1)	(0)	(0)	(10)

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Vacuolization Cytoplasmic Pituitary Gland Cyst	(10)	(0)	(1)	(0)	(0)	1 [1.0] (10) 1
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland Inflammation	(10) 5 [1.2]	(0)	(1) 1 [1.0]	(0)	(0)	(10) 2 [1.5]
HEMATOPOIETIC SYSTEM						
Lymph Node, Mandibular Hyperplasia, Lymphoid	(10) 3 [2.0]	(10) 4 [1.5]	(10) 1 [1.0]	(10) 1 [1.0]	(10)	(10) 2 [1.5]
Hyperplasia, Plasma Cell	4 [2.0]	5 [1.0]	7 [1.3]	7 [1.3]	7 [1.3]	8 [1.9]
Lymph Node, Mesenteric Atrophy	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Histiocyte	8 [2.6]	10 [1.9]	9 [1.9]	7 [2.0]	7 [1.6]	6 [1.7]
Thymus Atrophy	(10)	(10)	(10)	(10)	(10)	(10) 6 [1.0]
INTEGUMENTARY SYSTEM						
None						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						

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Fischer 344-Taconic RATS FEMALE	0 mg/kg	62.5 mg/kg	125 mg/kg	250 mg/kg	500 mg/kg	1000 mg/kg
RESPIRATORY SYSTEM						
Lung	(10)	(0)	(1)	(0)	(0)	(10)
Hemorrhage	1 [1.0]					2 [1.0]
Inflammation	8 [1.1]		1 [1.0]			9 [1.2]
Metaplasia, Osseous						1 [1.0]
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell						1 [2.0]
Inflammation	2 [1.0]	1 [1.0]	1 [1.0]	4 [1.0]	10 [1.2]	8 [1.0]
Glands, Olfactory Epithelium, Hyperplasia				2 [1.0]	1 [1.0]	4 [1.0]
Lamina Propria, Pigmentation, Histiocyte						1 [1.0]
Nasopharyngeal Duct, Degeneration					2 [1.5]	
Nerve, Atrophy				1 [1.0]	4 [1.0]	5 [1.8]
Olfactory Epithelium, Atrophy		1 [1.0]	1 [1.0]			7 [1.1]
Olfactory Epithelium, Hyperplasia, Basal Cell				1 [1.0]		
Olfactory Epithelium, Metaplasia					5 [1.2]	4 [1.0]
Olfactory Epithelium, Pigmentation				2 [1.0]	3 [1.0]	5 [1.0]
Respiratory Epithelium, Hyperplasia				1 [1.0]	1 [1.0]	
SPECIAL SENSES SYSTEM						
Eye	(10)	(1)	(1)	(0)	(0)	(10)
Atrophy						1 [2.0]
Cornea, Degeneration		1 [2.0]				
Harderian Gland	(10)	(0)	(1)	(0)	(0)	(10)
Inflammation	1 [1.0]					1 [1.0]
URINARY SYSTEM						
Kidney	(10)	(0)	(1)	(0)	(0)	(10)
Mineralization	5 [1.0]					5 [1.0]
Nephropathy						1 [1.0]

*** END OF REPORT ***

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