

**TDMS No.** 20101 - 02  
**Test Type:** 26-39 WEEKS  
**Route:** DOSED FEED  
**Species/Strain:** MICE/P53(C57BL/6)

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
Senna (powdered)  
**CAS Number:** 8013-11-4

**Date Report Requested:** 03/11/2010  
**Time Report Requested:** 11:54:36  
**First Dose M/F:** 06/26/07 / 06/25/07  
**Lab:** BAT

F1\_Rev.1\_MD

**C Number:** C20101B  
**Lock Date:** 09/03/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.2.0

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P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
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**Disposition Summary**

Animals Initially In Study	25	25	25	25	25	25
Early Deaths						
Natural Death		1			2	1
Survivors						
Terminal Sacrifice	25	24	25	25	23	24
Animals Examined Microscopically	25	25	25	25	25	25

ALIMENTARY SYSTEM

Intestine Large, Cecum Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(23)	(25) 22 (88%)
Intestine Large, Colon Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(24) 3 (13%)	(25) 25 (100%)
Intestine Large, Rectum Epithelium, Hyperplasia	(24)	(25)	(25)	(25)	(24)	(25) 1 (4%)
Intestine Small, Duodenum Ectopic Tissue	(25)	(25)	(25)	(25)	(23) 1 (4%)	(25)
Intestine Small, Jejunum Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(23)	(24) 1 (4%)
Liver Basophilic Focus	(25) 2 (8%)	(25) 3 (12%)	(25) 2 (8%)	(25)	(25)	(25) 4 (16%)
Clear Cell Focus				1 (4%)		
Degeneration, Cystic				1 (4%)		
Eosinophilic Focus		1 (4%)			1 (4%)	
Fibrosis				1 (4%)		
Hematopoietic Cell Proliferation		2 (8%)				
Inflammation, Chronic Active	15 (60%)	17 (68%)	19 (76%)	22 (88%)	14 (56%)	10 (40%)
Mixed Cell Focus			1 (4%)	1 (4%)	1 (4%)	
Necrosis	1 (4%)	1 (4%)		1 (4%)	1 (4%)	1 (4%)
Tension Lipidosis	1 (4%)					
Kupffer Cell, Hyperplasia, Multifocal					1 (4%)	
Pancreas	(25)	(25)	(25)	(25)	(25)	(25)
Stomach, Forestomach Inflammation	(25)	(25)	(25)	(25) 1 (4%)	(25)	(25)

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

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Epithelium, Hyperplasia Stomach, Glandular Mineralization Glands, Cyst	(25)	(25)	(25)	1 (4%) (25)	(25)	(25)
Tooth Malformation	2 (8%) (1) 1 (100%)	2 (8%) (0)	2 (8%) (0)	1 (4%) (0)	1 (4%) (0)	(25) (0)
<b>CARDIOVASCULAR SYSTEM</b>						
Blood Vessel Inflammation	(25)	(25)	(25)	(25)	(25)	(25)
Heart Mineralization Valve, Pigmentation, Melanin	(25)	1 (4%) (25)	(25)	(25)	(25) 1 (4%)	(25)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex Atrophy Embolus Bacterial Hypertrophy Subcapsular, Hyperplasia Adrenal Medulla	(24)	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)	(25) 4 (16%) 8 (32%) (25)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Coagulating Gland Epithelium, Hyperplasia Epididymis	(2) 2 (100%) (25)	(0) (25)	(1) 1 (100%) (25)	(0) (25)	(0) (25)	(3) 3 (100%) (25)

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Inflammation						1 (4%)
Epithelium, Karyomegaly	14 (56%)				1 (4%)	14 (56%)
Preputial Gland	(25)	(25)	(25)	(25)	(25)	(23)
Ectasia						1 (4%)
Hyperplasia					1 (4%)	
Duct, Ectasia	4 (16%)					2 (9%)
Prostate	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Mononuclear Cell	1 (4%)		2 (8%)	1 (4%)		
Inflammation					1 (4%)	1 (4%)
Seminal Vesicle	(25)	(25)	(25)	(25)	(25)	(25)
Testes	(25)	(25)	(25)	(25)	(25)	(25)
Germinal Epithelium, Degeneration			1 (4%)			
Rete Testes, Cyst	1 (4%)					
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia		1 (4%)				1 (4%)
Lymph Node, Mandibular	(25)	(25)	(25)	(25)	(24)	(25)
Atrophy				3 (12%)	2 (8%)	
Hyperplasia, Lymphoid			1 (4%)	2 (8%)		
Lymph Node, Mesenteric	(24)	(25)	(25)	(25)	(25)	(25)
Atrophy		2 (8%)				
Hyperplasia, Lymphoid				1 (4%)		
Spleen	(25)	(25)	(25)	(25)	(23)	(25)
Hematopoietic Cell Proliferation		1 (4%)	1 (4%)			
Infiltration Cellular, Plasma Cell						1 (4%)
Lymphoid Follicle, Atrophy		2 (8%)				1 (4%)
Lymphoid Follicle, Hyperplasia	1 (4%)	1 (4%)				1 (4%)
Thymus	(25)	(24)	(25)	(25)	(23)	(25)
Atrophy		1 (4%)		2 (8%)		1 (4%)
Cyst		1 (4%)	1 (4%)			
Cortex, Hyperplasia, Lymphoid					1 (4%)	
Epithelial Cell, Hyperplasia				1 (4%)		
Medulla, Hyperplasia, Lymphoid		2 (8%)	3 (12%)	2 (8%)	4 (17%)	

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P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(25)	(25)	(25)	(25)	(25)	(25)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(25)	(25)	(25)	(25)	(25)	(25)
Hyperostosis						1 (4%)
<b>NERVOUS SYSTEM</b>						
Brain	(25)	(25)	(25)	(25)	(25)	(25)
<b>RESPIRATORY SYSTEM</b>						
Lung	(25)	(25)	(25)	(25)	(25)	(25)
Thrombosis					1 (4%)	
Alveolar Epithelium, Hyperplasia						1 (4%)
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation	2 (8%)	1 (4%)	2 (8%)		1 (4%)	
Glands, Olfactory Epithelium, Hyperplasia			1 (4%)			
Glands, Respiratory Epithelium, Hyperplasia	1 (4%)	6 (24%)	2 (8%)	2 (8%)	3 (12%)	
Respiratory Epithelium, Cyst					1 (4%)	
Respiratory Epithelium, Hyperplasia	2 (8%)		1 (4%)	2 (8%)		1 (4%)
Septum, Hyalinization	15 (60%)	1 (4%)			2 (8%)	16 (64%)
<b>SPECIAL SENSES SYSTEM</b>						
Harderian Gland	(0)	(0)	(0)	(0)	(1)	(0)

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<b>URINARY SYSTEM</b>						
Kidney	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Mononuclear Cell	1 (4%)					
Inflammation					1 (4%)	1 (4%)
Mineralization		4 (16%)	1 (4%)		1 (4%)	
Necrosis					1 (4%)	
Nephropathy	7 (28%)	7 (28%)	7 (28%)	7 (28%)	9 (36%)	8 (32%)
Cortex, Cyst					1 (4%)	
Papilla, Necrosis						1 (4%)
Urinary Bladder	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation					1 (4%)	1 (4%)

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

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P53+/(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
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**Disposition Summary**

Animals Initially In Study	25	25	25	25	25	25
Early Deaths						
Moribund Sacrifice	2	2	2	2	2	1
Natural Death				1	1	
Survivors						
Terminal Sacrifice	23	23	23	22	22	24
Animals Examined Microscopically	25	25	25	25	25	25

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ALIMENTARY SYSTEM

Gallbladder	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation						1 (4%)
Intestine Large, Cecum	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia						19 (76%)
Intestine Large, Colon	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia					7 (28%)	25 (100%)
Intestine Large, Rectum	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia						1 (4%)
Intestine Small, Duodenum	(25)	(25)	(25)	(24)	(25)	(25)
Intestine Small, Jejunum	(25)	(25)	(25)	(25)	(25)	(25)
Diverticulum			1 (4%)	1 (4%)		
Liver	(25)	(25)	(25)	(25)	(25)	(25)
Basophilic Focus						1 (4%)
Clear Cell Focus						1 (4%)
Hematopoietic Cell Proliferation	1 (4%)				1 (4%)	1 (4%)
Infiltration Cellular, Mixed Cell				2 (8%)		
Inflammation, Chronic Active	13 (52%)	2 (8%)	1 (4%)	5 (20%)	6 (24%)	9 (36%)
Mixed Cell Focus	1 (4%)					
Necrosis					1 (4%)	
Necrosis, Focal	1 (4%)					
Tension Lipidosis				1 (4%)		
Pancreas	(25)	(25)	(25)	(25)	(25)	(25)
Atrophy					1 (4%)	
Salivary Glands	(25)	(25)	(25)	(25)	(25)	(25)

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Hyperplasia, Lymphoid Stomach, Forestomach Inflammation Epithelium, Hyperplasia	1 (4%) (25)	(25)	(25)	1 (4%) (25)	(25)	1 (4%) (25)
Stomach, Glandular Epithelium, Metaplasia, Squamous Glands, Cyst	(25)	(25)	(25)	(25)	(25)	(25)
Tooth	1 (4%) (0)	4 (16%) (1)	3 (12%) (0)	2 (8%) (0)	1 (4%) (0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>						
Heart Cardiomyopathy Embolus Tumor Infiltration Cellular, Lymphocyte Epicardium, Inflammation Valve, Thrombosis	(25)	(25)	(25)	(25)	(25)	(25)
		1 (4%)			2 (8%) 1 (4%) 1 (4%)	1 (4%)
<b>ENDOCRINE SYSTEM</b>						
Adrenal Cortex Hypertrophy Subcapsular, Hyperplasia Adrenal Medulla Pituitary Gland Pars Distalis, Hyperplasia Thyroid Gland Cyst	(25)	(25)	(25)	(25)	(25)	(25)
	16 (64%)	2 (8%)	1 (4%)	2 (8%)	1 (4%)	16 (64%)
	(25)	(25)	(25)	(25)	(25)	(25)
	(25)	(25)	(25)	(25)	(25)	(25)
	(25)	(25)	(25)	(25)	(25)	(25)
		1 (4%)				
<b>GENERAL BODY SYSTEM</b>						
Peritoneum	(1)	(0)	(0)	(0)	(0)	(0)

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<b>GENITAL SYSTEM</b>						
Ovary	(25)	(25)	(25)	(25)	(25)	(25)
Angiectasis		1 (4%)				
Atrophy	3 (12%)	3 (12%)	2 (8%)	3 (12%)	2 (8%)	4 (16%)
Cyst	1 (4%)	2 (8%)		3 (12%)	1 (4%)	1 (4%)
Mineralization			1 (4%)			
Pigmentation, Hemosiderin			1 (4%)			
Uterus	(25)	(25)	(25)	(25)	(25)	(25)
Endometrium, Hyperplasia, Cystic	15 (60%)	7 (28%)	3 (12%)	5 (20%)	6 (24%)	14 (56%)
<b>HEMATOPOIETIC SYSTEM</b>						
Bone Marrow	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia	1 (4%)	1 (4%)		1 (4%)		1 (4%)
Inflammation		1 (4%)				
Necrosis					1 (4%)	
Lymph Node	(2)	(1)	(0)	(0)	(0)	(0)
Lymph Node, Mandibular	(25)	(25)	(25)	(25)	(25)	(25)
Atrophy			1 (4%)	2 (8%)	1 (4%)	1 (4%)
Hyperplasia, Lymphoid	1 (4%)					
Infiltration Cellular, Mast Cell		1 (4%)				
Lymph Node, Mesenteric	(23)	(25)	(25)	(25)	(25)	(25)
Atrophy	1 (4%)	1 (4%)	2 (8%)	2 (8%)	2 (8%)	
Hyperplasia, Lymphoid						1 (4%)
Inflammation, Suppurative				1 (4%)		
Spleen	(25)	(25)	(25)	(25)	(25)	(25)
Hematopoietic Cell Proliferation	1 (4%)	1 (4%)		1 (4%)	1 (4%)	
Lymphoid Follicle, Atrophy	1 (4%)	1 (4%)				
Lymphoid Follicle, Hyperplasia		1 (4%)		2 (8%)		
Thymus	(24)	(22)	(22)	(22)	(22)	(24)
Atrophy	3 (13%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)	2 (8%)
Hyperplasia, Lymphoid	1 (4%)					
Medulla, Hyperplasia, Lymphoid	4 (17%)	3 (14%)	3 (14%)	6 (27%)	5 (23%)	4 (17%)

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<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(25)	(25)	(25)	(25)	(25)	(25)
Duct, Ectasia	1 (4%)				1 (4%)	1 (4%)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(25)	(25)	(25)	(25)	(25)	(25)
Callus	1 (4%)					
Fibro-Osseous Lesion		2 (8%)		2 (8%)	1 (4%)	1 (4%)
<b>NERVOUS SYSTEM</b>						
Brain	(25)	(25)	(25)	(25)	(25)	(25)
Peripheral Nerve	(1)	(0)	(1)	(1)	(1)	(0)
Degeneration	1 (100%)					
Spinal Cord	(1)	(0)	(2)	(2)	(1)	(1)
Degeneration			2 (100%)	2 (100%)		1 (100%)
Nerve, Degeneration	1 (100%)					
<b>RESPIRATORY SYSTEM</b>						
Lung	(25)	(25)	(25)	(25)	(25)	(25)
Alveolar Epithelium, Hyperplasia	1 (4%)					
Artery, Infiltration Cellular, Mixed Cell		1 (4%)				
Serosa, Inflammation					1 (4%)	
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation	1 (4%)	1 (4%)	1 (4%)	2 (8%)		1 (4%)
Inflammation, Suppurative				1 (4%)		
Glands, Olfactory Epithelium, Dilatation			1 (4%)			
Glands, Respiratory Epithelium, Hyperplasia	1 (4%)	6 (24%)	4 (16%)	4 (16%)	4 (16%)	
Olfactory Epithelium, Degeneration						1 (4%)
Septum, Hyalinization	17 (68%)	2 (8%)	3 (12%)	2 (8%)	3 (12%)	15 (60%)

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SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

Kidney	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia, Lymphoid						1 (4%)
Mineralization	1 (4%)		1 (4%)			
Nephropathy	3 (12%)	6 (24%)	5 (20%)	4 (16%)	9 (36%)	2 (8%)
Urinary Bladder	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Lymphocyte		1 (4%)	3 (12%)	2 (8%)		
Inflammation			1 (4%)			
Transitional Epithelium, Vacuolization Cytoplasmic					1 (4%)	

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