

TDMS No. 20101 - 02

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

Date Report Requested: 03/11/2010

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

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

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

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

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 [1.4]
Intestine Large, Colon Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(24) 3 [1.3]	(25) 25 [2.8]
Intestine Large, Rectum Epithelium, Hyperplasia	(24)	(25)	(25)	(25)	(24)	(25) 1 [2.0]
Intestine Small, Duodenum Ectopic Tissue	(25)	(25)	(25)	(25)	(23) 1	(25)
Intestine Small, Jejunum Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(23)	(24)
Liver	(25)	(25)	(25)	(25)	(25)	(25)
Basophilic Focus	2	3	2			4
Clear Cell Focus				1		
Degeneration, Cystic				1 [2.0]		
Eosinophilic Focus		1			1	
Fibrosis				1 [1.0]		
Hematopoietic Cell Proliferation		2 [1.0]				
Inflammation, Chronic Active	15 [1.0]	17 [1.0]	19 [1.0]	22 [1.0]	14 [1.0]	10 [1.0]
Mixed Cell Focus			1	1	1	
Necrosis	1 [1.0]	1 [1.0]		1 [1.0]	1 [1.0]	1 [2.0]
Tension Lipidosis	1					
Kupffer Cell, Hyperplasia, Multifocal					1 [2.0]	
Pancreas	(25)	(25)	(25)	(25)	(25)	(25)
Stomach, Forestomach Inflammation	(25)	(25)	(25)	(25)	(25)	(25)
				1 [1.0]		

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)

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
Epithelium, Hyperplasia Stomach, Glandular Mineralization Glands, Cyst	(25)	(25)	(25)	1 [1.0] (25)	(25)	(25)
Tooth Malformation	2 [1.0] (1) 1 [1.0]	2 [1.0] (0)	2 [1.0] (0)	1 [1.0] (0)	1 [1.0] (0)	(0)

CARDIOVASCULAR SYSTEM

Blood Vessel Inflammation	(25)	(25)	(25)	(25)	(25)	(25)
Heart Mineralization	(25)	1 [3.0] (25)	(25)	(25)	(25)	(25)
Valve, Pigmentation, Melanin	1				1 [1.0]	

ENDOCRINE SYSTEM

Adrenal Cortex Atrophy	(24)	(25)	(25)	(25)	(25)	(25)
Embolus Bacterial Hypertrophy				1 [2.0]	1	
Subcapsular, Hyperplasia	3 [1.0] 4 [1.3]	1 [1.0]	2 [1.0]	1 [1.0]	1 [1.0]	4 [1.5] 8 [1.1]
Adrenal Medulla	(24)	(25)	(25)	(25)	(25)	(25)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland Epithelium, Hyperplasia	(2) 2 [1.5]	(0)	(1) 1 [1.0]	(0)	(0)	(3) 3 [1.7]
Epididymis	(25)	(25)	(25)	(25)	(25)	(25)

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: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
Inflammation						1 [2.0]
Epithelium, Karyomegaly	14 [1.4]				1 [1.0]	14 [1.1]
Preputial Gland	(25)	(25)	(25)	(25)	(25)	(23)
Ectasia						1 [2.0]
Hyperplasia					1 [4.0]	
Duct, Ectasia	4 [3.0]					2 [4.0]
Prostate	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Mononuclear Cell	1 [1.0]		2 [1.0]	1 [1.0]		
Inflammation					1 [4.0]	1 [1.0]
Seminal Vesicle	(25)	(25)	(25)	(25)	(25)	(25)
Testes	(25)	(25)	(25)	(25)	(25)	(25)
Germinal Epithelium, Degeneration			1 [1.0]			
Rete Testes, Cyst	1 [2.0]					

HEMATOPOIETIC SYSTEM

Bone Marrow	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia		1 [2.0]				1 [4.0]
Lymph Node, Mandibular	(25)	(25)	(25)	(25)	(24)	(25)
Atrophy				3 [2.7]	2 [2.5]	
Hyperplasia, Lymphoid			1 [2.0]	2 [2.5]		
Lymph Node, Mesenteric	(24)	(25)	(25)	(25)	(25)	(25)
Atrophy		2 [3.5]				
Hyperplasia, Lymphoid				1 [2.0]		
Spleen	(25)	(25)	(25)	(25)	(23)	(25)
Hematopoietic Cell Proliferation		1 [3.0]	1 [2.0]			
Infiltration Cellular, Plasma Cell						1 [2.0]
Lymphoid Follicle, Atrophy		2 [1.5]				1 [3.0]
Lymphoid Follicle, Hyperplasia	1 [2.0]	1 [3.0]				1 [1.0]
Thymus	(25)	(24)	(25)	(25)	(23)	(25)
Atrophy		1 [3.0]		2 [1.5]		1 [4.0]
Cyst		1	1			
Cortex, Hyperplasia, Lymphoid					1 [2.0]	
Epithelial Cell, Hyperplasia				1 [1.0]		
Medulla, Hyperplasia, Lymphoid		2 [2.0]	3 [1.3]	2 [2.0]	4 [1.0]	

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)

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
INTEGUMENTARY SYSTEM						
Skin	(25)	(25)	(25)	(25)	(25)	(25)
MUSCULOSKELETAL SYSTEM						
Bone	(25)	(25)	(25)	(25)	(25)	(25)
Hyperostosis						1 [2.0]
NERVOUS SYSTEM						
Brain	(25)	(25)	(25)	(25)	(25)	(25)
RESPIRATORY SYSTEM						
Lung	(25)	(25)	(25)	(25)	(25)	(25)
Thrombosis					1 [1.0]	
Alveolar Epithelium, Hyperplasia						1 [4.0]
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation	2 [1.0]	1 [1.0]	2 [1.0]		1 [1.0]	
Glands, Olfactory Epithelium, Hyperplasia			1 [1.0]			
Glands, Respiratory Epithelium, Hyperplasia	1 [1.0]	6 [1.0]	2 [1.0]	2 [1.0]	3 [1.0]	
Respiratory Epithelium, Cyst					1 [1.0]	
Respiratory Epithelium, Hyperplasia	2 [1.0]		1 [1.0]	2 [1.0]		1 [1.0]
Septum, Hyalinization	15 [2.9]	1 [2.0]			2 [2.0]	16 [2.6]
SPECIAL SENSES SYSTEM						
Harderian Gland	(0)	(0)	(0)	(0)	(1)	(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)

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
URINARY SYSTEM						
Kidney	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Mononuclear Cell	1 [1.0]					
Inflammation					1 [3.0]	1 [4.0]
Mineralization		4 [1.0]	1 [1.0]		1 [1.0]	
Necrosis					1 [3.0]	
Nephropathy	7 [1.0]	7 [1.0]	7 [1.0]	7 [1.0]	9 [1.0]	8 [1.0]
Cortex, Cyst					1 [1.0]	
Papilla, Necrosis						1 [4.0]
Urinary Bladder	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation					1 [2.0]	1 [2.0]

*** END OF MALE ***

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: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

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

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

ALIMENTARY SYSTEM

Gallbladder	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation						1 [2.0]
Intestine Large, Cecum	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia						19 [1.3]
Intestine Large, Colon	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia					7 [1.0]	25 [2.7]
Intestine Large, Rectum	(25)	(25)	(25)	(25)	(25)	(25)
Epithelium, Hyperplasia						1 [1.0]
Intestine Small, Duodenum	(25)	(25)	(25)	(24)	(25)	(25)
Intestine Small, Jejunum	(25)	(25)	(25)	(25)	(25)	(25)
Diverticulum			1	1		
Liver	(25)	(25)	(25)	(25)	(25)	(25)
Basophilic Focus						1
Clear Cell Focus						1
Hematopoietic Cell Proliferation	1 [1.0]				1 [1.0]	1 [1.0]
Infiltration Cellular, Mixed Cell				2 [2.0]		
Inflammation, Chronic Active	13 [1.0]	2 [1.0]	1 [1.0]	5 [1.0]	6 [1.0]	9 [1.0]
Mixed Cell Focus	1					
Necrosis					1 [1.0]	
Necrosis, Focal	1 [1.0]					
Tension Lipidosis				1		
Pancreas	(25)	(25)	(25)	(25)	(25)	(25)
Atrophy					1 [1.0]	
Salivary Glands	(25)	(25)	(25)	(25)	(25)	(25)

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: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
Hyperplasia, Lymphoid Stomach, Forestomach Inflammation	1 [1.0] (25)	(25)	(25)	1 [1.0] (25)	(25)	1 [1.0] (25)
Epithelium, Hyperplasia Stomach, Glandular Epithelium, Metaplasia, Squamous Glands, Cyst	(25)	(25)	(25)	(25)	(25)	(25)
1	4 [1.0]	3 [1.0]	2 [1.0]	1 [1.0]		
Tooth	(0)	(1)	(0)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM						
Heart	(25)	(25)	(25)	(25)	(25)	(25)
Cardiomyopathy					2 [1.0]	1 [1.0]
Embolus Tumor		1				
Infiltration Cellular, Lymphocyte Epicardium, Inflammation					1 [2.0] 1 [2.0]	
Valve, Thrombosis				1 [3.0]		
ENDOCRINE SYSTEM						
Adrenal Cortex	(25)	(25)	(25)	(25)	(25)	(25)
Hypertrophy			1 [1.0]			
Subcapsular, Hyperplasia	16 [1.3]	2 [1.0]	1 [1.0]	2 [1.0]	1 [2.0]	16 [1.3]
Adrenal Medulla	(25)	(25)	(25)	(25)	(25)	(25)
Pituitary Gland	(25)	(25)	(25)	(25)	(25)	(25)
Pars Distalis, Hyperplasia			1 [1.0]			
Thyroid Gland	(25)	(25)	(25)	(25)	(25)	(25)
Cyst		1 [2.0]				
GENERAL BODY SYSTEM						
Peritoneum	(1)	(0)	(0)	(0)	(0)	(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)

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
GENITAL SYSTEM						
Ovary	(25)	(25)	(25)	(25)	(25)	(25)
Angiectasis		1 [3.0]				
Atrophy	3 [1.7]	3 [2.0]	2 [1.5]	3 [1.7]	2 [2.0]	4 [1.0]
Cyst	1 [1.0]	2 [1.0]		3 [1.0]	1 [1.0]	1
Mineralization			1 [1.0]			
Pigmentation, Hemosiderin			1 [1.0]			
Uterus	(25)	(25)	(25)	(25)	(25)	(25)
Endometrium, Hyperplasia, Cystic	15 [1.0]	7 [1.1]	3 [1.0]	5 [1.0]	6 [1.0]	14 [1.1]
HEMATOPOIETIC SYSTEM						
Bone Marrow	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia	1 [2.0]	1 [3.0]		1 [1.0]		1 [2.0]
Inflammation		1 [1.0]				
Necrosis					1 [2.0]	
Lymph Node	(2)	(1)	(0)	(0)	(0)	(0)
Lymph Node, Mandibular	(25)	(25)	(25)	(25)	(25)	(25)
Atrophy			1 [1.0]	2 [2.0]	1 [2.0]	1 [2.0]
Hyperplasia, Lymphoid	1 [2.0]					
Infiltration Cellular, Mast Cell		1 [2.0]				
Lymph Node, Mesenteric	(23)	(25)	(25)	(25)	(25)	(25)
Atrophy	1 [4.0]	1 [1.0]	2 [2.0]	2 [3.0]	2 [2.0]	
Hyperplasia, Lymphoid						1 [1.0]
Inflammation, Suppurative				1 [3.0]		
Spleen	(25)	(25)	(25)	(25)	(25)	(25)
Hematopoietic Cell Proliferation	1 [4.0]	1 [3.0]		1 [1.0]	1 [2.0]	
Lymphoid Follicle, Atrophy	1 [2.0]	1 [2.0]				
Lymphoid Follicle, Hyperplasia		1 [2.0]		2 [2.0]		
Thymus	(24)	(22)	(22)	(22)	(22)	(24)
Atrophy	3 [1.7]	1 [4.0]	1 [2.0]	1 [1.0]	1 [1.0]	2 [1.0]
Hyperplasia, Lymphoid	1 [2.0]					
Medulla, Hyperplasia, Lymphoid	4 [1.3]	3 [1.0]	3 [1.3]	6 [1.5]	5 [1.2]	4 [1.0]

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)

Test Type: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

P53+/(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
INTEGUMENTARY SYSTEM						
Mammary Gland	(25)	(25)	(25)	(25)	(25)	(25)
Duct, Ectasia	1 [2.0]				1 [2.0]	1 [1.0]
MUSCULOSKELETAL SYSTEM						
Bone	(25)	(25)	(25)	(25)	(25)	(25)
Callus	1					
Fibro-Osseous Lesion		2		2	1	1
NERVOUS SYSTEM						
Brain	(25)	(25)	(25)	(25)	(25)	(25)
Peripheral Nerve	(1)	(0)	(1)	(1)	(1)	(0)
Degeneration	1 [3.0]					
Spinal Cord	(1)	(0)	(2)	(2)	(1)	(1)
Degeneration			2 [2.5]	2 [3.5]		1 [4.0]
Nerve, Degeneration	1 [3.0]					
RESPIRATORY SYSTEM						
Lung	(25)	(25)	(25)	(25)	(25)	(25)
Alveolar Epithelium, Hyperplasia	1 [1.0]					
Artery, Infiltration Cellular, Mixed Cell		1 [3.0]				
Serosa, Inflammation					1 [2.0]	
Nose	(25)	(25)	(25)	(25)	(25)	(25)
Inflammation	1 [1.0]	1 [1.0]	1 [1.0]	2 [1.0]		1 [1.0]
Inflammation, Suppurative				1 [2.0]		
Glands, Olfactory Epithelium, Dilatation			1 [1.0]			
Glands, Respiratory Epithelium, Hyperplasia	1 [1.0]	6 [1.0]	4 [1.0]	4 [1.0]	4 [1.0]	
Olfactory Epithelium, Degeneration						1 [1.0]
Septum, Hyalinization	17 [1.6]	2 [1.5]	3 [1.7]	2 [1.0]	3 [1.3]	15 [1.9]

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: 26-39 WEEKS

Senna (powdered)

Time Report Requested: 11:54:36

Route: DOSED FEED

CAS Number: 8013-11-4

First Dose M/F: 06/26/07 / 06/25/07

Species/Strain: MICE/P53(C57BL/6)

Lab: BAT

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

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

Kidney	(25)	(25)	(25)	(25)	(25)	(25)
Hyperplasia, Lymphoid						1 [1.0]
Mineralization	1 [1.0]		1 [1.0]			
Nephropathy	3 [1.0]	6 [1.0]	5 [1.0]	4 [1.0]	9 [1.0]	2 [1.0]
Urinary Bladder	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Lymphocyte		1 [2.0]	3 [2.0]	2 [2.0]		
Inflammation			1 [1.0]			
Transitional Epithelium, Vacuolization Cytoplasmic					1 [2.0]	

*** 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)