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

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	ATES OF NON-NEOPL Senna (po CAS Numbe	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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 Early Deaths Natural Death	25	25 1	25	25	25 2	25 1
Survivors		•			-	
Terminal Sacrifice Animals Examined Microscopically	25 25	24 25	25 25	25 25	23 25	24 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) 1 (4%)	(25)	(23)	(24)
Liver Basophilic Focus Clear Cell Focus Degeneration, Cystic	(25) 2 (8%)	(25) 3 (12%)	(25) 2 (8%)	(25) 1 (4%) 1 (4%)	(25)	(25) 4 (16%)
Eosinophilic Focus Fibrosis		1 (4%)		1 (4%)	1 (4%)	
Hematopoietic Cell Proliferation Inflammation, Chronic Active	15 (60%)	2 (8%) 17 (68%)	19 (76%)	22 (88%)	14 (56%)	10 (40%)
Mixed Cell Focus Necrosis Tension Lipidosis	1 (4%) 1 (4%)	1 (4%)	1 (4%)	1 (4%) 1 (4%)	1 (4%) 1 (4%)	1 (4%)
Kupffer Cell, Hyperplasia, Multifocal	1 (170)				1 (4%)	
Pancreas Stomach, Forestomach Inflammation	(25) (25)	(25) (25)	(25) (25)	(25) (25) 1 (4%)	(25) (25)	(25) (25)

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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	(25)	(25)	(25) 1 (4%) 2 (8%)	1 (4%) (25) 1 (4%)	(25)	(25)
Glands, Cyst Tooth Malformation	2 (8%) (1) 1 (100%)	2 (8%) (0)	2 (8%) (0)	(0)	1 (4%) (0)	(0)
CARDIOVASCULAR SYSTEM						
Blood Vessel Inflammation	(25)	(25) 1 (4%)	(25)	(25)	(25)	(25)
Heart Mineralization Valve, Pigmentation, Melanin	(25) 1 (4%)	(25)	(25)	(25)	(25) 1 (4%)	(25)
ENDOCRINE SYSTEM						
Adrenal Cortex Atrophy	(24)	(25)	(25)	(25) 1 (4%)	(25)	(25)
Embolus Bacterial Hypertrophy Subcapsular, Hyperplasia	3 (13%) 4 (17%)	1 (4%)	2 (8%)	1 (4%)	1 (4%) 1 (4%)	4 (16%) 8 (32%)
Adrenal Medulla	(24)	(25)	(25)	(25)	(25)	(25)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Coagulating Gland Epithelium, Hyperplasia Epididymis	(2) 2 (100%) (25)	(0) (25)	(1) 1 (100%) (25)	(0) (25)	(0) (25)	(3) 3 (100%) (25)

TDMS No. 20101 - 02

Route: DOSED FEED

Test Type: 26-39 WEEKS

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

253+/-(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
Inflammation						1 (4%)
Epithelium, Karyomegaly	14 (56%)				1 (4%)	14 (56%)
Preputial Gland	(25)	(25)	(25)	(25)	(25)	(23)
Ectasia	(20)	(20)	(20)	(20)	(20)	1 (4%)
Hyperplasia					1 (4%)	1 (170)
Duct, Ectasia	4 (16%)				1 (170)	2 (9%)
Prostate	(25)	(25)	(25)	(25)	(25)	(25)
Infiltration Cellular, Mononuclear Cell	1 (4%)	(20)	2 (8%)	1 (4%)	(20)	(20)
Inflammation	1 (+70)		2 (070)	1 (470)	1 (4%)	1 (4%)
Seminal Vesicle	(25)	(25)	(25)	(25)	(25)	(25)
Testes	(25)	(25)	(25)	(25)	(25)	(25)
Germinal Epithelium, Degeneration	(20)	(20)	(23) 1 (4%)	(20)	(20)	(20)
Rete Testes, Cyst	1 (4%)		1 (470)			
Rele Tesles, Cysi	1 (4%)					
IEMATOPOIETIC SYSTEM						
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	x - /	1 (4%)	1 (4%)	\ - /	x - /	(-)
Infiltration Cellular, Plasma Cell			x /			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	(20)	1 (4%)	(-0)	2 (8%)	(_0)	1 (4%)
Cyst		1 (4%)	1 (4%)	2 (070)		י (1,10)
Cortex, Hyperplasia, Lymphoid		· (-• /•)	· (+/0)		1 (4%)	
Epithelial Cell, Hyperplasia				1 (4%)	· (+/0)	
Medulla, Hyperplasia, Lymphoid		2 (8%)	3 (12%)	2 (8%)	4 (17%)	
iviedulia, Hyperplasia, Lympholu		∠ (070)	3 (12%)	∠ (070)	4 (1770)	

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	ATES OF NON-NEOP Senna (p CAS Numbe	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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 Hyperostosis	(25)	(25)	(25)	(25)	(25)	(25) 1 (4%)
NERVOUS SYSTEM				·		·
Brain	(25)	(25)	(25)	(25)	(25)	(25)
RESPIRATORY SYSTEM						
Lung Thrombosis Alveolar Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)
Nose Inflammation Glands, Olfactory Epithelium, Hyperplasia	(25) 2 (8%)	(25) 1 (4%)	(25) 2 (8%) 1 (4%)	(25)	(25) 1 (4%)	(25)
Glands, Respiratory Epithelium, Hyperplasia Respiratory Epithelium, Cyst	1 (4%)	6 (24%)	2 (8%)	2 (8%)	3 (12%) 1 (4%)	
Respiratory Epithelium, Hyperplasia Septum, Hyalinization	2 (8%) 15 (60%)	1 (4%)	1 (4%)	2 (8%)	2 (8%)	1 (4%) 16 (64%)
SPECIAL SENSES SYSTEM			·			
Harderian Gland	(0)	(0)	(0)	(0)	(1)	(0)

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 Lab: BAT				
P53+/-(C57BL/6) MICE MALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
URINARY SYSTEM						
Kidney Infiltration Cellular, Mononuclear Cell Inflammation	(25) 1 (4%)	(25)	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)
Mineralization Necrosis		4 (16%)	1 (4%)		1 (4%) 1 (4%)	. ()
Nephropathy Cortex, Cyst	7 (28%)	7 (28%)	7 (28%)	7 (28%)	9 (36%) 1 (4%)	8 (32%)
Papilla, Necrosis Urinary Bladder Inflammation	(25)	(25)	(25)	(25)	(25) 1 (4%)	1 (4%) (25) 1 (4%)

*** END OF MALE ***

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

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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 Natural Death	2	2	2	2 1	2 1	1
Survivors Terminal Sacrifice	23	23	23	22	22	24
Animals Examined Microscopically	25	25	25	25	25	25
LIMENTARY SYSTEM						
Gallbladder Inflammation	(25)	(25)	(25)	(25)	(25)	(25) 1 (4%)
Intestine Large, Cecum Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(25)	(25) 19 (76%)
Intestine Large, Colon Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(25) 7 (28%)	(25) 25 (100%)
Intestine Large, Rectum Epithelium, Hyperplasia	(25)	(25)	(25)	(25)	(25)	(25) 1 (4%)
Intestine Small, Duodenum	(25)	(25)	(25)	(24)	(25)	(25)
Intestine Small, Jejunum Diverticulum	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)	(25)	(25)
Liver Basophilic Focus Clear Cell Focus	(25)	(25)	(25)	(25)	(25)	(25) 1 (4%) 1 (4%)
Hematopoietic Cell Proliferation Infiltration Cellular, Mixed Cell	1 (4%)			2 (8%)	1 (4%)	1 (4%)
Inflammation, Chronic Active Mixed Cell Focus	13 (52%) 1 (4%)	2 (8%)	1 (4%)	5 (20%)	6 (24%)	9 (36%)
Necrosis Necrosis, Focal	1 (4%)				1 (4%)	
Tension Lipidosis	()	(0-)		1 (4%)		()
Pancreas Atrophy	(25)	(25)	(25)	(25)	(25) 1 (4%)	(25)
Salivary Glands	(25)	(25)	(25)	(25)	(25)	(25)

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 Lab: BAT				
P53+/-(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
Hyperplasia, Lymphoid	1 (4%)			1 (4%)		1 (4%)
Stomach, Forestomach Inflammation Epithelium, Hyperplasia	(25)	(25)	(25) 1 (4%) 1 (4%)	(25)	(25)	(25)
Stomach, Glandular Epithelium, Metaplasia, Squamous	(25)	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)	(25)
Glands, Cyst Tooth	1 (4%) (0)	4 (16%) (1)	3 (12%) (0)	2 (8%) (0)	1 (4%) (0)	(0)
CARDIOVASCULAR SYSTEM						
Heart Cardiomyopathy Embolus Tumor	(25)	(25) 1 (4%)	(25)	(25)	(25) 2 (8%)	(25) 1 (4%)
Infiltration Cellular, Lymphocyte Epicardium, Inflammation		1 (470)			1 (4%) 1 (4%)	
Valve, Thrombosis				1 (4%)		
ENDOCRINE SYSTEM						
Adrenal Cortex Hypertrophy	(25)	(25)	(25) 1 (4%)	(25)	(25)	(25)
Subcapsular, Hyperplasia	16 (64%)	2 (8%)	1 (4%)	2 (8%)	1 (4%)	16 (64%)
Adrenal Medulla	(25)	(25)	(25)	(25)	(25)	(25)
Pituitary Gland Pars Distalis, Hyperplasia	(25)	(25)	(25)	(25)	(25)	(25)
Thyroid Gland	(25)	(25)	1 (4%) (25)	(25)	(25)	(25)
Cyst	(20)	1 (4%)	(20)	(20)	(20)	(_0)
GENERAL BODY SYSTEM		·				
Peritoneum	(1)	(0)	(0)	(0)	(0)	(0)

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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 (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	、 <i>,</i>	. ,	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%)
HEMATOPOIETIC SYSTEM						
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	. (170)	1 (170)	2 (070)	<u> </u>	2 (070)	1 (4%)
Inflammation, Suppurative				1 (4%)		. (170)
Spleen	(25)	(25)	(25)	(25)	(25)	(25)
Hematopoietic Cell Proliferation	1 (4%)	1 (4%)	(-0)	1 (4%)	1 (4%)	(20)
Lymphoid Follicle, Atrophy	1 (4%)	1 (4%)		. (170)	. (170)	
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%)	1 (070)	1 (370)	i (070)	1 (370)	~ (0 /0)
Medulla, Hyperplasia, Lymphoid		2 (1 40/)	2 (1 40/)	6 (270/)	5 (220/)	1 (170/)
	4 (17%)	3 (14%)	3 (14%)	6 (27%)	5 (23%)	4 (17%)

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

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	ATES OF NON-NEOP Senna (p CAS Numbe	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 Lab: BAT			
P53+/-(C57BL/6) MICE FEMALE	0 ppm	100 ppm	300 ppm	1000 ppm	3000 ppm	10,000 ppm
INTEGUMENTARY SYSTEM						
Mammary Gland Duct, Ectasia	(25) 1 (4%)	(25)	(25)	(25)	(25) 1 (4%)	(25) 1 (4%)
MUSCULOSKELETAL SYSTEM						
Bone	(25)	(25)	(25)	(25)	(25)	(25)
Callus Fibro-Osseous Lesion	1 (4%)	2 (8%)		2 (8%)	1 (4%)	1 (4%)
NERVOUS SYSTEM	,					
Brain	(25)	(25)	(25)	(25)	(25)	(25)
Peripheral Nerve	(1)	(0)	(1)	(1)	(1)	(0)
Degeneration Spinal Cord	1 (100%) (1)	(0)	(2)	(2)	(1)	(1)
Degeneration	(')	(0)	2 (100%)	2 (100%)	(')	1 (100%)
Nerve, Degeneration	1 (100%)					
RESPIRATORY SYSTEM						
Lung	(25)	(25)	(25)	(25)	(25)	(25)
Alveolar Epithelium, Hyperplasia	1 (4%)		. ,		. ,	
Artery, Infiltration Cellular, Mixed Cell		1 (4%)				
Serosa, Inflammation	(25)	(05)	(05)	(05)	1 (4%)	(25)
Nose Inflammation	(25) 1 (4%)	(25) 1 (4%)	(25) 1 (4%)	(25) 2 (8%)	(25)	(25) 1 (4%)
Inflammation, Suppurative		. (. (. / • /	1 (4%)		. (170)
Glands, Olfactory Epithelium, Dilatation			1 (4%)	. ,		
Glands, Respiratory Epithelium, Hyperplasia	1 (4%)	6 (24%)	4 (16%)	4 (16%)	4 (16%)	
Olfactory Epithelium, Degeneration	17 (600/)	2 (00/)	2 (100/)	2 (00/)	2 (100/)	1 (4%) 15 (60%)
Septum, Hyalinization	17 (68%)	2 (8%)	3 (12%)	2 (8%)	3 (12%)	15 (60%)

TDMS No. 20101 - 02 Test Type: 26-39 WEEKS Route: DOSED FEED Species/Strain: MICE/P53(C57BL/6)	P03: INCIDENCE R	Date Report Requested: 03/11/2010 Time Report Requested: 11:54:36 First Dose M/F: 06/26/07 / 06/25/07 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 Hyperplasia, Lymphoid Mineralization	(25) 1 (4%)	(25)	(25) 1 (4%)	(25)	(25)	(25) 1 (4%)
Nephropathy Urinary Bladder Infiltration Cellular, Lymphocyte Inflammation	3 (12%) (25)	6 (24%) (25) 1 (4%)	5 (20%) (25) 3 (12%) 1 (4%)	4 (16%) (25) 2 (8%)	9 (36%) (25)	2 (8%) (25)
Transitional Epithelium, Vacuolization Cytoplasmic			. (. , , ,		1 (4%)	

*** END OF REPORT ***