

Experiment Number: 20203 - 03
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: RATS/Wistar Han

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

Green tea extract
CAS Number: GREENTEAEXTR

Date Report Requested: 08/21/2013
Time Report Requested: 07:54:39
First Dose M/F: 07/18/07 / 07/19/07
Lab: BAT

F1_Rev.2_RE

NTP Study Number: C20203
Lock Date: 11/12/2010
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.0_001
PWG Approval Date: NONE

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Disposition Summary

Animals Initially In Study	60	50	50	60
Scheduled Sacrifice	10			10
Early Deaths				
Dosing Accident				2
Moribund Sacrifice	12	7	5	5
Natural Death	3	6	2	19
Survivors				
Natural Death			1	
Terminal Sacrifice	35	37	42	24
Animals Examined Microscopically	60	50	50	60

ALIMENTARY SYSTEM

Esophagus	(60)	(50)	(50)	(60)
Inflammation	1 (2%)	1 (2%)		
Perforation				2 (3%)
Muscularis, Degeneration			1 (2%)	
Intestine Large, Cecum	(60)	(50)	(50)	(60)
Inflammation	1 (2%)			3 (5%)
Ulcer				1 (2%)
Epithelium, Hyperplasia				1 (2%)
Intestine Large, Colon	(60)	(50)	(50)	(60)
Inflammation				1 (2%)
Parasite Metazoan		1 (2%)	1 (2%)	
Epithelium, Necrosis			1 (2%)	1 (2%)
Intestine Large, Rectum	(60)	(50)	(50)	(60)
Inflammation				1 (2%)
Parasite Metazoan	5 (8%)	1 (2%)	4 (8%)	
Muscularis, Hyperplasia		1 (2%)		
Intestine Small, Duodenum	(60)	(47)	(49)	(58)
Epithelium, Regeneration			1 (2%)	
Mucosa, Necrosis		1 (2%)	1 (2%)	10 (17%)
Intestine Small, Ileum	(60)	(48)	(49)	(55)
Mucosa, Necrosis		1 (2%)	2 (4%)	6 (11%)

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

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Intestine Small, Jejunum	(59)	(47)	(48)	(56)
Mucosa, Necrosis			2 (4%)	9 (16%)
Muscularis, Hyperplasia			1 (2%)	
Liver	(60)	(50)	(50)	(60)
Angiectasis	2 (3%)	1 (2%)	3 (6%)	
Basophilic Focus	20 (33%)	20 (40%)	33 (66%)	11 (18%)
Clear Cell Focus	28 (47%)	36 (72%)	34 (68%)	20 (33%)
Deformity	1 (2%)			
Degeneration, Cystic				1 (2%)
Eosinophilic Focus	5 (8%)	5 (10%)	5 (10%)	
Fatty Change	2 (3%)	2 (4%)	1 (2%)	1 (2%)
Hematopoietic Cell Proliferation	4 (7%)		1 (2%)	
Hematopoietic Cell Proliferation, Granulocytic		1 (2%)		
Hepatodiaphragmatic Nodule	1 (2%)		1 (2%)	1 (2%)
Inflammation	3 (5%)	7 (14%)	5 (10%)	2 (3%)
Inflammation, Chronic Active			1 (2%)	
Mixed Cell Focus	10 (17%)	9 (18%)	12 (24%)	7 (12%)
Necrosis	1 (2%)	2 (4%)	2 (4%)	13 (22%)
Pigmentation		2 (4%)	1 (2%)	1 (2%)
Vacuolization Cytoplasmic, Focal	3 (5%)	15 (30%)	9 (18%)	1 (2%)
Bile Duct, Hyperplasia	11 (18%)	14 (28%)	6 (12%)	10 (17%)
Bile Duct, Hyperplasia, Cystic				1 (2%)
Hepatocyte, Atrophy	1 (2%)			
Hepatocyte, Regeneration	1 (2%)			
Oval Cell, Hyperplasia				2 (3%)
Portal, Fibrosis		1 (2%)		
Portal, Infiltration Cellular, Mononuclear Cell			2 (4%)	
Mesentery	(3)	(2)	(1)	(1)
Inflammation		1 (50%)		
Necrosis	2 (67%)	1 (50%)		1 (100%)
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(60)	(50)	(50)	(60)
Basophilic Focus	1 (2%)			
Lipomatosis		1 (2%)		
Pigmentation, Hemosiderin			1 (2%)	
Acinus, Atrophy	7 (12%)	6 (12%)	9 (18%)	5 (8%)

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Acinus, Hyperplasia	3 (5%)			
Acinus, Necrosis				1 (2%)
Salivary Glands	(60)	(50)	(50)	(58)
Amyloid Deposition	1 (2%)			
Atrophy	1 (2%)			
Necrosis				1 (2%)
Duct, Cyst			1 (2%)	
Stomach, Forestomach	(60)	(50)	(50)	(60)
Erosion	2 (3%)			
Inflammation	3 (5%)	2 (4%)		
Ulcer		3 (6%)		2 (3%)
Epithelium, Degeneration, Hydropic			1 (2%)	
Epithelium, Hyperkeratosis	1 (2%)	1 (2%)		
Epithelium, Hyperplasia	7 (12%)	6 (12%)	7 (14%)	8 (13%)
Stomach, Glandular	(59)	(50)	(50)	(60)
Cyst, Squamous			1 (2%)	
Inflammation	2 (3%)			1 (2%)
Mineralization	1 (2%)			1 (2%)
Mucosa, Hyalinization			1 (2%)	
Mucosa, Necrosis		3 (6%)	3 (6%)	21 (35%)
Mucosa, Pigmentation		1 (2%)		
Tooth	(1)	(1)	(0)	(0)
Inflammation	1 (100%)			

CARDIOVASCULAR SYSTEM

Blood Vessel	(60)	(50)	(50)	(60)
Adventitia, Aorta, Inflammation			1 (2%)	1 (2%)
Heart	(60)	(50)	(50)	(60)
Cardiomyopathy	47 (78%)	43 (86%)	40 (80%)	28 (47%)
Inflammation			1 (2%)	1 (2%)
Endocardium, Hyperplasia		1 (2%)		
Epicardium, Inflammation			1 (2%)	5 (8%)
Myocardium, Necrosis				3 (5%)
Pericardium, Inflammation				1 (2%)

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
ENDOCRINE SYSTEM				
Adrenal Cortex	(60)	(50)	(50)	(60)
Angiectasis		1 (2%)		
Degeneration, Cystic	2 (3%)	1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation, Granulocytic	1 (2%)			
Hyperplasia	22 (37%)	22 (44%)	25 (50%)	8 (13%)
Hypertrophy	20 (33%)	24 (48%)	14 (28%)	6 (10%)
Infiltration Cellular, Lipocyte		1 (2%)		
Necrosis	2 (3%)			5 (8%)
Adrenal Medulla	(60)	(50)	(50)	(60)
Hyperplasia		1 (2%)	2 (4%)	
Islets, Pancreatic	(60)	(50)	(50)	(60)
Parathyroid Gland	(57)	(44)	(49)	(55)
Hyperplasia	2 (4%)		1 (2%)	1 (2%)
Inflammation				1 (2%)
Pituitary Gland	(60)	(50)	(50)	(60)
Pars Distalis, Atrophy		1 (2%)		
Pars Distalis, Hyperplasia	12 (20%)	10 (20%)	13 (26%)	8 (13%)
Pars Intermedia, Hyperplasia			1 (2%)	
Thyroid Gland	(60)	(50)	(50)	(59)
Amyloid Deposition			1 (2%)	
Hemorrhage				1 (2%)
C-cell, Hyperplasia	37 (62%)	30 (60%)	30 (60%)	15 (25%)
Follicle, Cyst	1 (2%)			
Follicular Cell, Hyperplasia		1 (2%)	3 (6%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

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Epididymis	(60)	(50)	(50)	(60)
Granuloma Sperm	1 (2%)		1 (2%)	
Spermatocele	1 (2%)			
Preputial Gland	(60)	(50)	(50)	(60)
Inflammation	1 (2%)	1 (2%)		1 (2%)
Prostate	(60)	(50)	(50)	(60)
Inflammation	5 (8%)	4 (8%)		2 (3%)
Epithelium, Hyperplasia	6 (10%)	13 (26%)	6 (12%)	8 (13%)
Seminal Vesicle	(60)	(50)	(50)	(60)
Inflammation	2 (3%)	5 (10%)		2 (3%)
Epithelium, Hyperplasia	1 (2%)	2 (4%)		
Testes	(60)	(50)	(50)	(60)
Atrophy	9 (15%)	13 (26%)	13 (26%)	5 (8%)
Degeneration, Cystic	3 (5%)	7 (14%)	7 (14%)	
Mineralization				2 (3%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(59)	(50)	(50)	(60)
Hyperplasia	10 (17%)	9 (18%)	11 (22%)	13 (22%)
Hyperplasia, Histiocytic		1 (2%)		
Lymph Node	(4)	(0)	(1)	(1)
Mediastinal, Degeneration, Cystic	1 (25%)			
Mediastinal, Hemorrhage	1 (25%)			
Mediastinal, Hyperplasia, Lymphoid	2 (50%)			1 (100%)
Lymph Node, Mandibular	(59)	(50)	(50)	(58)
Degeneration, Cystic	5 (8%)	8 (16%)	4 (8%)	3 (5%)
Hemorrhage			1 (2%)	
Hyperplasia, Lymphoid				1 (2%)
Hyperplasia, Plasma Cell	6 (10%)	1 (2%)	2 (4%)	7 (12%)
Lymph Node, Mesenteric	(60)	(50)	(50)	(60)
Atrophy				1 (2%)
Degeneration, Cystic	2 (3%)		1 (2%)	1 (2%)
Hemorrhage			1 (2%)	
Spleen	(60)	(50)	(50)	(60)

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Angiectasis		1 (2%)		
Depletion Lymphoid	1 (2%)	2 (4%)	1 (2%)	13 (22%)
Hematopoietic Cell Proliferation	7 (12%)	1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Lymphoid	1 (2%)		1 (2%)	
Thymus	(59)	(49)	(50)	(60)
Atrophy				1 (2%)
Hemorrhage	1 (2%)			
Hyperplasia				1 (2%)
Inflammation				1 (2%)

INTEGUMENTARY SYSTEM

Mammary Gland	(60)	(50)	(50)	(60)
Duct, Dilatation	1 (2%)			
Skin	(60)	(50)	(50)	(60)
Cyst Epithelial Inclusion	3 (5%)	3 (6%)	1 (2%)	
Hyperplasia	2 (3%)	1 (2%)		
Inflammation	2 (3%)			
Ulcer	8 (13%)	4 (8%)	2 (4%)	
Hair Follicle, Cyst Epithelial Inclusion, Multiple		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(60)	(50)	(50)	(60)
Skeletal Muscle	(0)	(0)	(0)	(1)
Cyst				1 (100%)

NERVOUS SYSTEM

Brain	(60)	(50)	(50)	(60)
Ventricle, Developmental Malformation		1 (2%)		
Peripheral Nerve	(0)	(1)	(0)	(1)
Spinal Cord	(0)	(1)	(0)	(1)
Degeneration		1 (100%)		

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
RESPIRATORY SYSTEM				
Lung	(60)	(50)	(50)	(60)
Hemorrhage				2 (3%)
Inflammation, Suppurative		1 (2%)	3 (6%)	10 (17%)
Inflammation, Chronic Active	11 (18%)	6 (12%)	7 (14%)	14 (23%)
Mineralization	1 (2%)			
Alveolar Epithelium, Hyperplasia	2 (3%)	4 (8%)	5 (10%)	5 (8%)
Alveolar Epithelium, Metaplasia				1 (2%)
Alveolus, Infiltration Cellular, Histiocyte	25 (42%)	21 (42%)	28 (56%)	27 (45%)
Bronchiole, Hyperplasia			1 (2%)	
Nose	(60)	(50)	(50)	(60)
Foreign Body	8 (13%)	5 (10%)	4 (8%)	6 (10%)
Inflammation, Suppurative	11 (18%)	12 (24%)	20 (40%)	44 (73%)
Inflammation, Acute				1 (2%)
Epithelium, Goblet Cell, Nasopharyngeal Duct, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	
Epithelium, Nasopharyngeal Duct, Degeneration		1 (2%)		3 (5%)
Epithelium, Nasopharyngeal Duct, Hyperplasia			2 (4%)	5 (8%)
Epithelium, Nasopharyngeal Duct, Metaplasia, Squamous		1 (2%)		1 (2%)
Epithelium, Nasopharyngeal Duct, Necrosis				3 (5%)
Epithelium, Nasopharyngeal Duct, Pigmentation				2 (3%)
Epithelium, Nasopharyngeal Duct, Regeneration			2 (4%)	2 (3%)
Goblet Cell, Hyperplasia	1 (2%)			2 (3%)
Goblet Cell, Nasopharyngeal Duct, Hyperplasia		1 (2%)		
Lamina Propria, Mineralization		33 (66%)	34 (68%)	45 (75%)
Lamina Propria, Pigmentation		4 (8%)	11 (22%)	25 (42%)
Lumen, Pigmentation, Histiocyte		1 (2%)		
Nasopharyngeal Duct, Foreign Body		2 (4%)	1 (2%)	3 (5%)
Nasopharyngeal Duct, Inflammation, Suppurative		6 (12%)	8 (16%)	22 (37%)
Nasopharyngeal Duct, Mineralization				1 (2%)

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Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nerve, Atrophy		33 (66%)	44 (88%)	49 (82%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	31 (52%)	30 (60%)	22 (44%)	4 (7%)
Olfactory Epithelium, Atrophy	1 (2%)	38 (76%)	41 (82%)	46 (77%)
Olfactory Epithelium, Hyperplasia, Basal Cell		1 (2%)	9 (18%)	28 (47%)
Olfactory Epithelium, Metaplasia, Respiratory	4 (7%)	40 (80%)	43 (86%)	50 (83%)
Olfactory Epithelium, Necrosis	1 (2%)	3 (6%)		14 (23%)
Olfactory Epithelium, Pigmentation	6 (10%)	18 (36%)	12 (24%)	24 (40%)
Olfactory Epithelium, Squamous Metaplasia			1 (2%)	4 (7%)
Olfactory Epithelium, Ulcer				1 (2%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	23 (38%)	30 (60%)	29 (58%)	10 (17%)
Respiratory Epithelium, Atrophy		2 (4%)	5 (10%)	6 (10%)
Respiratory Epithelium, Degeneration				3 (5%)
Respiratory Epithelium, Hyperplasia	3 (5%)	1 (2%)	4 (8%)	8 (13%)
Respiratory Epithelium, Metaplasia, Squamous		1 (2%)	3 (6%)	9 (15%)
Respiratory Epithelium, Necrosis				4 (7%)
Respiratory Epithelium, Pigmentation	2 (3%)	6 (12%)	7 (14%)	7 (12%)
Turbinates, Deformity		16 (32%)	22 (44%)	35 (58%)
Turbinates, Hyperostosis		18 (36%)	27 (54%)	40 (67%)
Trachea	(60)	(50)	(50)	(60)
Inflammation				3 (5%)
Epithelium, Hyperplasia			1 (2%)	

SPECIAL SENSES SYSTEM

Eye	(60)	(50)	(50)	(60)
Cataract			1 (2%)	1 (2%)
Synechia		1 (2%)	1 (2%)	
Ciliary Body, Inflammation		1 (2%)		
Cornea, Inflammation	1 (2%)			
Retina, Atrophy	1 (2%)		2 (4%)	1 (2%)
Retina, Dysplasia		1 (2%)		
Retina, Hyperplasia, Reticulum Cell	1 (2%)			
Harderian Gland	(60)	(50)	(50)	(60)
Hyperplasia			1 (2%)	

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Inflammation Zymbal's Gland	1 (2%) (1)	1 (2%) (0)	(0)	1 (2%) (0)
URINARY SYSTEM				
Kidney	(60)	(50)	(50)	(60)
Accumulation, Hyaline Droplet				1 (2%)
Casts Granular				1 (2%)
Cyst	1 (2%)	3 (6%)	2 (4%)	2 (3%)
Hydronephrosis	2 (3%)	2 (4%)	2 (4%)	4 (7%)
Infarct				2 (3%)
Infiltration Cellular, Lipocyte				1 (2%)
Inflammation	15 (25%)	10 (20%)	13 (26%)	10 (17%)
Nephropathy	47 (78%)	40 (80%)	44 (88%)	29 (48%)
Papilla, Necrosis	2 (3%)			1 (2%)
Renal Tubule, Hyperplasia			2 (4%)	
Transitional Epithelium, Hyperplasia	1 (2%)	4 (8%)	1 (2%)	2 (3%)
Ureter	(1)	(0)	(0)	(0)
Urinary Bladder	(60)	(50)	(50)	(60)
Transitional Epithelium, Hyperplasia				1 (2%)

*** END OF MALE ***

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Disposition Summary

Animals Initially In Study	60	50	50	60
Scheduled Sacrifice	10			10
Early Deaths				
Dosing Accident			1	3
Moribund Sacrifice	14	12	17	8
Natural Death	10	10	9	35
Survivors				
Terminal Sacrifice	26	28	23	4
Animals Examined Microscopically	60	50	50	60

ALIMENTARY SYSTEM

Esophagus	(60)	(50)	(50)	(60)
Inflammation		1 (2%)		
Perforation				1 (2%)
Muscularis, Degeneration	1 (2%)			
Intestine Large, Cecum	(59)	(49)	(48)	(54)
Inflammation	1 (2%)		1 (2%)	1 (2%)
Lymphoid Tissue, Hyperplasia	1 (2%)	1 (2%)		
Intestine Large, Colon	(59)	(49)	(48)	(54)
Hyperplasia, Lymphoid			1 (2%)	
Inflammation				1 (2%)
Parasite Metazoan	1 (2%)		1 (2%)	
Intestine Large, Rectum	(59)	(49)	(50)	(55)
Inflammation			1 (2%)	
Parasite Metazoan	1 (2%)			1 (2%)
Thrombosis				1 (2%)
Intestine Small, Duodenum	(57)	(48)	(48)	(49)
Mucosa, Necrosis			1 (2%)	5 (10%)
Intestine Small, Ileum	(55)	(46)	(47)	(46)
Mucosa, Necrosis				5 (11%)
Serosa, Hemorrhage			1 (2%)	
Serosa, Inflammation			1 (2%)	
Intestine Small, Jejunum	(55)	(43)	(45)	(50)

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Necrosis, Hemorrhagic Mucosa, Necrosis		1 (2%)		6 (12%)
Liver	(60)	(48)	(49)	(56)
Angiectasis	1 (2%)	4 (8%)		
Basophilic Focus	38 (63%)	38 (79%)	35 (71%)	16 (29%)
Clear Cell Focus	14 (23%)	8 (17%)	6 (12%)	5 (9%)
Degeneration, Cystic	1 (2%)			
Eosinophilic Focus	3 (5%)	4 (8%)	1 (2%)	4 (7%)
Fatty Change	7 (12%)	1 (2%)		
Hematopoietic Cell Proliferation		4 (8%)	5 (10%)	
Hematopoietic Cell Proliferation, Granulocytic		3 (6%)	2 (4%)	1 (2%)
Hepatodiaphragmatic Nodule			1 (2%)	
Inflammation	5 (8%)	3 (6%)	4 (8%)	7 (13%)
Mixed Cell Focus	7 (12%)	4 (8%)	1 (2%)	2 (4%)
Necrosis	3 (5%)	2 (4%)	5 (10%)	25 (45%)
Pigmentation	1 (2%)	1 (2%)	2 (4%)	5 (9%)
Vacuolization Cytoplasmic, Focal	6 (10%)	2 (4%)	4 (8%)	1 (2%)
Bile Duct, Concretion			1 (2%)	
Bile Duct, Cyst		2 (4%)	2 (4%)	
Bile Duct, Dilatation			1 (2%)	
Bile Duct, Hyperplasia	21 (35%)	11 (23%)	13 (27%)	18 (32%)
Bile Duct, Hyperplasia, Cystic	1 (2%)			
Hepatocyte, Hyperplasia, Regenerative				2 (4%)
Hepatocyte, Hypertrophy				1 (2%)
Hepatocyte, Regeneration	1 (2%)			
Oval Cell, Hyperplasia	1 (2%)	2 (4%)	3 (6%)	17 (30%)
Portal, Infiltration Cellular, Mononuclear Cell	2 (3%)	1 (2%)		
Serosa, Fibrosis			1 (2%)	
Serosa, Inflammation			1 (2%)	
Mesentery	(6)	(3)	(3)	(2)
Degeneration, Cystic			1 (33%)	
Necrosis	4 (67%)			
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(60)	(49)	(48)	(54)
Inflammation	1 (2%)	1 (2%)	2 (4%)	
Lipomatosis			1 (2%)	

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

Experiment Number: 20203 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/Wistar Han

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

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 08/21/2013

Time Report Requested: 07:54:39

First Dose M/F: 07/18/07 / 07/19/07

Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Acinus, Atrophy	3 (5%)	4 (8%)	2 (4%)	2 (4%)
Acinus, Cytoplasmic Alteration		1 (2%)		
Duct, Cyst		1 (2%)		
Salivary Glands	(59)	(48)	(50)	(56)
Inflammation	1 (2%)			
Duct, Cyst		1 (2%)		
Stomach, Forestomach	(60)	(50)	(49)	(54)
Erosion	2 (3%)	2 (4%)		1 (2%)
Inflammation	5 (8%)	1 (2%)		2 (4%)
Mineralization		1 (2%)	1 (2%)	2 (4%)
Ulcer	2 (3%)	1 (2%)	2 (4%)	2 (4%)
Epithelium, Hyperkeratosis	1 (2%)			
Epithelium, Hyperplasia	3 (5%)	2 (4%)	1 (2%)	2 (4%)
Stomach, Glandular	(60)	(49)	(49)	(54)
Inflammation	4 (7%)	1 (2%)	1 (2%)	2 (4%)
Mineralization	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Necrosis		1 (2%)		
Epithelium, Degeneration	1 (2%)			
Epithelium, Hyperplasia	1 (2%)		2 (4%)	
Glands, Hyperplasia				1 (2%)
Mucosa, Necrosis		1 (2%)	7 (14%)	20 (37%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(60)	(48)	(50)	(56)
Adventitia, Aorta, Inflammation			2 (4%)	
Heart	(60)	(48)	(50)	(58)
Cardiomyopathy	20 (33%)	24 (50%)	18 (36%)	12 (21%)
Inflammation	1 (2%)		1 (2%)	2 (3%)
Mineralization				1 (2%)
Endocardium, Fibrosis				1 (2%)
Endocardium, Hyperplasia				1 (2%)
Epicardium, Inflammation		2 (4%)	2 (4%)	4 (7%)

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

Experiment Number: 20203 - 03
 Test Type: CHRONIC
 Route: GAVAGE
 Species/Strain: RATS/Wistar Han

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 Green tea extract
 CAS Number: GREENTEAEXTR

Date Report Requested: 08/21/2013
 Time Report Requested: 07:54:39
 First Dose M/F: 07/18/07 / 07/19/07
 Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
ENDOCRINE SYSTEM				
Adrenal Cortex	(60)	(49)	(49)	(57)
Angiectasis			2 (4%)	
Atrophy			1 (2%)	
Degeneration, Cystic	1 (2%)			1 (2%)
Hemorrhage			1 (2%)	1 (2%)
Hyperplasia	21 (35%)	25 (51%)	27 (55%)	7 (12%)
Hypertrophy	13 (22%)	15 (31%)	10 (20%)	4 (7%)
Mineralization			1 (2%)	
Necrosis	3 (5%)			3 (5%)
Adrenal Medulla	(60)	(49)	(49)	(57)
Hyperplasia	2 (3%)			
Vacuolization Cytoplasmic		2 (4%)		
Islets, Pancreatic	(60)	(49)	(48)	(54)
Parathyroid Gland	(57)	(46)	(48)	(54)
Pituitary Gland	(60)	(50)	(50)	(60)
Angiectasis		1 (2%)		
Pars Distalis, Angiectasis				1 (2%)
Pars Distalis, Cyst	1 (2%)			
Pars Distalis, Hyperplasia	12 (20%)	13 (26%)	17 (34%)	13 (22%)
Pars Intermedia, Angiectasis		1 (2%)		1 (2%)
Pars Intermedia, Hyperplasia	1 (2%)			
Thyroid Gland	(60)	(49)	(50)	(57)
C-cell, Hyperplasia	29 (48%)	14 (29%)	6 (12%)	4 (7%)
Follicular Cell, Hyperplasia	2 (3%)	1 (2%)		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(59)	(49)	(50)	(56)
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Experiment Number: 20203 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/Wistar Han

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

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 08/21/2013

Time Report Requested: 07:54:39

First Dose M/F: 07/18/07 / 07/19/07

Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation	4 (7%)	2 (4%)		2 (4%)
Duct, Cyst			1 (2%)	
Ovary	(60)	(49)	(49)	(54)
Cyst	8 (13%)	12 (24%)	10 (20%)	6 (11%)
Inflammation	1 (2%)	5 (10%)	3 (6%)	6 (11%)
Oviduct	(1)	(0)	(0)	(0)
Uterus	(60)	(49)	(49)	(54)
Congestion				1 (2%)
Decidual Reaction		1 (2%)		
Hemorrhage	1 (2%)			
Infiltration Cellular, Plasma Cell				1 (2%)
Inflammation	3 (5%)	4 (8%)	2 (4%)	5 (9%)
Cervix, Fibrosis	1 (2%)			
Endometrium, Hyperplasia, Cystic	10 (17%)	14 (29%)	15 (31%)	10 (19%)
Vagina	(1)	(2)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(60)	(50)	(50)	(60)
Hyperplasia	6 (10%)	14 (28%)	16 (32%)	13 (22%)
Lymph Node	(3)	(1)	(4)	(6)
Bronchial, Hyperplasia, Plasma Cell				1 (17%)
Bronchial, Inflammation			1 (25%)	
Iliac, Hyperplasia, Lymphoid			1 (25%)	
Lumbar, Hyperplasia, Lymphoid				1 (17%)
Mediastinal, Degeneration, Cystic			1 (25%)	
Mediastinal, Hemorrhage		1 (100%)		
Mediastinal, Hyperplasia	1 (33%)			
Mediastinal, Hyperplasia, Plasma Cell			1 (25%)	
Mediastinal, Infiltration Cellular, Histiocyte				1 (17%)
Mediastinal, Pigmentation, Hemosiderin			1 (25%)	1 (17%)
Renal, Hyperplasia, Plasma Cell				2 (33%)
Renal, Inflammation			1 (25%)	
Lymph Node, Mandibular	(59)	(48)	(50)	(56)
Atrophy			1 (2%)	1 (2%)

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Experiment Number: 20203 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/Wistar Han

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

Green tea extract

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Date Report Requested: 08/21/2013

Time Report Requested: 07:54:39

First Dose M/F: 07/18/07 / 07/19/07

Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Congestion				1 (2%)
Degeneration, Cystic	2 (3%)	4 (8%)	5 (10%)	2 (4%)
Hyperplasia, Plasma Cell	12 (20%)	3 (6%)	3 (6%)	9 (16%)
Inflammation				1 (2%)
Lymph Node, Mesenteric	(60)	(49)	(48)	(55)
Atrophy				1 (2%)
Congestion				1 (2%)
Hyperplasia, Plasma Cell			1 (2%)	1 (2%)
Infiltration Cellular, Histiocyte				1 (2%)
Spleen	(60)	(49)	(48)	(53)
Depletion Lymphoid		7 (14%)	5 (10%)	17 (32%)
Fibrosis		1 (2%)		
Hematopoietic Cell Proliferation	11 (18%)	7 (14%)	10 (21%)	5 (9%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Inflammation			1 (2%)	
Lymphoid Follicle, Hyperplasia	1 (2%)			
Thymus	(59)	(47)	(50)	(57)
Cyst				1 (2%)
Hemorrhage				1 (2%)
Inflammation		1 (2%)		

INTEGUMENTARY SYSTEM

Mammary Gland	(60)	(49)	(49)	(57)
Hyperplasia	3 (5%)	3 (6%)	1 (2%)	
Duct, Dilatation				1 (2%)
Epithelium, Cytoplasmic Alteration		1 (2%)		
Skin	(60)	(50)	(50)	(60)
Hyperkeratosis	1 (2%)			
Hyperplasia				1 (2%)
Inflammation				1 (2%)
Ulcer			1 (2%)	

MUSCULOSKELETAL SYSTEM

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Route: GAVAGE

Species/Strain: RATS/Wistar Han

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

Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 08/21/2013

Time Report Requested: 07:54:39

First Dose M/F: 07/18/07 / 07/19/07

Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Bone	(60)	(50)	(50)	(59)
Skeletal Muscle	(0)	(0)	(3)	(2)

NERVOUS SYSTEM

Brain	(60)	(50)	(50)	(60)
Inflammation			1 (2%)	2 (3%)
Cerebellum, Vacuolization Cytoplasmic		1 (2%)		
Peripheral Nerve	(1)	(2)	(0)	(0)
Spinal Cord	(1)	(2)	(0)	(0)
Degeneration	1 (100%)			

RESPIRATORY SYSTEM

Lung	(60)	(49)	(50)	(58)
Congestion		1 (2%)	2 (4%)	3 (5%)
Edema		2 (4%)	2 (4%)	1 (2%)
Fibrosis		1 (2%)		
Hemorrhage		1 (2%)		2 (3%)
Inflammation, Suppurative	1 (2%)	3 (6%)	2 (4%)	9 (16%)
Inflammation, Chronic Active	14 (23%)	11 (22%)	13 (26%)	10 (17%)
Alveolar Epithelium, Hyperplasia	3 (5%)	7 (14%)	7 (14%)	3 (5%)
Alveolus, Infiltration Cellular, Histiocyte	23 (38%)	31 (63%)	18 (36%)	17 (29%)
Serosa, Inflammation			1 (2%)	
Nose	(59)	(49)	(50)	(59)
Foreign Body	3 (5%)	2 (4%)	4 (8%)	8 (14%)
Inflammation, Suppurative	5 (8%)	3 (6%)	17 (34%)	36 (61%)
Inflammation, Acute				1 (2%)
Epithelium, Goblet Cell, Nasopharyngeal Duct, Hyperplasia	4 (7%)	4 (8%)		
Epithelium, Nasopharyngeal Duct, Accumulation, Hyaline Droplet	1 (2%)	5 (10%)	3 (6%)	
Epithelium, Nasopharyngeal Duct, Degeneration			1 (2%)	4 (7%)
Epithelium, Nasopharyngeal Duct, Hyperplasia		1 (2%)	4 (8%)	1 (2%)

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Green tea extract

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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Epithelium, Nasopharyngeal Duct, Inflammation, Suppurative			1 (2%)	
Epithelium, Nasopharyngeal Duct, Necrosis		1 (2%)	2 (4%)	7 (12%)
Epithelium, Nasopharyngeal Duct, Regeneration				9 (15%)
Lamina Propria, Mineralization	3 (5%)	23 (47%)	30 (60%)	22 (37%)
Lamina Propria, Pigmentation	1 (2%)		6 (12%)	15 (25%)
Nasopharyngeal Duct, Foreign Body	1 (2%)		1 (2%)	2 (3%)
Nasopharyngeal Duct, Inflammation, Suppurative		2 (4%)	5 (10%)	15 (25%)
Nasopharyngeal Duct, Inflammation, Acute				1 (2%)
Nasopharyngeal Duct, Mineralization			1 (2%)	
Nerve, Atrophy		38 (78%)	41 (82%)	39 (66%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	33 (56%)	31 (63%)	17 (34%)	5 (8%)
Olfactory Epithelium, Atrophy	2 (3%)	35 (71%)	42 (84%)	36 (61%)
Olfactory Epithelium, Hyperplasia, Basal Cell			8 (16%)	20 (34%)
Olfactory Epithelium, Metaplasia, Respiratory	2 (3%)	42 (86%)	43 (86%)	40 (68%)
Olfactory Epithelium, Necrosis		3 (6%)	1 (2%)	18 (31%)
Olfactory Epithelium, Pigmentation		11 (22%)	7 (14%)	9 (15%)
Olfactory Epithelium, Regeneration				1 (2%)
Olfactory Epithelium, Squamous Metaplasia		2 (4%)	1 (2%)	5 (8%)
Respiratory Epithelium, Accumulation, Hyaline Droplet	28 (47%)	31 (63%)	19 (38%)	8 (14%)
Respiratory Epithelium, Atrophy		8 (16%)	9 (18%)	3 (5%)
Respiratory Epithelium, Degeneration	1 (2%)			
Respiratory Epithelium, Hyperplasia	1 (2%)	1 (2%)	2 (4%)	4 (7%)
Respiratory Epithelium, Hyperplasia, Basal Cell	1 (2%)			
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)	1 (2%)	1 (2%)	4 (7%)
Respiratory Epithelium, Necrosis		1 (2%)	2 (4%)	17 (29%)
Respiratory Epithelium, Pigmentation		1 (2%)	5 (10%)	5 (8%)
Respiratory Epithelium, Regeneration				2 (3%)
Squamous Epithelium, Hyperplasia				1 (2%)
Turbinate, Deformity		6 (12%)	20 (40%)	16 (27%)
Turbinate, Hyperostosis		18 (37%)	32 (64%)	36 (61%)
Trachea	(60)	(50)	(50)	(60)
Hemorrhage				1 (2%)

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Route: GAVAGE

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Green tea extract

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Lab: BAT

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation Glands, Cyst	1 (2%)			1 (2%)

SPECIAL SENSES SYSTEM

Eye	(58)	(50)	(50)	(59)
Cataract		1 (2%)	1 (2%)	
Synechia				2 (3%)
Anterior Chamber, Hemorrhage	1 (2%)			
Anterior Chamber, Posterior Chamber, Exudate			1 (2%)	
Cornea, Inflammation	1 (2%)		1 (2%)	
Optic Nerve, Degeneration	1 (2%)			
Posterior Chamber, Hemorrhage			1 (2%)	
Retina, Atrophy		1 (2%)		
Retina, Dysplasia			1 (2%)	1 (2%)
Harderian Gland	(58)	(50)	(50)	(59)
Hyperplasia			1 (2%)	
Inflammation	2 (3%)	3 (6%)		
Zymbal's Gland	(0)	(0)	(1)	(0)

URINARY SYSTEM

Kidney	(60)	(49)	(49)	(55)
Atrophy			1 (2%)	
Cyst	2 (3%)	1 (2%)	2 (4%)	
Hydronephrosis	2 (3%)		2 (4%)	3 (5%)
Infarct		1 (2%)		
Inflammation	11 (18%)	7 (14%)	5 (10%)	1 (2%)
Necrosis	1 (2%)			
Nephropathy	21 (35%)	16 (33%)	17 (35%)	4 (7%)
Papilla, Mineralization				1 (2%)
Papilla, Necrosis	1 (2%)		1 (2%)	1 (2%)
Pelvis, Dilatation	1 (2%)			
Transitional Epithelium, Hyperplasia	7 (12%)	3 (6%)	6 (12%)	
Urinary Bladder	(59)	(49)	(49)	(54)

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation	1 (2%)	1 (2%)		

*** END OF REPORT ***

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