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

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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 [4.0]	1 [2.0]		
Perforation				2
Muscularis, Degeneration			1 [1.0]	
Intestine Large, Cecum	(60)	(50)	(50)	(60)
Inflammation	1 [1.0]			3 [1.3]
Ulcer				1 [2.0]
Epithelium, Hyperplasia				1 [2.0]
Intestine Large, Colon	(60)	(50)	(50)	(60)
Inflammation				1 [2.0]
Parasite Metazoan		1	1	
Epithelium, Necrosis			1 [2.0]	1 [1.0]
Intestine Large, Rectum	(60)	(50)	(50)	(60)
Inflammation				1 [3.0]
Parasite Metazoan	5	1	4	
Muscularis, Hyperplasia		1 [4.0]		
Intestine Small, Duodenum	(60)	(47)	(49)	(58)
Epithelium, Regeneration			1 [2.0]	
Mucosa, Necrosis		1 [1.0]	1 [2.0]	10 [2.4]
Intestine Small, Ileum	(60)	(48)	(49)	(55)
Mucosa, Necrosis		1 [1.0]	2 [1.5]	6 [1.7]

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)

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Intestine Small, Jejunum	(59)	(47)	(48)	(56)
Mucosa, Necrosis			2 [1.0]	9 [2.0]
Muscularis, Hyperplasia			1 [2.0]	
Liver	(60)	(50)	(50)	(60)
Angiectasis	2 [1.5]	1 [2.0]	3 [1.7]	
Basophilic Focus	20	20	33	11
Clear Cell Focus	28	36	34	20
Deformity	1 [1.0]			
Degeneration, Cystic				1 [3.0]
Eosinophilic Focus	5	5	5	
Fatty Change	2 [2.5]	2 [1.5]	1 [2.0]	1 [2.0]
Hematopoietic Cell Proliferation	4 [1.5]		1 [1.0]	
Hematopoietic Cell Proliferation, Granulocytic		1 [2.0]		
Hepatodiaphragmatic Nodule	1		1	1
Inflammation	3 [1.0]	7 [1.1]	5 [1.0]	2 [1.0]
Inflammation, Chronic Active			1 [1.0]	
Mixed Cell Focus	10	9	12	7
Necrosis	1 [1.0]	2 [1.0]	2 [1.5]	13 [2.9]
Pigmentation		2 [3.0]	1 [2.0]	1 [3.0]
Vacuolization Cytoplasmic, Focal	3	15	9	1
Bile Duct, Hyperplasia	11 [1.0]	14 [1.2]	6 [1.2]	10 [1.3]
Bile Duct, Hyperplasia, Cystic				1 [3.0]
Hepatocyte, Atrophy	1 [4.0]			
Hepatocyte, Regeneration	1 [3.0]			
Oval Cell, Hyperplasia				2 [1.5]
Portal, Fibrosis		1 [2.0]		
Portal, Infiltration Cellular, Mononuclear Cell			2 [1.5]	
Mesentery	(3)	(2)	(1)	(1)
Inflammation		1 [4.0]		
Necrosis	2 [3.0]	1 [3.0]		1 [3.0]
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(60)	(50)	(50)	(60)
Basophilic Focus	1			
Lipomatosis		1 [2.0]		
Pigmentation, Hemosiderin			1 [1.0]	
Acinus, Atrophy	7 [1.3]	6 [1.3]	9 [1.4]	5 [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)

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Acinus, Hyperplasia	3 [1.7]			
Acinus, Necrosis				1 [2.0]
Salivary Glands	(60)	(50)	(50)	(58)
Amyloid Deposition	1 [2.0]			
Atrophy	1 [2.0]			
Necrosis				1 [3.0]
Duct, Cyst			1 [4.0]	
Stomach, Forestomach	(60)	(50)	(50)	(60)
Erosion	2 [1.5]			
Inflammation	3 [2.7]	2 [2.0]		
Ulcer		3 [2.7]		2 [1.5]
Epithelium, Degeneration, Hydropic			1 [2.0]	
Epithelium, Hyperkeratosis	1 [4.0]	1 [1.0]		
Epithelium, Hyperplasia	7 [2.6]	6 [2.8]	7 [1.6]	8 [1.5]
Stomach, Glandular	(59)	(50)	(50)	(60)
Cyst, Squamous			1	
Inflammation	2 [1.5]			1 [1.0]
Mineralization	1 [1.0]			1 [1.0]
Mucosa, Hyalinization			1 [1.0]	
Mucosa, Necrosis		3 [2.0]	3 [1.7]	21 [2.5]
Mucosa, Pigmentation		1 [1.0]		
Tooth	(1)	(1)	(0)	(0)
Inflammation	1 [3.0]			
CARDIOVASCULAR SYSTEM				
Blood Vessel	(60)	(50)	(50)	(60)
Adventitia, Aorta, Inflammation			1 [2.0]	1 [3.0]
Heart	(60)	(50)	(50)	(60)
Cardiomyopathy	47 [1.3]	43 [1.6]	40 [1.3]	28 [1.4]
Inflammation			1 [1.0]	1 [2.0]
Endocardium, Hyperplasia		1 [3.0]		
Epicardium, Inflammation			1 [1.0]	5 [2.2]
Myocardium, Necrosis				3 [2.0]
Pericardium, Inflammation				1 [4.0]

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

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 [2.0]		
Degeneration, Cystic	2 [1.0]	1 [3.0]	1 [1.0]	
Hematopoietic Cell Proliferation, Granulocytic	1 [3.0]			
Hyperplasia	22 [1.7]	22 [1.5]	25 [1.4]	8 [1.4]
Hypertrophy	20 [2.0]	24 [1.8]	14 [2.1]	6 [1.8]
Infiltration Cellular, Lipocyte		1 [4.0]		
Necrosis	2 [1.0]			5 [2.0]
Adrenal Medulla	(60)	(50)	(50)	(60)
Hyperplasia		1 [3.0]	2 [1.5]	
Islets, Pancreatic	(60)	(50)	(50)	(60)
Parathyroid Gland	(57)	(44)	(49)	(55)
Hyperplasia	2 [2.0]		1 [2.0]	1 [2.0]
Inflammation				1 [2.0]
Pituitary Gland	(60)	(50)	(50)	(60)
Pars Distalis, Atrophy		1 [1.0]		
Pars Distalis, Hyperplasia	12 [2.6]	10 [2.0]	13 [2.2]	8 [2.1]
Pars Intermedia, Hyperplasia			1 [2.0]	
Thyroid Gland	(60)	(50)	(50)	(59)
Amyloid Deposition			1 [1.0]	
Hemorrhage				1 [2.0]
C-cell, Hyperplasia	37 [1.7]	30 [1.5]	30 [1.4]	15 [1.4]
Follicle, Cyst	1 [4.0]			
Follicular Cell, Hyperplasia		1 [2.0]	3 [2.0]	
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)

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Epididymis	(60)	(50)	(50)	(60)
Granuloma Sperm	1 [3.0]		1 [3.0]	
Spermatocele	1 [4.0]			
Preputial Gland	(60)	(50)	(50)	(60)
Inflammation	1 [1.0]	1 [4.0]		1 [2.0]
Prostate	(60)	(50)	(50)	(60)
Inflammation	5 [3.4]	4 [3.8]		2 [4.0]
Epithelium, Hyperplasia	6 [1.5]	13 [1.3]	6 [1.3]	8 [1.3]
Seminal Vesicle	(60)	(50)	(50)	(60)
Inflammation	2 [2.0]	5 [2.4]		2 [2.5]
Epithelium, Hyperplasia	1 [1.0]	2 [1.0]		
Testes	(60)	(50)	(50)	(60)
Atrophy	9 [2.2]	13 [1.8]	13 [2.5]	5 [3.0]
Degeneration, Cystic	3 [3.0]	7 [3.9]	7 [3.7]	
Mineralization				2 [1.5]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(59)	(50)	(50)	(60)
Hyperplasia	10 [2.0]	9 [1.8]	11 [1.4]	13 [1.7]
Hyperplasia, Histiocytic		1 [3.0]		
Lymph Node	(4)	(0)	(1)	(1)
Mediastinal, Degeneration, Cystic	1 [3.0]			
Mediastinal, Hemorrhage	1 [2.0]			
Mediastinal, Hyperplasia, Lymphoid	2 [3.5]			1 [2.0]
Lymph Node, Mandibular	(59)	(50)	(50)	(58)
Degeneration, Cystic	5 [2.0]	8 [2.1]	4 [2.0]	3 [2.3]
Hemorrhage			1 [2.0]	
Hyperplasia, Lymphoid				1 [2.0]
Hyperplasia, Plasma Cell	6 [2.0]	1 [3.0]	2 [2.0]	7 [1.9]
Lymph Node, Mesenteric	(60)	(50)	(50)	(60)
Atrophy				1 [3.0]
Degeneration, Cystic	2 [3.0]		1 [2.0]	1 [2.0]
Hemorrhage			1 [2.0]	
Spleen	(60)	(50)	(50)	(60)

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

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Angiectasis		1 [2.0]		
Depletion Lymphoid	1 [2.0]	2 [2.0]	1 [1.0]	13 [2.2]
Hematopoietic Cell Proliferation	7 [2.4]	1 [4.0]	1 [1.0]	1 [1.0]
Hyperplasia, Lymphoid	1 [2.0]		1 [2.0]	
Thymus	(59)	(49)	(50)	(60)
Atrophy				1 [1.0]
Hemorrhage	1 [2.0]			
Hyperplasia				1 [2.0]
Inflammation				1 [3.0]
INTEGUMENTARY SYSTEM				
Mammary Gland	(60)	(50)	(50)	(60)
Duct, Dilatation	1 [2.0]			
Skin	(60)	(50)	(50)	(60)
Cyst Epithelial Inclusion	3	3	1	
Hyperplasia	2 [3.0]	1 [2.0]		
Inflammation	2 [2.0]			
Ulcer	8 [3.8]	4 [4.0]	2 [4.0]	
Hair Follicle, Cyst Epithelial Inclusion, Multiple		1		
MUSCULOSKELETAL SYSTEM				
Bone	(60)	(50)	(50)	(60)
Skeletal Muscle	(0)	(0)	(0)	(1)
Cyst				1 [3.0]
NERVOUS SYSTEM				
Brain	(60)	(50)	(50)	(60)
Ventricle, Developmental Malformation		1		
Peripheral Nerve	(0)	(1)	(0)	(1)
Spinal Cord	(0)	(1)	(0)	(1)
Degeneration		1 [2.0]		

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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 [1.5]
Inflammation, Suppurative		1 [2.0]	3 [3.7]	10 [3.7]
Inflammation, Chronic Active	11 [1.1]	6 [1.0]	7 [1.1]	14 [1.4]
Mineralization	1 [1.0]			
Alveolar Epithelium, Hyperplasia	2 [1.0]	4 [1.0]	5 [2.2]	5 [1.0]
Alveolar Epithelium, Metaplasia				1 [2.0]
Alveolus, Infiltration Cellular, Histiocyte	25 [1.2]	21 [1.1]	28 [1.1]	27 [1.4]
Bronchiole, Hyperplasia			1 [1.0]	
Nose	(60)	(50)	(50)	(60)
Foreign Body	8	5	4	6
Inflammation, Suppurative	11 [1.7]	12 [1.8]	20 [2.0]	44 [2.3]
Inflammation, Acute				1 [1.0]
Epithelium, Goblet Cell, Nasopharyngeal Duct, Hyperplasia	1 [1.0]	1 [2.0]	1 [1.0]	
Epithelium, Nasopharyngeal Duct, Degeneration		1 [2.0]		3 [2.7]
Epithelium, Nasopharyngeal Duct, Hyperplasia			2 [1.0]	5 [1.8]
Epithelium, Nasopharyngeal Duct, Metaplasia, Squamous		1 [2.0]		1 [2.0]
Epithelium, Nasopharyngeal Duct, Necrosis				3 [2.0]
Epithelium, Nasopharyngeal Duct, Pigmentation				2 [1.0]
Epithelium, Nasopharyngeal Duct, Regeneration			2 [1.5]	2 [3.5]
Goblet Cell, Hyperplasia	1 [1.0]			2 [1.0]
Goblet Cell, Nasopharyngeal Duct, Hyperplasia		1 [1.0]		
Lamina Propria, Mineralization		33 [1.4]	34 [1.4]	45 [1.5]
Lamina Propria, Pigmentation		4 [1.3]	11 [1.6]	25 [2.4]
Lumen, Pigmentation, Histiocyte		1 [3.0]		
Nasopharyngeal Duct, Foreign Body		2	1	3
Nasopharyngeal Duct, Inflammation, Suppurative		6 [1.5]	8 [2.0]	22 [2.0]
Nasopharyngeal Duct, Mineralization				1 [1.0]

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

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Nerve, Atrophy		33 [1.7]	44 [2.0]	49 [2.4]
Olfactory Epithelium, Accumulation, Hyaline Droplet	31 [2.6]	30 [1.8]	22 [1.5]	4 [1.5]
Olfactory Epithelium, Atrophy	1 [1.0]	38 [1.8]	41 [2.0]	46 [2.0]
Olfactory Epithelium, Hyperplasia, Basal Cell		1 [1.0]	9 [1.0]	28 [1.8]
Olfactory Epithelium, Metaplasia, Respiratory	4 [1.3]	40 [2.2]	43 [2.4]	50 [2.8]
Olfactory Epithelium, Necrosis	1 [2.0]	3 [2.0]		14 [1.9]
Olfactory Epithelium, Pigmentation	6 [1.7]	18 [1.6]	12 [1.3]	24 [1.5]
Olfactory Epithelium, Squamous Metaplasia			1 [1.0]	4 [1.3]
Olfactory Epithelium, Ulcer				1 [2.0]
Respiratory Epithelium, Accumulation, Hyaline Droplet	23 [1.5]	30 [1.6]	29 [1.7]	10 [1.5]
Respiratory Epithelium, Atrophy		2 [1.5]	5 [1.4]	6 [1.5]
Respiratory Epithelium, Degeneration				3 [2.0]
Respiratory Epithelium, Hyperplasia	3 [1.3]	1 [2.0]	4 [1.3]	8 [1.3]
Respiratory Epithelium, Metaplasia, Squamous		1 [1.0]	3 [1.3]	9 [1.4]
Respiratory Epithelium, Necrosis				4 [2.8]
Respiratory Epithelium, Pigmentation	2 [1.0]	6 [1.2]	7 [1.1]	7 [1.3]
Turbinate, Deformity		16	22	35
Turbinate, Hyperostosis		18 [1.5]	27 [1.9]	40 [2.2]
Trachea	(60)	(50)	(50)	(60)
Inflammation				3 [2.7]
Epithelium, Hyperplasia			1 [1.0]	
SPECIAL SENSES SYSTEM				
Eye	(60)	(50)	(50)	(60)
Cataract			1 [1.0]	1 [3.0]
Synechia		1 [2.0]	1 [4.0]	
Ciliary Body, Inflammation		1 [2.0]		
Cornea, Inflammation	1 [3.0]			
Retina, Atrophy	1 [1.0]		2 [3.0]	1 [2.0]
Retina, Dysplasia		1 [1.0]		
Retina, Hyperplasia, Reticulum Cell	1 [2.0]			
Harderian Gland	(60)	(50)	(50)	(60)
Hyperplasia			1 [2.0]	

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

Wistar Han RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation	1 [1.0]	1 [2.0]		1 [1.0]
Zymbal's Gland	(1)	(0)	(0)	(0)
URINARY SYSTEM				
Kidney	(60)	(50)	(50)	(60)
Accumulation, Hyaline Droplet				1 [1.0]
Casts Granular				1 [2.0]
Cyst	1 [3.0]	3 [2.3]	2 [1.5]	2 [2.5]
Hydronephrosis	2 [1.5]	2 [2.5]	2 [1.5]	4 [1.3]
Infarct				2 [2.0]
Infiltration Cellular, Lipocyte				1 [1.0]
Inflammation	15 [1.5]	10 [1.8]	13 [1.7]	10 [1.6]
Nephropathy	47 [1.3]	40 [1.2]	44 [1.1]	29 [1.0]
Papilla, Necrosis	2 [1.0]			1 [2.0]
Renal Tubule, Hyperplasia			2 [1.0]	
Transitional Epithelium, Hyperplasia	1 [1.0]	4 [1.8]	1 [1.0]	2 [2.0]
Ureter	(1)	(0)	(0)	(0)
Urinary Bladder	(60)	(50)	(50)	(60)
Transitional Epithelium, Hyperplasia				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)

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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 [4.0]		
Perforation				1
Muscularis, Degeneration	1 [1.0]			
Intestine Large, Cecum	(59)	(49)	(48)	(54)
Inflammation	1 [1.0]		1 [4.0]	1 [2.0]
Lymphoid Tissue, Hyperplasia	1 [2.0]	1 [2.0]		
Intestine Large, Colon	(59)	(49)	(48)	(54)
Hyperplasia, Lymphoid			1 [2.0]	
Inflammation				1 [2.0]
Parasite Metazoan	1		1	
Intestine Large, Rectum	(59)	(49)	(50)	(55)
Inflammation			1 [1.0]	
Parasite Metazoan	1			1
Thrombosis				1 [2.0]
Intestine Small, Duodenum	(57)	(48)	(48)	(49)
Mucosa, Necrosis			1 [1.0]	5 [2.2]
Intestine Small, Ileum	(55)	(46)	(47)	(46)
Mucosa, Necrosis				5 [1.0]
Serosa, Hemorrhage			1 [3.0]	
Serosa, Inflammation			1 [3.0]	
Intestine Small, Jejunum	(55)	(43)	(45)	(50)

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)

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Necrosis, Hemorrhagic		1 [4.0]		
Mucosa, Necrosis			1 [1.0]	6 [1.0]
Liver	(60)	(48)	(49)	(56)
Angiectasis	1 [2.0]	4 [2.3]		
Basophilic Focus	38	38	35	16
Clear Cell Focus	14	8	6	5
Degeneration, Cystic	1 [1.0]			
Eosinophilic Focus	3	4	1	4
Fatty Change	7 [1.9]	1 [2.0]		
Hematopoietic Cell Proliferation		4 [2.3]	5 [2.4]	
Hematopoietic Cell Proliferation, Granulocytic		3 [2.3]	2 [2.5]	1 [3.0]
Hepatodiaphragmatic Nodule			1	
Inflammation	5 [1.4]	3 [1.0]	4 [1.3]	7 [1.1]
Mixed Cell Focus	7	4	1	2
Necrosis	3 [2.7]	2 [2.0]	5 [2.6]	25 [3.2]
Pigmentation	1 [3.0]	1 [2.0]	2 [3.5]	5 [2.6]
Vacuolization Cytoplasmic, Focal	6	2	4	1
Bile Duct, Concretion			1 [1.0]	
Bile Duct, Cyst		2 [2.0]	2 [2.5]	
Bile Duct, Dilatation			1 [2.0]	
Bile Duct, Hyperplasia	21 [1.2]	11 [1.3]	13 [1.2]	18 [1.4]
Bile Duct, Hyperplasia, Cystic	1 [3.0]			
Hepatocyte, Hyperplasia, Regenerative				2 [3.5]
Hepatocyte, Hypertrophy				1 [1.0]
Hepatocyte, Regeneration	1 [3.0]			
Oval Cell, Hyperplasia	1 [1.0]	2 [1.0]	3 [1.7]	17 [1.2]
Portal, Infiltration Cellular, Mononuclear Cell	2 [1.0]	1 [1.0]		
Serosa, Fibrosis			1 [1.0]	
Serosa, Inflammation			1 [3.0]	
Mesentery	(6)	(3)	(3)	(2)
Degeneration, Cystic			1 [2.0]	
Necrosis	4 [3.0]			
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(60)	(49)	(48)	(54)
Inflammation	1 [1.0]	1 [3.0]	2 [1.0]	
Lipomatosis			1 [2.0]	

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

Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Acinus, Atrophy	3 [1.3]	4 [2.0]	2 [1.5]	2 [1.0]
Acinus, Cytoplasmic Alteration		1 [1.0]		
Duct, Cyst		1 [2.0]		
Salivary Glands	(59)	(48)	(50)	(56)
Inflammation	1 [2.0]			
Duct, Cyst		1 [4.0]		
Stomach, Forestomach	(60)	(50)	(49)	(54)
Erosion	2 [3.0]	2 [2.0]		1 [2.0]
Inflammation	5 [2.0]	1 [2.0]		2 [1.5]
Mineralization		1 [1.0]	1 [1.0]	2 [1.5]
Ulcer	2 [3.0]	1 [3.0]	2 [2.5]	2 [2.0]
Epithelium, Hyperkeratosis	1 [1.0]			
Epithelium, Hyperplasia	3 [3.0]	2 [1.5]	1 [3.0]	2 [1.5]
Stomach, Glandular	(60)	(49)	(49)	(54)
Inflammation	4 [1.8]	1 [1.0]	1 [1.0]	2 [1.5]
Mineralization	1 [1.0]	2 [1.5]	2 [1.5]	2 [1.5]
Necrosis		1 [2.0]		
Epithelium, Degeneration	1 [2.0]			
Epithelium, Hyperplasia	1 [3.0]		2 [2.0]	
Glands, Hyperplasia				1 [2.0]
Mucosa, Necrosis		1 [2.0]	7 [1.1]	20 [1.9]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(60)	(48)	(50)	(56)
Adventitia, Aorta, Inflammation			2 [2.0]	
Heart	(60)	(48)	(50)	(58)
Cardiomyopathy	20 [1.4]	24 [1.3]	18 [1.4]	12 [1.1]
Inflammation	1 [2.0]		1 [2.0]	2 [1.5]
Mineralization				1 [2.0]
Endocardium, Fibrosis				1 [2.0]
Endocardium, Hyperplasia				1 [2.0]
Epicardium, Inflammation		2 [2.0]	2 [2.0]	4 [1.5]

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

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 [3.0]	
Atrophy			1 [3.0]	
Degeneration, Cystic	1 [2.0]			1 [2.0]
Hemorrhage			1 [3.0]	1 [3.0]
Hyperplasia	21 [1.6]	25 [1.6]	27 [1.8]	7 [1.3]
Hypertrophy	13 [1.8]	15 [2.3]	10 [1.6]	4 [2.0]
Mineralization			1 [2.0]	
Necrosis	3 [1.0]			3 [3.0]
Adrenal Medulla	(60)	(49)	(49)	(57)
Hyperplasia	2 [1.0]			
Vacuolization Cytoplasmic		2 [2.0]		
Islets, Pancreatic	(60)	(49)	(48)	(54)
Parathyroid Gland	(57)	(46)	(48)	(54)
Pituitary Gland	(60)	(50)	(50)	(60)
Angiectasis		1 [2.0]		
Pars Distalis, Angiectasis				1 [3.0]
Pars Distalis, Cyst	1 [2.0]			
Pars Distalis, Hyperplasia	12 [2.1]	13 [2.4]	17 [2.9]	13 [2.3]
Pars Intermedia, Angiectasis		1 [3.0]		1 [4.0]
Pars Intermedia, Hyperplasia	1 [2.0]			
Thyroid Gland	(60)	(49)	(50)	(57)
C-cell, Hyperplasia	29 [1.3]	14 [1.7]	6 [1.0]	4 [1.5]
Follicular Cell, Hyperplasia	2 [2.5]	1 [2.0]		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(59)	(49)	(50)	(56)

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation	4 [2.3]	2 [2.5]		2 [1.5]
Duct, Cyst			1 [3.0]	
Ovary	(60)	(49)	(49)	(54)
Cyst	8 [2.8]	12 [2.4]	10 [2.6]	6 [3.2]
Inflammation	1 [2.0]	5 [2.4]	3 [2.3]	6 [3.0]
Oviduct	(1)	(0)	(0)	(0)
Uterus	(60)	(49)	(49)	(54)
Congestion				1 [2.0]
Decidual Reaction		1 [2.0]		
Hemorrhage	1 [4.0]			
Infiltration Cellular, Plasma Cell				1 [4.0]
Inflammation	3 [1.3]	4 [2.5]	2 [2.0]	5 [3.4]
Cervix, Fibrosis	1 [2.0]			
Endometrium, Hyperplasia, Cystic	10 [2.2]	14 [1.9]	15 [2.5]	10 [2.6]
Vagina	(1)	(2)	(0)	(0)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(60)	(50)	(50)	(60)
Hyperplasia	6 [1.7]	14 [2.1]	16 [2.4]	13 [2.5]
Lymph Node	(3)	(1)	(4)	(6)
Bronchial, Hyperplasia, Plasma Cell				1 [2.0]
Bronchial, Inflammation			1 [4.0]	
Iliac, Hyperplasia, Lymphoid			1 [3.0]	
Lumbar, Hyperplasia, Lymphoid				1 [2.0]
Mediastinal, Degeneration, Cystic			1 [2.0]	
Mediastinal, Hemorrhage		1 [2.0]		
Mediastinal, Hyperplasia	1 [4.0]			
Mediastinal, Hyperplasia, Plasma Cell			1 [3.0]	
Mediastinal, Infiltration Cellular, Histiocyte				1 [2.0]
Mediastinal, Pigmentation, Hemosiderin			1 [1.0]	1 [2.0]
Renal, Hyperplasia, Plasma Cell				2 [3.0]
Renal, Inflammation			1 [3.0]	
Lymph Node, Mandibular	(59)	(48)	(50)	(56)
Atrophy			1 [4.0]	1 [3.0]

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Congestion				1 [4.0]
Degeneration, Cystic	2 [2.0]	4 [1.8]	5 [1.8]	2 [2.0]
Hyperplasia, Plasma Cell	12 [2.3]	3 [2.0]	3 [2.3]	9 [2.4]
Inflammation				1 [2.0]
Lymph Node, Mesenteric	(60)	(49)	(48)	(55)
Atrophy				1 [3.0]
Congestion				1 [3.0]
Hyperplasia, Plasma Cell			1 [2.0]	1 [3.0]
Infiltration Cellular, Histiocyte				1 [2.0]
Spleen	(60)	(49)	(48)	(53)
Depletion Lymphoid		7 [1.7]	5 [1.8]	17 [1.7]
Fibrosis		1 [2.0]		
Hematopoietic Cell Proliferation	11 [2.1]	7 [3.1]	10 [3.0]	5 [3.0]
Hyperplasia, Lymphoid	1 [1.0]	1 [3.0]	3 [2.0]	1 [2.0]
Inflammation			1 [2.0]	
Lymphoid Follicle, Hyperplasia	1 [1.0]			
Thymus	(59)	(47)	(50)	(57)
Cyst				1 [3.0]
Hemorrhage				1 [3.0]
Inflammation		1 [2.0]		
INTEGUMENTARY SYSTEM				
Mammary Gland	(60)	(49)	(49)	(57)
Hyperplasia	3 [1.7]	3 [3.0]	1 [4.0]	
Duct, Dilatation				1 [3.0]
Epithelium, Cytoplasmic Alteration		1 [2.0]		
Skin	(60)	(50)	(50)	(60)
Hyperkeratosis	1 [1.0]			
Hyperplasia				1 [2.0]
Inflammation				1 [2.0]
Ulcer			1 [3.0]	
MUSCULOSKELETAL SYSTEM				

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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 [3.0]	2 [2.0]
Cerebellum, Vacuolization Cytoplasmic		1 [1.0]		
Peripheral Nerve	(1)	(2)	(0)	(0)
Spinal Cord	(1)	(2)	(0)	(0)
Degeneration	1 [2.0]			
RESPIRATORY SYSTEM				
Lung	(60)	(49)	(50)	(58)
Congestion		1 [3.0]	2 [2.5]	3 [3.0]
Edema		2 [3.0]	2 [3.0]	1 [2.0]
Fibrosis		1 [2.0]		
Hemorrhage		1 [2.0]		2 [2.0]
Inflammation, Suppurative	1 [2.0]	3 [2.0]	2 [3.5]	9 [3.4]
Inflammation, Chronic Active	14 [1.2]	11 [1.5]	13 [1.1]	10 [1.4]
Alveolar Epithelium, Hyperplasia	3 [1.3]	7 [1.4]	7 [1.3]	3 [1.7]
Alveolus, Infiltration Cellular, Histiocyte	23 [1.2]	31 [1.2]	18 [1.3]	17 [1.3]
Serosa, Inflammation			1 [2.0]	
Nose	(59)	(49)	(50)	(59)
Foreign Body	3	2	4	8
Inflammation, Suppurative	5 [1.2]	3 [2.0]	17 [1.5]	36 [2.1]
Inflammation, Acute				1 [1.0]
Epithelium, Goblet Cell, Nasopharyngeal Duct, Hyperplasia	4 [1.0]	4 [1.3]		
Epithelium, Nasopharyngeal Duct, Accumulation, Hyaline Droplet	1 [1.0]	5 [2.0]	3 [1.7]	
Epithelium, Nasopharyngeal Duct, Degeneration			1 [3.0]	4 [2.5]
Epithelium, Nasopharyngeal Duct, Hyperplasia		1 [1.0]	4 [1.0]	1 [2.0]

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Epithelium, Nasopharyngeal Duct, Inflammation, Suppurative			1 [2.0]	
Epithelium, Nasopharyngeal Duct, Necrosis		1 [1.0]	2 [3.5]	7 [3.0]
Epithelium, Nasopharyngeal Duct, Regeneration				9 [3.0]
Lamina Propria, Mineralization	3 [1.0]	23 [1.1]	30 [1.4]	22 [1.5]
Lamina Propria, Pigmentation	1 [1.0]		6 [1.2]	15 [1.9]
Nasopharyngeal Duct, Foreign Body	1		1	2
Nasopharyngeal Duct, Inflammation, Suppurative		2 [1.0]	5 [1.2]	15 [2.3]
Nasopharyngeal Duct, Inflammation, Acute				1 [1.0]
Nasopharyngeal Duct, Mineralization			1 [1.0]	
Nerve, Atrophy		38 [1.6]	41 [2.1]	39 [2.2]
Olfactory Epithelium, Accumulation, Hyaline Droplet	33 [2.0]	31 [1.7]	17 [1.5]	5 [1.0]
Olfactory Epithelium, Atrophy	2 [1.5]	35 [1.6]	42 [1.7]	36 [1.8]
Olfactory Epithelium, Hyperplasia, Basal Cell			8 [1.1]	20 [1.7]
Olfactory Epithelium, Metaplasia, Respiratory	2 [1.0]	42 [2.1]	43 [2.7]	40 [2.8]
Olfactory Epithelium, Necrosis		3 [1.7]	1 [2.0]	18 [1.8]
Olfactory Epithelium, Pigmentation		11 [1.0]	7 [1.3]	9 [1.1]
Olfactory Epithelium, Regeneration				1 [2.0]
Olfactory Epithelium, Squamous Metaplasia		2 [1.0]	1 [1.0]	5 [1.4]
Respiratory Epithelium, Accumulation, Hyaline Droplet	28 [1.1]	31 [1.6]	19 [1.6]	8 [1.6]
Respiratory Epithelium, Atrophy		8 [1.5]	9 [1.7]	3 [1.0]
Respiratory Epithelium, Degeneration	1 [1.0]			
Respiratory Epithelium, Hyperplasia	1 [1.0]	1 [1.0]	2 [1.0]	4 [1.5]
Respiratory Epithelium, Hyperplasia, Basal Cell	1 [2.0]			
Respiratory Epithelium, Metaplasia, Squamous	1 [1.0]	1 [1.0]	1 [1.0]	4 [1.5]
Respiratory Epithelium, Necrosis		1 [2.0]	2 [1.5]	17 [2.4]
Respiratory Epithelium, Pigmentation		1 [1.0]	5 [1.2]	5 [1.0]
Respiratory Epithelium, Regeneration				2 [2.0]
Squamous Epithelium, Hyperplasia				1 [1.0]
Turbinate, Deformity		6	20	16
Turbinate, Hyperostosis		18 [1.3]	32 [1.7]	36 [2.2]
Trachea	(60)	(50)	(50)	(60)
Hemorrhage				1 [2.0]

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Wistar Han RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Inflammation				1 [2.0]
Glands, Cyst	1 [1.0]			
SPECIAL SENSES SYSTEM				
Eye	(58)	(50)	(50)	(59)
Cataract		1 [3.0]	1 [3.0]	
Synechia				2 [3.0]
Anterior Chamber, Hemorrhage	1 [3.0]			
Anterior Chamber, Posterior Chamber, Exudate			1 [4.0]	
Cornea, Inflammation	1 [3.0]		1 [4.0]	
Optic Nerve, Degeneration	1 [1.0]			
Posterior Chamber, Hemorrhage			1 [1.0]	
Retina, Atrophy		1 [3.0]		
Retina, Dysplasia			1 [2.0]	1 [2.0]
Harderian Gland	(58)	(50)	(50)	(59)
Hyperplasia			1 [3.0]	
Inflammation	2 [2.0]	3 [1.3]		
Zymbal's Gland	(0)	(0)	(1)	(0)
URINARY SYSTEM				
Kidney	(60)	(49)	(49)	(55)
Atrophy			1 [4.0]	
Cyst	2 [1.5]	1 [1.0]	2 [1.5]	
Hydronephrosis	2 [1.5]		2 [2.5]	3 [2.3]
Infarct		1 [2.0]		
Inflammation	11 [1.7]	7 [1.4]	5 [1.8]	1 [1.0]
Necrosis	1 [1.0]			
Nephropathy	21 [1.1]	16 [1.1]	17 [1.1]	4 [1.0]
Papilla, Mineralization				1 [1.0]
Papilla, Necrosis	1 [1.0]		1 [3.0]	1 [1.0]
Pelvis, Dilatation	1 [1.0]			
Transitional Epithelium, Hyperplasia	7 [1.9]	3 [2.0]	6 [1.7]	
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 [2.0]	1 [2.0]		

*** END OF REPORT ***

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