Experiment Number: 20725 - 03

Species/Strain: RATS/Wistar Han

Test Type: CHRONIC

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 04/12/2016

AVERAGE SEVERITY GRADES[b]

2,3-Butanedione **CAS Number:** 431-03-8 Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Lab: BNW

F1_RE

NTP Study Number: C20725

10/11/2012 Lock Date:

ALL Cage Range:

Route: RESPIRATORY EXPOSURE WHOLE BODY

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Include ALL **Treatment Groups:**

Study Gender: Both

TDMSE Version: 3.0.2.3_002

PWG Approval Date: 01/15/2016

Test Type: CHRONIC

Experiment Number: 20725 - 03

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Disposition Summary				
Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	12	11	15	18
Natural Death	2	2	2	10
Survivors				
Moribund Sacrifice		1		
Terminal Sacrifice	36	36	33	22
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Metaplasia, Squamous	1 [2.0]	2 [1.5]	3 [2.0]	1 [2.0]
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation		1 [4.0]		
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 [1.0]	2 [1.0]	6 [1.0]	1 [1.0]
Basophilic Focus	12	16	18	4
Clear Cell Focus	27	21	27	12
Degeneration, Cystic	1 [2.0]		2 [1.5]	
Eosinophilic Focus	1	1	3	1
Fatty Change, Focal	2 [1.0]		1 [1.0]	
Fatty Change, Diffuse	1 [4.0]			
Hematopoietic Cell Proliferation	2 [1.0]		1 [1.0]	1 [1.0]
Hepatodiaphragmatic Nodule	1		3	3
Infiltration Cellular, Lymphocyte	1 [2.0]			
Infiltration Cellular, Mixed Cell	5 [1.0]		5 [1.0]	4 [1.0]
Mixed Cell Focus	2	4	1	
Necrosis, Focal	1 [1.0]	1 [1.0]	1 [3.0]	

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Route: RESPIRATORY EXPOSURE WHOLE BODY

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
Pigmentation, Hemosiderin		1 [2.0]	1 [2.0]		
Tension Lipidosis			1 [1.0]		
Bile Duct, Cyst		2		1	
Bile Duct, Dilatation				1 [4.0]	
Bile Duct, Hyperplasia	5 [1.2]	3 [1.0]	4 [1.0]	1 [1.0]	
Centrilobular, Necrosis	1 [3.0]				
Serosa, Fibrosis		1 [2.0]			
Mesentery	(5)	(4)	(3)	(2)	
Fat, Necrosis	3 [1.0]	2 [2.0]	2 [1.0]	2 [1.5]	
Oral Mucosa	(1)	(1)	(0)	(0)	
Pancreas	(50)	(50)	(50)	(50)	
Atrophy	1 [4.0]	7 [1.1]	2 [2.5]	4 [1.0]	
Basophilic Focus		1 [1.0]			
Inflammation				1 [1.0]	
Acinus, Hyperplasia	1 [1.0]	1 [1.0]			
Salivary Glands	(50)	(50)	(50)	(50)	
Basophilic Focus	,	,	,	1 [1.0]	
Inflammation		1 [2.0]	1 [2.0]		
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Inflammation	1 [2.0]	()	4 [1.5]	,	
Ulcer			1 [3.0]		
Epithelium, Hyperplasia	1 [3.0]	3 [1.3]	4 [2.0]	1 [3.0]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Inflammation	1 [3.0]			2 [1.0]	
Mineralization		1 [1.0]	1 [1.0]		
Aorta, Mineralization		1 [1.0]			
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	31 [1.3]	38 [1.4]	28 [1.2]	25 [1.2]	
Inflammation, Suppurative			1 [4.0]		
Epicardium, Fibrosis, Focal			-	1 [2.0]	
Septum Interventricular, Necrosis, Acute	1 [1.0]				

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Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

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Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
Valve, Degeneration		1 [1.0]			
Valve, Inflammation, Chronic		1 [1.0]			
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	
Degeneration, Cystic	2 [1.0]	2 [1.0]	2 [1.0]	2 [1.5]	
Hematopoietic Cell Proliferation			2 [2.0]		
Infiltration Cellular, Lipocyte				1 [3.0]	
Bilateral, Necrosis, Multifocal				1 [3.0]	
Zona Fasciculata, Hyperplasia	2 [1.0]				
Zona Fasciculata, Hyperplasia, Focal	4 [1.5]	4 [1.3]	3 [1.0]	6 [1.3]	
Zona Fasciculata, Hyperplasia, Multifocal		2 [1.5]	1 [2.0]		
Zona Fasciculata, Hypertrophy	3 [1.3]	2 [1.5]			
Zona Fasciculata, Hypertrophy, Focal	12 [2.2]	12 [1.5]	11 [1.5]	6 [1.7]	
Zona Fasciculata, Hypertrophy, Multifocal	14 [2.5]	9 [1.9]	18 [2.0]	11 [1.9]	
Adrenal Medulla	(50)	(50)	(50)	(50)	
Hyperplasia	1 [2.0]	2 [1.0]	. ,	1 [1.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	5 [1.4]	1 [1.0]	5 [1.0]	2 [1.5]	
Parathyroid Gland	(49)	(46)	(49)	(47)	
Hyperplasia, Focal	1 [2.0]	1 [1.0]	1 [1.0]	,	
Pituitary Gland	(50)	(50)	(50)	(50)	
Fibrosis	,	, ,	` '	1 [2.0]	
Pars Distalis, Hyperplasia	16 [2.1]	18 [2.1]	23 [1.7]	10 [1.9]	
Pars Intermedia, Hyperplasia	1 [2.0]	3 [2.0]	1 [2.0]		
Thyroid Gland	(50)	(50)	(50)	(50)	
C-cell, Hyperplasia	8 [1.6]	13 [1.4]	8 [1.3]	2 [1.5]	
Follicular Cell, Hyperplasia	4 [1.3]	2 [3.0]	1 [2.0]	1 [2.0]	
Follicular Cell, Hypertrophy	2 [2.0]	2 [2.0]	5 [1.8]	5 [2.0]	

GENERAL BODY SYSTEM

None

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Species/Strain: RATS/Wistar Han

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
GENITAL SYSTEM					
Epididymis	(50)	(50)	(50)	(50)	
Granuloma Sperm	1 [3.0]	1 [4.0]			
Inflammation				1 [2.0]	
Preputial Gland	(50)	(50)	(50)	(50)	
Inflammation		1 [2.0]			
Prostate	(50)	(50)	(50)	(50)	
Inflammation	21 [1.2]	18 [1.4]	18 [1.3]	12 [1.3]	
Epithelium, Ventral, Hyperplasia	9 [1.4]	9 [1.4]	7 [1.3]	10 [1.2]	
Seminal Vesicle	(50)	(50)	(50)	(50)	
Hyperplasia		1 [1.0]			
Inflammation		1 [2.0]			
Testes	(50)	(50)	(50)	(50)	
Edema	4 [2.0]	2 [3.0]			
Germinal Epithelium, Degeneration	5 [2.4]	10 [2.8]	4 [3.3]	4 [2.8]	
Interstitial Cell, Hyperplasia	4 [2.0]	1 [1.0]	3 [2.3]	1 [1.0]	
Rete Testes, Inflammation, Granulomatous			1 [2.0]		
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Myeloid Cell, Hyperplasia	15 [2.9]	12 [2.8]	16 [2.8]	32 [2.9]	
Lymph Node	(6)	(4)	(9)	(7)	
Axillary, Infiltration Cellular, Plasma Cell	1 [2.0]		1 [3.0]		
Deep Cervical, Infiltration Cellular, Plasma Cell				1 [1.0]	
Iliac, Ectasia		1 [2.0]			
Iliac, Infiltration Cellular, Plasma Cell				2 [3.0]	
Inguinal, Infiltration Cellular, Plasma Cell	1 [2.0]				
Lumbar, Ectasia			1 [3.0]		
Lumbar, Hyperplasia, Lymphoid	1 [2.0]				
Lumbar, Infiltration Cellular, Plasma Cell	5 [2.8]	3 [1.7]	6 [2.8]	3 [3.3]	
Pancreatic, Inflammation			1 [3.0]		
Popliteal, Hyperplasia, Lymphoid	1 [3.0]		2 [2.5]		

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star Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
Popliteal, Infiltration Cellular, Plasma Cell			4 [3.3]	2 [3.5]	
Popliteal, Inflammation, Chronic Active	1 [2.0]			• •	
Renal, Ectasia				1 [2.0]	
Renal, Infiltration Cellular, Plasma Cell	2 [3.0]	1 [2.0]	1 [3.0]	4 [2.5]	
Lymph Node, Bronchial	(41)	(46)	(43)	(42)	
Atrophy	,	1 [3.0]	2 [3.0]	1 [2.0]	
Inflammation, Suppurative				1 [3.0]	
Lymph Node, Mandibular	(48)	(44)	(49)	(48)	
Ectasia	,	,	()	1 [2.0]	
Hemorrhage			1 [2.0]	,	
Hyperplasia, Lymphoid			,	1 [2.0]	
Infiltration Cellular, Plasma Cell				5 [2.0]	
Lymph Node, Mediastinal	(42)	(47)	(47)	(47)	
Atrophy	1 [2.0]	()	()	1 [3.0]	
Ectasia	1 [3.0]			11	
Infiltration Cellular, Plasma Cell	£1		1 [2.0]		
Inflammation			,	1 [3.0]	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Ectasia	()	1 [4.0]	()	()	
Hyperplasia, Lymphoid		1 [2.0]			
Inflammation		1 [3.0]			
Necrosis	1 [1.0]	. []			
Spleen	(50)	(50)	(50)	(50)	
Congestion	1 [4.0]	()	()	()	
Cyst	. []		1		
Hematopoietic Cell Proliferation	41 [1.9]	41 [1.9]	36 [1.7]	37 [1.8]	
Inflammation	[]	[]	1 [2.0]	[]	
Pigmentation, Hemosiderin	18 [1.2]	22 [1.0]	20 [1.1]	20 [1.2]	
Lymphoid Follicle, Atrophy	6 [1.7]	5 [2.2]	4 [2.3]	12 [2.2]	
Thymus	(47)	(48)	(48)	(48)	
Atrophy	46 [2.7]	47 [2.7]	45 [2.6]	47 [2.5]	
Hemorrhage	1 [3.0]	[=]	.0 [0]	[=.0]	
Hyperplasia, Lymphoid	1 [3.0]	2 [2.0]	1 [3.0]		

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Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
INTEGUMENTARY SYSTEM					
Mammary Gland	(12)	(9)	(14)	(22)	
Galactocele			1 [2.0]	1 [2.0]	
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion				2	
Dorsal, Inflammation, Chronic Active			1 [2.0]		
Dorsal, Ulcer, Focal			1 [2.0]		
Epidermis, Cyst			1		
Epidermis, Hyperplasia	2 [2.5]				
Foot, Inflammation, Acute	3 [3.3]			1 [3.0]	
Foot, Inflammation, Chronic Active	11 [3.3]	7 [3.1]	17 [3.2]	23 [3.0]	
Foot, Ulcer	14 [3.5]	7 [3.4]	17 [3.4]	22 [2.9]	
Inguinal, Inflammation, Granulomatous	[]	. []	1 [3.0]	()	
Inguinal, Ulcer, Focal			1 [2.0]		
Prepuce, Inflammation, Acute	1 [2.0]		. []		
Prepuce, Ulcer, Focal	1 [2.0]				
Tail, Cyst Epithelial Inclusion	,		1		
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Hyperostosis	(00)	(00)	1 [3.0]	(88)	
Osteosclerosis			1 [0.0]	1 [2.0]	
Skeletal Muscle	(6)	(3)	(4)	(6)	
	(0)				
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Cerebrum, Gray Matter, Hemorrhage, Focal	1 [1.0]	(30)	(30)	1 [2.0]	
Cranial Nerve, Glial Cell, Hyperplasia	1 [3.0]	1 [3.0]		. [=.0]	
Peripheral Nerve	(6)	(1)	(3)	(6)	
Axon, Degeneration	(0)	('')	(0)	1 [1.0]	
Spinal Cord	(6)	(1)	(3)	(6)	

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
RESPIRATORY SYSTEM					
Larynx	(50)	(50)	(50)	(50)	
Foreign Body	2				
Inflammation, Chronic Active	14 [1.1]	7 [1.1]	7 [1.0]	33 [1.2]	
Respiratory Epithelium, Metaplasia, Squamous		1 [1.0]		45 [2.3]	
Squamous Epithelium, Hyperplasia	2 [1.0]	2 [2.0]	8 [1.3]	46 [2.4]	
Squamous Epithelium, Ulcer, Focal				15 [1.3]	
Squamous Epithelium, Ulcer, Multifocal				3 [2.7]	
Lung	(50)	(49)	(50)	(50)	
Inflammation, Suppurative			1 [2.0]	15 [2.4]	
Inflammation, Granulomatous	4 [1.0]	3 [1.0]	1 [1.0]	4 [1.0]	
Inflammation, Chronic Active	1 [1.0]	2 [1.0]			
Metaplasia, Osseous		1 [1.0]			
Thrombus	1				
Alveolar Epithelium, Hyperplasia	1 [2.0]	4 [1.0]	2 [1.0]	8 [1.1]	
Alveolar Epithelium, Hyperplasia, Focal	3 [2.3]	3 [2.0]	5 [2.0]	1 [1.0]	
Alveolus, Edema				1 [3.0]	
Alveolus, Infiltration Cellular, Histiocyte	10 [1.1]	14 [1.2]	16 [1.1]	34 [1.4]	
Bronchiole, Epithelium, Hyperplasia				33 [1.3]	
Bronchus, Epithelium, Atrophy			1 [1.0]	23 [1.0]	
Bronchus, Epithelium, Hyperplasia			2 [1.0]	47 [1.2]	
Bronchus, Epithelium, Metaplasia, Squamous				2 [1.0]	
Bronchus, Epithelium, Regeneration			4 [1.0]	9 [1.0]	
Bronchus, Submucosa, Fibrosis				5 [1.0]	
Interstitium, Fibrosis		1 [1.0]	1 [1.0]	11 [1.3]	
Peribronchial, Inflammation, Chronic Active				13 [1.5]	
Pleura, Fibrosis				2 [1.0]	
Pleura, Fibrosis, Focal	1 [1.0]				
Nose	(50)	(50)	(50)	(50)	
Foreign Body	1	ì í	2	. ,	
Inflammation, Suppurative	3 [1.0]	4 [1.5]	35 [1.9]	50 [3.9]	
Inflammation, Chronic Active	1 [2.0]		2 [1.5]		
Polyp, Inflammatory	1 [2.0]				

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Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
Lamina Propria, Fibrosis			28 [1.0]	38 [1.2]	
Nerve, Hyperplasia		1 [3.0]			
Olfactory Epithelium, Accumulation, Hyaline Droplet	10 [1.9]	6 [1.5]	4 [1.8]	4 [1.3]	
Olfactory Epithelium, Atrophy		5 [1.4]	27 [1.4]	22 [1.3]	
Olfactory Epithelium, Metaplasia, Respiratory	1 [1.0]	3 [1.3]	6 [1.7]	50 [3.2]	
Olfactory Epithelium, Necrosis				6 [1.3]	
Respiratory Epithelium, Hyperplasia		2 [1.0]	5 [1.2]	50 [3.7]	
Respiratory Epithelium, Metaplasia, Squamous			5 [1.0]	34 [2.0]	
Respiratory Epithelium, Necrosis				2 [1.0]	
Turbinate, Atrophy			1 [1.0]	1 [2.0]	
Turbinate, Hyperostosis				10 [1.2]	
Pleura	(0)	(1)	(0)	(0)	
Trachea	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	,	,	, ,	1 [2.0]	
Inflammation, Chronic Active			1 [1.0]	8 [1.3]	
Epithelium, Atrophy				7 [1.1]	
Epithelium, Hyperplasia			1 [1.0]	32 [1.2]	
Epithelium, Metaplasia, Squamous				12 [1.2]	
Epithelium, Necrosis				6 [1.0]	
Epithelium, Regeneration			5 [1.0]	12 [1.1]	
Submucosa, Fibrosis				27 [1.1]	
SPECIAL SENSES SYSTEM					
Ear	(0)	(0)	(1)	(0)	
Eye	(50)	(50)	(49)	(49)	
Anterior Chamber, Inflammation, Suppurative		1 [1.0]	6 [1.3]	3 [2.0]	
Bilateral, Phthisis Bulbi			1 [4.0]		
Cornea, Inflammation, Chronic Active	1 [1.0]	6 [2.3]	16 [1.6]	28 [1.3]	
Cornea, Mineralization	1 [1.0]	4 [1.0]	1 [1.0]		
Cornea, Necrosis				2 [1.0]	
Cornea, Epithelium, Hyperplasia		2 [1.0]	3 [1.7]	6 [1.2]	
Cornea, Epithelium, Ulcer		1 [1.0]	4 [1.3]	6 [1.5]	
Iris, Inflammation, Acute		1 [1.0]	3 [1.0]	1 [2.0]	

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Route: RESPIRATORY EXPOSURE WHOLE BODY

Experiment Number: 20725 - 03

Species/Strain: RATS/Wistar Han

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Lab: BNW

Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm	
Lens, Cataract	1 [2.0]	5 [1.6]	6 [1.3]	3 [1.7]	
Retina, Degeneration	8 [2.1]	11 [2.2]	11 [2.5]	6 [1.8]	
Unilateral, Inflammation, Pyogranulomatous				1 [4.0]	
Unilateral, Phthisis Bulbi		1 [4.0]	3 [3.7]	1 [3.0]	
Harderian Gland	(50)	(50)	(50)	(50)	
Hyperplasia	1 [1.0]	,	1 [1.0]	3 [1.3]	
Metaplasia	1 [2.0]				
Lacrimal Gland	(0)	(0)	(0)	(1)	
Metaplasia	(-)	(-7	(-)	1 [2.0]	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Calculus Micro Observation Only	4	10	2	7	
Fibrosis, Focal			1 [1.0]		
Infarct	1 [2.0]	1 [1.0]	1 [1.0]		
Infiltration Cellular, Lymphoid			1 [2.0]		
Nephropathy	33 [1.7]	40 [1.7]	41 [1.6]	30 [1.4]	
Thrombosis			1 [1.0]		
Cortex, Cyst			2 [1.0]	1 [3.0]	
Papilla, Necrosis	1 [2.0]				
Pelvis, Dilatation	1 [1.0]	3 [2.7]	2 [2.5]	1 [1.0]	
Pelvis, Inflammation	10 [1.9]	11 [1.3]	8 [1.8]	14 [1.5]	
Pelvis, Transitional Epithelium, Hyperplasia	1 [3.0]	1 [1.0]			
Renal Tubule, Dilatation	1 [3.0]				
Ureter	(0)	(1)	(0)	(0)	
Inflammation		1 [4.0]			
Urinary Bladder	(50)	(50)	(50)	(50)	
Calculus Gross Observation		1			
Hemorrhage			1 [3.0]		
Inflammation		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: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Disposition Summary					
Animals Initially In Study	50	50	50	50	
Early Deaths					
Moribund Sacrifice	15	18	26	15	
Natural Death	1	1		4	
Survivors					
Moribund Sacrifice				1	
Terminal Sacrifice	34	31	24	30	
Animals Examined Microscopically	50	50	50	50	
ALIMENTARY SYSTEM					
Esophagus	(50)	(50)	(50)	(50)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)	
Inflammation	1 [3.0]	, ,			
Intestine Large, Colon	(50)	(50)	(50)	(50)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	
Intestine Small, Ileum	(50)	(50)	(50)	(50)	
Peyer's Patch, Hyperplasia, Lymphoid			1 [3.0]		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	
Liver	(50)	(50)	(50)	(50)	
Angiectasis	1 [1.0]	3 [1.0]	2 [1.0]	1 [1.0]	
Basophilic Focus	34	30	29	26	
Clear Cell Focus	6	8	5	2	
Eosinophilic Focus	3	5	7	4	
Fatty Change, Diffuse	1 [3.0]	1 [2.0]	2 [2.0]		
Hematopoietic Cell Proliferation	2 [1.0]	2 [1.5]	3 [1.0]	1 [2.0]	
Hepatodiaphragmatic Nodule	3			2	
Infiltration Cellular, Lymphoid		1 [2.0]			
Infiltration Cellular, Mixed Cell	6 [1.0]	6 [1.0]	3 [1.0]	3 [1.0]	
Mixed Cell Focus		2		1	
Necrosis, Multifocal		1 [2.0]	2 [1.5]		
Pigmentation, Hemosiderin	1 [4.0]	1 [3.0]			
Bile Duct, Cyst	2	1		1	

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Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Bile Duct, Dilatation		1 [2.0]			
Bile Duct, Hyperplasia	8 [1.5]	12 [1.4]	15 [1.6]	10 [1.6]	
Centrilobular, Degeneration		1 [2.0]			
Kupffer Cell, Hyperplasia			1 [2.0]		
Oval Cell, Hyperplasia		1 [1.0]			
Mesentery	(8)	(10)	(4)	(4)	
Fat, Necrosis	8 [1.3]	8 [1.5]	4 [1.3]	3 [1.3]	
Pancreas	(50)	(50)	(50)	(50)	
Atrophy	1 [1.0]	2 [2.0]	3 [1.3]	2 [1.5]	
Basophilic Focus		2 [1.0]	1 [2.0]	2 [1.0]	
Inflammation			2 [1.5]		
Salivary Glands	(50)	(50)	(50)	(50)	
Inflammation	,	1 [3.0]	1 [2.0]	,	
Stomach, Forestomach	(50)	(50)	(50)	(50)	
Inflammation	3 [3.3]	5 [2.2]	3 [3.3]	1 [3.0]	
Mineralization			1 [1.0]		
Ulcer	2 [3.5]	1 [4.0]	2 [3.0]	1 [3.0]	
Epithelium, Erosion		1 [1.0]			
Epithelium, Hyperplasia	3 [2.0]	6 [2.0]	3 [2.7]	2 [1.5]	
Stomach, Glandular	(50)	(50)	(50)	(50)	
Mineralization	,	,	1 [1.0]	,	
Epithelium, Necrosis				1 [1.0]	
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	
Inflammation	,	(1 [1.0]	1 [1.0]	
Media, Hypertrophy			1 [3.0]	,	
Heart	(50)	(50)	(50)	(50)	
Cardiomyopathy	21 [1.1]	28 [1.3]	24 [1.2]	27 [1.2]	
ENDOCRINE SYSTEM					
Adrenal Cortex Amyloid Deposition	(50)	(50)	(50) 1 [2.0]	(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)

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Lab: BNW

Vistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Angiectasis		2 [3.0]	1 [3.0]		
Degeneration, Cystic	12 [1.1]	7 [1.6]	12 [1.3]	12 [1.3]	
Hematopoietic Cell Proliferation	1 [2.0]	2 [2.5]	3 [3.0]	1 [3.0]	
Zona Fasciculata, Hyperplasia, Focal	3 [1.0]	2 [1.5]	7 [1.7]	7 [1.3]	
Zona Fasciculata, Hyperplasia, Multifocal	4 [1.8]	1 [1.0]		3 [1.7]	
Zona Fasciculata, Hypertrophy	1 [2.0]				
Zona Fasciculata, Hypertrophy, Focal	17 [1.6]	9 [2.2]	13 [2.2]	15 [1.7]	
Zona Fasciculata, Hypertrophy, Multifocal	5 [1.6]	3 [2.0]	2 [2.0]	3 [2.7]	
Adrenal Medulla	(50)	(50)	(49)	(50)	
Hyperplasia	1 [1.0]			1 [4.0]	
Islets, Pancreatic	(50)	(50)	(50)	(50)	
Hyperplasia	4 [1.5]	2 [1.5]	1 [1.0]		
Parathyroid Gland	(46)	(44)	(46)	(42)	
Pituitary Gland	(50)	(50)	(50)	(50)	
Pars Distalis, Angiectasis, Focal				1 [2.0]	
Pars Distalis, Hyperplasia	18 [2.0]	16 [3.1]	24 [2.1]	18 [2.3]	
Pars Intermedia, Hyperplasia			1 [2.0]		
Thyroid Gland	(50)	(50)	(50)	(50)	
C-cell, Hyperplasia	20 [1.8]	27 [1.5]	22 [2.0]	16 [1.8]	
Follicular Cell, Hyperplasia	2 [1.5]	4 [1.0]	1 [3.0]	2 [3.0]	
Follicular Cell, Hypertrophy			2 [2.5]		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM	l
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Clitoral Gland	(49)	(50)	(50)	(49)
Ectasia	1 [2.0]	2 [2.5]	2 [2.5]	
Inflammation		2 [1.5]		
Ovary	(50)	(50)	(50)	(50)
Atrophy	27 [2.0]	22 [1.8]	25 [2.2]	27 [2.0]
Cyst	18	16	20	23
Germinal Epithelium, Hyperplasia				1 [2.0]

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: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Thecal Cell, Hyperplasia	1 [3.0]				
Uterus	(50)	(50)	(50)	(50)	
Adenomyosis		1 [3.0]			
Adenomyosis, Focal	2 [1.0]				
Angiectasis, Focal				1 [4.0]	
Fibrosis, Focal				1 [1.0]	
Inflammation, Chronic Active			1 [3.0]		
Cervix, Cyst, Squamous		1			
Cervix, Hyperplasia, Squamous	7 [1.9]	5 [1.4]	8 [1.8]	10 [2.0]	
Cervix, Hypertrophy, Stromal			2 [2.0]	1 [2.0]	
Endometrial Glands, Hyperplasia, Atypical		1 [2.0]			
Endometrial Glands, Hyperplasia, Focal				1 [3.0]	
Endometrium, Decidual Reaction, Focal			1 [1.0]		
Endometrium, Hyperplasia, Cystic	24 [1.5]	16 [1.4]	17 [1.5]	25 [1.8]	
Endometrium, Hyperplasia, Focal			3 [2.7]	1 [2.0]	
Endometrium, Metaplasia, Squamous	5 [1.4]	1 [1.0]	7 [1.3]	6 [1.2]	
Serosa, Cyst Multilocular	1				
Vagina	(0)	(1)	(2)	(0)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	
Myeloid Cell, Hyperplasia	12 [2.9]	19 [3.2]	20 [3.0]	36 [2.9]	
Lymph Node	(1)	(3)	(2)	(5)	
Axillary, Hyperplasia, Lymphoid	()	()	()	1 [2.0]	
Deep Cervical, Infiltration Cellular, Plasma Cell				2 [2.5]	
Iliac, Infiltration Cellular, Plasma Cell			1 [2.0]		
Lumbar, Ectasia	1 [2.0]		,		
Lumbar, Infiltration Cellular, Plasma Cell			1 [3.0]	1 [2.0]	
Popliteal, Inflammation		1 [3.0]			
Renal, Infiltration Cellular, Plasma Cell				1 [3.0]	
Lymph Node, Bronchial	(43)	(44)	(43)	(42)	
Lymph Node, Mandibular	(46)	(48)	(45)	(48)	
Ectasia	\ -/	(- /	1 [2.0]	1 [2.0]	
Hyperplasia, Atypical		1 [3.0]			

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: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Infiltration Cellular, Plasma Cell		1 [2.0]		2 [2.0]	
Lymph Node, Mediastinal	(44)	(47)	(48)	(50)	
Atrophy				1 [4.0]	
Hyperplasia, Lymphoid				1 [2.0]	
Infiltration Cellular, Plasma Cell		1 [2.0]		1 [2.0]	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	
Atrophy		2 [2.0]	2 [3.0]	5 [3.2]	
Fibrosis, Focal	1 [3.0]				
Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]	1 [3.0]		
Infiltration Cellular, Plasma Cell			1 [2.0]		
Inflammation	1 [2.0]				
Spleen	(50)	(50)	(50)	(50)	
Hematopoietic Cell Proliferation	37 [2.1]	40 [2.0]	38 [2.2]	39 [2.0]	
Pigmentation, Hemosiderin	42 [1.3]	39 [1.3]	38 [1.3]	39 [1.5]	
Capsule, Thrombosis		1 [3.0]			
Lymphoid Follicle, Atrophy	12 [1.5]	6 [2.2]	5 [2.0]	7 [2.6]	
Lymphoid Follicle, Hyperplasia		1 [3.0]			
Thymus	(49)	(50)	(49)	(50)	
Atrophy	45 [1.9]	42 [2.1]	45 [2.1]	49 [2.2]	
Cyst			1		
Hyperplasia, Lymphoid		2 [2.5]			
INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(50)	
Galactocele	4 [2.5]	4 [2.5]	2 [2.0]	1 [1.0]	
Hyperplasia	1 [1.0]	2 [3.5]	2 [2.0]	1 [2.0]	
Inflammation				1 [3.0]	
Duct, Dilatation			1 [3.0]		
Skin	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion	1	1			
Dermis, Thrombosis	1 [1.0]				
Dorsal, Inflammation, Acute				1 [2.0]	
Ear, Inflammation, Acute	1 [1.0]	2 [1.0]			
Ear, Inflammation, Chronic Active		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: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Ear, Ulcer, Multifocal		1 [2.0]			
Ear, Epidermis, Hyperplasia		1 [2.0]			
Epidermis, Hyperplasia		1 [2.0]		1 [2.0]	
Epidermis, Ulcer, Multifocal	1 [1.0]			1 [1.0]	
Foot, Inflammation, Chronic Active				4 [2.8]	
Foot, Ulcer, Focal				4 [3.0]	
Inguinal, Inflammation, Pyogranulomatous		1 [4.0]		2 [3.5]	
Inguinal, Inflammation, Acute				1 [3.0]	
Lateral, Inflammation, Acute		1 [3.0]			
Lateral, Ulcer, Focal		1 [4.0]			
Neck, Inflammation, Chronic Active	1 [3.0]				
Neck, Ulcer, Diffuse	1 [4.0]				
Other, Inflammation, Multifocal	1 [2.0]				
Subcutaneous Tissue, Abscess		1 [3.0]			
Tail, Inflammation, Chronic Active		1 [3.0]			
Tail, Ulcer, Multifocal		1 [2.0]			
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	
Osteosclerosis	(00)	(00)	1 [2.0]	1 [1.0]	
Tarsal, Tendon, Inflammation			1 [3.0]	. [0]	
Skeletal Muscle	(3)	(7)	(5)	(5)	
	(0)	(.,	(0)	(0)	
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	
Compression	(30)	1 [3.0]	(00)	(00)	
Hemorrhage		1 [3.0]			
Choroid Plexus, Hyperplasia		. [0.0]	1 [3.0]		
Peripheral Nerve	(3)	(5)	(5)	(5)	
Spinal Cord	(3)	(5)	(5)	(5)	
Gliosis	(0)	1 [3.0]	(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: CHRONIC

Experiment Number: 20725 - 03

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

2,3-Butanedione CAS Number: 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
RESPIRATORY SYSTEM					
Larynx	(50)	(50)	(50)	(50)	
Foreign Body	,	,	1	,	
Inflammation, Chronic Active	4 [1.0]	2 [1.0]	4 [1.0]	25 [1.3]	
Respiratory Epithelium, Hyperplasia				2 [1.5]	
Respiratory Epithelium, Metaplasia, Squamous				35 [2.3]	
Respiratory Epithelium, Regeneration				2 [1.0]	
Squamous Epithelium, Hyperplasia	1 [1.0]	1 [2.0]	6 [1.0]	48 [2.5]	
Squamous Epithelium, Ulcer, Focal				5 [1.2]	
Squamous Epithelium, Ulcer, Multifocal				1 [4.0]	
Lung	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	()	()	()	3 [2.3]	
Inflammation, Granulomatous	2 [1.0]	1 [1.0]	3 [1.0]	13 [1.0]	
Inflammation, Chronic Active	2 [1.0]	,	- 1 - 1		
Thrombus	1			1	
Alveolar Epithelium, Hyperplasia	1 [1.0]	1 [1.0]	1 [1.0]	3 [1.3]	
Alveolar Epithelium, Hyperplasia, Focal	1 [1.0]	1 [1.0]	1	1 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte	13 [1.1]	11 [1.0]	10 [1.0]	32 [1.3]	
Bronchiole, Epithelium, Hyperplasia			8 [1.0]	39 [1.4]	
Bronchus, Epithelium, Atrophy				7 [1.0]	
Bronchus, Epithelium, Hyperplasia				46 [1.4]	
Bronchus, Epithelium, Metaplasia, Squamous				1 [1.0]	
Bronchus, Epithelium, Necrosis				1 [3.0]	
Bronchus, Epithelium, Regeneration			1 [1.0]	2 [1.0]	
Bronchus, Submucosa, Inflammation, Suppurative				1 [3.0]	
Bronchus, Submucosa, Necrosis				1 [2.0]	
Interstitium, Fibrosis	1 [1.0]	1 [1.0]	1 [2.0]	9 [1.2]	
Peribronchial, Inflammation, Chronic Active	1 [1.0]	2 [1.0]		27 [1.5]	
Pleura, Fibrosis				1 [1.0]	
Nose	(50)	(50)	(50)	(50)	
Foreign Body	• •	, ,	, ,	1	
Inflammation, Suppurative	4 [1.8]	3 [1.0]	11 [1.5]	49 [3.9]	
Lamina Propria, Fibrosis	1 [1.0]	1 [1.0]	17 [1.0]	46 [1.4]	

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: CHRONIC Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

Experiment Number: 20725 - 03

2,3-Butanedione **CAS Number:** 431-03-8 Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Olfactory Epithelium, Accumulation, Hyaline Droplet	5 [1.8]	10 [1.6]	3 [1.3]	1 [1.0]	
Olfactory Epithelium, Atrophy	1 [1.0]	1 [1.0]	14 [1.4]	24 [1.9]	
Olfactory Epithelium, Metaplasia, Respiratory	1 [4.0]		18 [1.3]	46 [2.8]	
Olfactory Epithelium, Necrosis				4 [2.8]	
Respiratory Epithelium, Hyperplasia	1 [2.0]		2 [1.0]	44 [3.4]	
Respiratory Epithelium, Metaplasia, Squamous	1 [2.0]		1 [2.0]	44 [1.8]	
Respiratory Epithelium, Necrosis				3 [3.3]	
Turbinate, Hyperostosis				8 [1.0]	
Trachea	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	, ,	, ,	` ,	1 [2.0]	
Inflammation, Chronic Active				20 [2.0]	
Epithelium, Atrophy				4 [1.0]	
Epithelium, Hyperplasia				30 [1.5]	
Epithelium, Metaplasia, Squamous				3 [2.0]	
Epithelium, Necrosis				1 [2.0]	
Epithelium, Regeneration				3 [1.0]	
Epithelium, Ulcer				1 [4.0]	
Submucosa, Fibrosis				19 [1.8]	
Submucosa, Necrosis				1 [2.0]	
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	
Inflammation, Chronic Active		1 [4.0]	1 [4.0]		
Retinal Detachment			1 [3.0]		
Anterior Chamber, Inflammation, Suppurative	1 [1.0]		6 [2.5]	5 [1.8]	
Cornea, Inflammation, Chronic Active	2 [1.5]	6 [2.0]	23 [1.9]	31 [2.0]	
Cornea, Mineralization		1 [1.0]		2 [1.0]	
Cornea, Necrosis			1 [1.0]		
Cornea, Endothelium, Rupture		1 [2.0]		1 [1.0]	
Cornea, Epithelium, Hyperplasia		3 [2.0]	8 [1.4]	5 [1.4]	
Cornea, Epithelium, Ulcer		1 [2.0]	2 [2.5]	13 [1.8]	
Iris, Inflammation, Acute		1	5 [1.8]	4 [1.0]	
Lens, Cataract	1 [1.0]	1 [3.0]	6 [1.5]	9 [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)

Experiment Number: 20725 - 03

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 04/12/2016 AVERAGE SEVERITY GRADES[b]

Test Type: CHRONIC

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/Wistar Han

2,3-Butanedione **CAS Number:** 431-03-8

Time Report Requested: 16:27:55 First Dose M/F: 08/17/09 / 08/17/09

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm	
Retina, Degeneration	10 [1.7]	7 [1.9]	11 [1.8]	15 [1.6]	
Unilateral, Phthisis Bulbi		1 [2.0]		8 [3.1]	
Harderian Gland	(50)	(50)	(50)	(50)	
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	
Accumulation, Hyaline Droplet		1 [2.0]	2 [2.0]		
Calculus Gross Observation		1	1		
Calculus Micro Observation Only	27	29	35	27	
Infarct	1 [1.0]		2 [1.0]		
Nephropathy	12 [1.0]	11 [1.5]	10 [1.2]	11 [1.0]	
Thrombosis		1 [2.0]			
Cortex, Cyst	1 [1.0]		2 [2.0]		
Papilla, Necrosis		1 [1.0]			
Pelvis, Dilatation		2 [3.0]		2 [2.0]	
Pelvis, Inflammation	5 [1.0]	8 [1.8]	6 [1.5]	6 [1.2]	
Renal Tubule, Dilatation	• •	1 [3.0]			
Renal Tubule, Necrosis				1 [4.0]	
Urinary Bladder	(50)	(50)	(50)	(50)	
Calculus Gross Observation	, ,	1	• •	, ,	
Hemorrhage		1 [3.0]			
Hyperplasia		1 [2.0]			
Inflammation		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)