

Experiment Number: 20725 - 03
Test Type: CHRONIC
Route: RESPIRATORY EXPOSURE WHOLE BODY
Species/Strain: RATS/Wistar Han

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
2,3-Butanedione
CAS Number: 431-03-8

Date Report Requested: 04/12/2016
Time Report Requested: 16:27:54
First Dose M/F: 08/17/09 / 08/17/09
Lab: BNW

F1_RE

NTP Study Number: C20725
Lock Date: 10/11/2012
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: 01/15/2016

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
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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%)	2 (4%)	3 (6%)	1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	2 (4%)	6 (12%)	1 (2%)
Basophilic Focus	12 (24%)	16 (32%)	18 (36%)	4 (8%)
Clear Cell Focus	27 (54%)	21 (42%)	27 (54%)	12 (24%)
Degeneration, Cystic	1 (2%)		2 (4%)	
Eosinophilic Focus	1 (2%)	1 (2%)	3 (6%)	1 (2%)
Fatty Change, Focal	2 (4%)		1 (2%)	
Fatty Change, Diffuse	1 (2%)			
Hematopoietic Cell Proliferation	2 (4%)		1 (2%)	1 (2%)
Hepatodiaphragmatic Nodule	1 (2%)		3 (6%)	3 (6%)
Infiltration Cellular, Lymphocyte	1 (2%)			
Infiltration Cellular, Mixed Cell	5 (10%)		5 (10%)	4 (8%)
Mixed Cell Focus	2 (4%)	4 (8%)	1 (2%)	
Necrosis, Focal	1 (2%)	1 (2%)	1 (2%)	

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Pigmentation, Hemosiderin		1 (2%)	1 (2%)	
Tension Lipidosis			1 (2%)	
Bile Duct, Cyst		2 (4%)		1 (2%)
Bile Duct, Dilatation				1 (2%)
Bile Duct, Hyperplasia	5 (10%)	3 (6%)	4 (8%)	1 (2%)
Centrilobular, Necrosis	1 (2%)			
Serosa, Fibrosis		1 (2%)		
Mesentery	(5)	(4)	(3)	(2)
Fat, Necrosis	3 (60%)	2 (50%)	2 (67%)	2 (100%)
Oral Mucosa	(1)	(1)	(0)	(0)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	7 (14%)	2 (4%)	4 (8%)
Basophilic Focus		1 (2%)		
Inflammation				1 (2%)
Acinus, Hyperplasia	1 (2%)	1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Basophilic Focus				1 (2%)
Inflammation		1 (2%)	1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Inflammation	1 (2%)		4 (8%)	
Ulcer			1 (2%)	
Epithelium, Hyperplasia	1 (2%)	3 (6%)	4 (8%)	1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 (2%)			2 (4%)
Mineralization		1 (2%)	1 (2%)	
Aorta, Mineralization		1 (2%)		
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	31 (62%)	38 (76%)	28 (56%)	25 (50%)
Inflammation, Suppurative			1 (2%)	
Epicardium, Fibrosis, Focal				1 (2%)
Septum Interventricular, Necrosis, Acute	1 (2%)			

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Valve, Degeneration		1 (2%)		
Valve, Inflammation, Chronic		1 (2%)		

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Degeneration, Cystic	2 (4%)	2 (4%)	2 (4%)	2 (4%)
Hematopoietic Cell Proliferation			2 (4%)	
Infiltration Cellular, Lipocyte				1 (2%)
Bilateral, Necrosis, Multifocal				1 (2%)
Zona Fasciculata, Hyperplasia	2 (4%)			
Zona Fasciculata, Hyperplasia, Focal	4 (8%)	4 (8%)	3 (6%)	6 (12%)
Zona Fasciculata, Hyperplasia, Multifocal		2 (4%)	1 (2%)	
Zona Fasciculata, Hypertrophy	3 (6%)	2 (4%)		
Zona Fasciculata, Hypertrophy, Focal	12 (24%)	12 (24%)	11 (22%)	6 (12%)
Zona Fasciculata, Hypertrophy, Multifocal	14 (28%)	9 (18%)	18 (36%)	11 (22%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)	2 (4%)		1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	5 (10%)	1 (2%)	5 (10%)	2 (4%)
Parathyroid Gland	(49)	(46)	(49)	(47)
Hyperplasia, Focal	1 (2%)	1 (2%)	1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Fibrosis				1 (2%)
Pars Distalis, Hyperplasia	16 (32%)	18 (36%)	23 (46%)	10 (20%)
Pars Intermedia, Hyperplasia	1 (2%)	3 (6%)	1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	8 (16%)	13 (26%)	8 (16%)	2 (4%)
Follicular Cell, Hyperplasia	4 (8%)	2 (4%)	1 (2%)	1 (2%)
Follicular Cell, Hypertrophy	2 (4%)	2 (4%)	5 (10%)	5 (10%)

GENERAL BODY SYSTEM

None

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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 (2%)	1 (2%)		
Inflammation				1 (2%)
Preputial Gland	(50)	(50)	(50)	(50)
Inflammation		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Inflammation	21 (42%)	18 (36%)	18 (36%)	12 (24%)
Epithelium, Ventral, Hyperplasia	9 (18%)	9 (18%)	7 (14%)	10 (20%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)		
Inflammation		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Edema	4 (8%)	2 (4%)		
Germinal Epithelium, Degeneration	5 (10%)	10 (20%)	4 (8%)	4 (8%)
Interstitial Cell, Hyperplasia	4 (8%)	1 (2%)	3 (6%)	1 (2%)
Rete Testes, Inflammation, Granulomatous			1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Myeloid Cell, Hyperplasia	15 (30%)	12 (24%)	16 (32%)	32 (64%)
Lymph Node	(6)	(4)	(9)	(7)
Axillary, Infiltration Cellular, Plasma Cell	1 (17%)		1 (11%)	
Deep Cervical, Infiltration Cellular, Plasma Cell				1 (14%)
Iliac, Ectasia		1 (25%)		
Iliac, Infiltration Cellular, Plasma Cell				2 (29%)
Inguinal, Infiltration Cellular, Plasma Cell	1 (17%)			
Lumbar, Ectasia			1 (11%)	
Lumbar, Hyperplasia, Lymphoid	1 (17%)			
Lumbar, Infiltration Cellular, Plasma Cell	5 (83%)	3 (75%)	6 (67%)	3 (43%)
Pancreatic, Inflammation			1 (11%)	
Popliteal, Hyperplasia, Lymphoid	1 (17%)		2 (22%)	

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Popliteal, Infiltration Cellular, Plasma Cell			4 (44%)	2 (29%)
Popliteal, Inflammation, Chronic Active	1 (17%)			
Renal, Ectasia				1 (14%)
Renal, Infiltration Cellular, Plasma Cell	2 (33%)	1 (25%)	1 (11%)	4 (57%)
Lymph Node, Bronchial	(41)	(46)	(43)	(42)
Atrophy		1 (2%)	2 (5%)	1 (2%)
Inflammation, Suppurative				1 (2%)
Lymph Node, Mandibular	(48)	(44)	(49)	(48)
Ectasia				1 (2%)
Hemorrhage			1 (2%)	
Hyperplasia, Lymphoid				1 (2%)
Infiltration Cellular, Plasma Cell				5 (10%)
Lymph Node, Mediastinal	(42)	(47)	(47)	(47)
Atrophy	1 (2%)			1 (2%)
Ectasia	1 (2%)			
Infiltration Cellular, Plasma Cell			1 (2%)	
Inflammation				1 (2%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Ectasia		1 (2%)		
Hyperplasia, Lymphoid		1 (2%)		
Inflammation		1 (2%)		
Necrosis	1 (2%)			
Spleen	(50)	(50)	(50)	(50)
Congestion	1 (2%)			
Cyst			1 (2%)	
Hematopoietic Cell Proliferation	41 (82%)	41 (82%)	36 (72%)	37 (74%)
Inflammation			1 (2%)	
Pigmentation, Hemosiderin	18 (36%)	22 (44%)	20 (40%)	20 (40%)
Lymphoid Follicle, Atrophy	6 (12%)	5 (10%)	4 (8%)	12 (24%)
Thymus	(47)	(48)	(48)	(48)
Atrophy	46 (98%)	47 (98%)	45 (94%)	47 (98%)
Hemorrhage	1 (2%)			
Hyperplasia, Lymphoid	1 (2%)	2 (4%)	1 (2%)	

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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 (7%)	1 (5%)
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion				2 (4%)
Dorsal, Inflammation, Chronic Active			1 (2%)	
Dorsal, Ulcer, Focal			1 (2%)	
Epidermis, Cyst			1 (2%)	
Epidermis, Hyperplasia	2 (4%)			
Foot, Inflammation, Acute	3 (6%)			1 (2%)
Foot, Inflammation, Chronic Active	11 (22%)	7 (14%)	17 (34%)	23 (46%)
Foot, Ulcer	14 (28%)	7 (14%)	17 (34%)	22 (44%)
Inguinal, Inflammation, Granulomatous			1 (2%)	
Inguinal, Ulcer, Focal			1 (2%)	
Prepuce, Inflammation, Acute	1 (2%)			
Prepuce, Ulcer, Focal	1 (2%)			
Tail, Cyst Epithelial Inclusion			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis			1 (2%)	
Osteosclerosis				1 (2%)
Skeletal Muscle	(6)	(3)	(4)	(6)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Cerebrum, Gray Matter, Hemorrhage, Focal	1 (2%)			1 (2%)
Cranial Nerve, Glial Cell, Hyperplasia	1 (2%)	1 (2%)		
Peripheral Nerve	(6)	(1)	(3)	(6)
Axon, Degeneration				1 (17%)
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 (4%)			
Inflammation, Chronic Active	14 (28%)	7 (14%)	7 (14%)	33 (66%)
Respiratory Epithelium, Metaplasia, Squamous		1 (2%)		45 (90%)
Squamous Epithelium, Hyperplasia	2 (4%)	2 (4%)	8 (16%)	46 (92%)
Squamous Epithelium, Ulcer, Focal				15 (30%)
Squamous Epithelium, Ulcer, Multifocal				3 (6%)
Lung	(50)	(49)	(50)	(50)
Inflammation, Suppurative			1 (2%)	15 (30%)
Inflammation, Granulomatous	4 (8%)	3 (6%)	1 (2%)	4 (8%)
Inflammation, Chronic Active	1 (2%)	2 (4%)		
Metaplasia, Osseous		1 (2%)		
Thrombus	1 (2%)			
Alveolar Epithelium, Hyperplasia	1 (2%)	4 (8%)	2 (4%)	8 (16%)
Alveolar Epithelium, Hyperplasia, Focal	3 (6%)	3 (6%)	5 (10%)	1 (2%)
Alveolus, Edema				1 (2%)
Alveolus, Infiltration Cellular, Histiocyte	10 (20%)	14 (29%)	16 (32%)	34 (68%)
Bronchiole, Epithelium, Hyperplasia				33 (66%)
Bronchus, Epithelium, Atrophy			1 (2%)	23 (46%)
Bronchus, Epithelium, Hyperplasia			2 (4%)	47 (94%)
Bronchus, Epithelium, Metaplasia, Squamous				2 (4%)
Bronchus, Epithelium, Regeneration			4 (8%)	9 (18%)
Bronchus, Submucosa, Fibrosis				5 (10%)
Interstitial, Fibrosis		1 (2%)	1 (2%)	11 (22%)
Peribronchial, Inflammation, Chronic Active				13 (26%)
Pleura, Fibrosis				2 (4%)
Pleura, Fibrosis, Focal	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Foreign Body	1 (2%)	1 (2%)	2 (4%)	
Inflammation, Suppurative	3 (6%)	4 (8%)	35 (70%)	50 (100%)
Inflammation, Chronic Active	1 (2%)		2 (4%)	
Polyp, Inflammatory	1 (2%)			

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Wistar Han RATS MALE	Control	12.5 ppm	25 ppm	50 ppm
Lamina Propria, Fibrosis			28 (56%)	38 (76%)
Nerve, Hyperplasia		1 (2%)		
Olfactory Epithelium, Accumulation, Hyaline Droplet	10 (20%)	6 (12%)	4 (8%)	4 (8%)
Olfactory Epithelium, Atrophy		5 (10%)	27 (54%)	22 (44%)
Olfactory Epithelium, Metaplasia, Respiratory	1 (2%)	3 (6%)	6 (12%)	50 (100%)
Olfactory Epithelium, Necrosis				6 (12%)
Respiratory Epithelium, Hyperplasia		2 (4%)	5 (10%)	50 (100%)
Respiratory Epithelium, Metaplasia, Squamous			5 (10%)	34 (68%)
Respiratory Epithelium, Necrosis				2 (4%)
Turbinate, Atrophy			1 (2%)	1 (2%)
Turbinate, Hyperostosis				10 (20%)
Pleura	(0)	(1)	(0)	(0)
Trachea	(50)	(50)	(50)	(50)
Inflammation, Suppurative				1 (2%)
Inflammation, Chronic Active			1 (2%)	8 (16%)
Epithelium, Atrophy				7 (14%)
Epithelium, Hyperplasia			1 (2%)	32 (64%)
Epithelium, Metaplasia, Squamous				12 (24%)
Epithelium, Necrosis				6 (12%)
Epithelium, Regeneration			5 (10%)	12 (24%)
Submucosa, Fibrosis				27 (54%)

SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(1)	(0)
Eye	(50)	(50)	(49)	(49)
Anterior Chamber, Inflammation, Suppurative		1 (2%)	6 (12%)	3 (6%)
Bilateral, Phthisis Bulbi			1 (2%)	
Cornea, Inflammation, Chronic Active	1 (2%)	6 (12%)	16 (33%)	28 (57%)
Cornea, Mineralization	1 (2%)	4 (8%)	1 (2%)	
Cornea, Necrosis				2 (4%)
Cornea, Epithelium, Hyperplasia		2 (4%)	3 (6%)	6 (12%)
Cornea, Epithelium, Ulcer		1 (2%)	4 (8%)	6 (12%)
Iris, Inflammation, Acute		1 (2%)	3 (6%)	1 (2%)

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Lens, Cataract	1 (2%)	5 (10%)	6 (12%)	3 (6%)
Retina, Degeneration	8 (16%)	11 (22%)	11 (22%)	6 (12%)
Unilateral, Inflammation, Pyogranulomatous				1 (2%)
Unilateral, Phthisis Bulbi		1 (2%)	3 (6%)	1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)		1 (2%)	3 (6%)
Metaplasia	1 (2%)			
Lacrimal Gland	(0)	(0)	(0)	(1)
Metaplasia				1 (100%)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Calculus Micro Observation Only	4 (8%)	10 (20%)	2 (4%)	7 (14%)
Fibrosis, Focal			1 (2%)	
Infarct	1 (2%)	1 (2%)	1 (2%)	
Infiltration Cellular, Lymphoid			1 (2%)	
Nephropathy	33 (66%)	40 (80%)	41 (82%)	30 (60%)
Thrombosis			1 (2%)	
Cortex, Cyst			2 (4%)	1 (2%)
Papilla, Necrosis	1 (2%)			
Pelvis, Dilatation	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Pelvis, Inflammation	10 (20%)	11 (22%)	8 (16%)	14 (28%)
Pelvis, Transitional Epithelium, Hyperplasia	1 (2%)	1 (2%)		
Renal Tubule, Dilatation	1 (2%)			
Ureter	(0)	(1)	(0)	(0)
Inflammation		1 (100%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Calculus Gross Observation		1 (2%)		
Hemorrhage			1 (2%)	
Inflammation		1 (2%)		

*** END OF MALE ***

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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 (2%)			
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 (2%)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Basophilic Focus	34 (68%)	30 (60%)	29 (58%)	26 (52%)
Clear Cell Focus	6 (12%)	8 (16%)	5 (10%)	2 (4%)
Eosinophilic Focus	3 (6%)	5 (10%)	7 (14%)	4 (8%)
Fatty Change, Diffuse	1 (2%)	1 (2%)	2 (4%)	
Hematopoietic Cell Proliferation	2 (4%)	2 (4%)	3 (6%)	1 (2%)
Hepatodiaphragmatic Nodule	3 (6%)			2 (4%)
Infiltration Cellular, Lymphoid		1 (2%)		
Infiltration Cellular, Mixed Cell	6 (12%)	6 (12%)	3 (6%)	3 (6%)
Mixed Cell Focus		2 (4%)		1 (2%)
Necrosis, Multifocal		1 (2%)	2 (4%)	
Pigmentation, Hemosiderin	1 (2%)	1 (2%)		
Bile Duct, Cyst	2 (4%)	1 (2%)		1 (2%)

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

Experiment Number: 20725 - 03
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: RATS/Wistar Han

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
 2,3-Butanedione
 CAS Number: 431-03-8

Date Report Requested: 04/12/2016
 Time Report Requested: 16:27:54
 First Dose M/F: 08/17/09 / 08/17/09
 Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Bile Duct, Dilatation		1 (2%)		
Bile Duct, Hyperplasia	8 (16%)	12 (24%)	15 (30%)	10 (20%)
Centrilobular, Degeneration		1 (2%)		
Kupffer Cell, Hyperplasia			1 (2%)	
Oval Cell, Hyperplasia		1 (2%)		
Mesentery	(8)	(10)	(4)	(4)
Fat, Necrosis	8 (100%)	8 (80%)	4 (100%)	3 (75%)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Basophilic Focus		2 (4%)	1 (2%)	2 (4%)
Inflammation			2 (4%)	
Salivary Glands	(50)	(50)	(50)	(50)
Inflammation		1 (2%)	1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Inflammation	3 (6%)	5 (10%)	3 (6%)	1 (2%)
Mineralization			1 (2%)	
Ulcer	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Epithelium, Erosion		1 (2%)		
Epithelium, Hyperplasia	3 (6%)	6 (12%)	3 (6%)	2 (4%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Mineralization			1 (2%)	
Epithelium, Necrosis				1 (2%)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation			1 (2%)	1 (2%)
Media, Hypertrophy			1 (2%)	
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	21 (42%)	28 (56%)	24 (48%)	27 (54%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Amyloid Deposition			1 (2%)	

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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Angiectasis		2 (4%)	1 (2%)	
Degeneration, Cystic	12 (24%)	7 (14%)	12 (24%)	12 (24%)
Hematopoietic Cell Proliferation	1 (2%)	2 (4%)	3 (6%)	1 (2%)
Zona Fasciculata, Hyperplasia, Focal	3 (6%)	2 (4%)	7 (14%)	7 (14%)
Zona Fasciculata, Hyperplasia, Multifocal	4 (8%)	1 (2%)		3 (6%)
Zona Fasciculata, Hypertrophy	1 (2%)			
Zona Fasciculata, Hypertrophy, Focal	17 (34%)	9 (18%)	13 (26%)	15 (30%)
Zona Fasciculata, Hypertrophy, Multifocal	5 (10%)	3 (6%)	2 (4%)	3 (6%)
Adrenal Medulla	(50)	(50)	(49)	(50)
Hyperplasia	1 (2%)			1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	4 (8%)	2 (4%)	1 (2%)	
Parathyroid Gland	(46)	(44)	(46)	(42)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Angiectasis, Focal				1 (2%)
Pars Distalis, Hyperplasia	18 (36%)	16 (32%)	24 (48%)	18 (36%)
Pars Intermedia, Hyperplasia			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	20 (40%)	27 (54%)	22 (44%)	16 (32%)
Follicular Cell, Hyperplasia	2 (4%)	4 (8%)	1 (2%)	2 (4%)
Follicular Cell, Hypertrophy			2 (4%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(49)	(50)	(50)	(49)
Ectasia	1 (2%)	2 (4%)	2 (4%)	
Inflammation		2 (4%)		
Ovary	(50)	(50)	(50)	(50)
Atrophy	27 (54%)	22 (44%)	25 (50%)	27 (54%)
Cyst	18 (36%)	16 (32%)	20 (40%)	23 (46%)
Germinal Epithelium, Hyperplasia				1 (2%)

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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Thecal Cell, Hyperplasia	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Adenomyosis		1 (2%)		
Adenomyosis, Focal	2 (4%)			
Angiectasis, Focal				1 (2%)
Fibrosis, Focal				1 (2%)
Inflammation, Chronic Active			1 (2%)	
Cervix, Cyst, Squamous		1 (2%)		
Cervix, Hyperplasia, Squamous	7 (14%)	5 (10%)	8 (16%)	10 (20%)
Cervix, Hypertrophy, Stromal			2 (4%)	1 (2%)
Endometrial Glands, Hyperplasia, Atypical		1 (2%)		
Endometrial Glands, Hyperplasia, Focal				1 (2%)
Endometrium, Decidual Reaction, Focal			1 (2%)	
Endometrium, Hyperplasia, Cystic	24 (48%)	16 (32%)	17 (34%)	25 (50%)
Endometrium, Hyperplasia, Focal			3 (6%)	1 (2%)
Endometrium, Metaplasia, Squamous	5 (10%)	1 (2%)	7 (14%)	6 (12%)
Serosa, Cyst Multilocular	1 (2%)			
Vagina	(0)	(1)	(2)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Myeloid Cell, Hyperplasia	12 (24%)	19 (38%)	20 (40%)	36 (72%)
Lymph Node	(1)	(3)	(2)	(5)
Axillary, Hyperplasia, Lymphoid				1 (20%)
Deep Cervical, Infiltration Cellular, Plasma Cell				2 (40%)
Iliac, Infiltration Cellular, Plasma Cell			1 (50%)	
Lumbar, Ectasia	1 (100%)			
Lumbar, Infiltration Cellular, Plasma Cell			1 (50%)	1 (20%)
Popliteal, Inflammation		1 (33%)		
Renal, Infiltration Cellular, Plasma Cell				1 (20%)
Lymph Node, Bronchial	(43)	(44)	(43)	(42)
Lymph Node, Mandibular	(46)	(48)	(45)	(48)
Ectasia			1 (2%)	1 (2%)
Hyperplasia, Atypical		1 (2%)		

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 2,3-Butanedione
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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Infiltration Cellular, Plasma Cell		1 (2%)		2 (4%)
Lymph Node, Mediastinal	(44)	(47)	(48)	(50)
Atrophy				1 (2%)
Hyperplasia, Lymphoid				1 (2%)
Infiltration Cellular, Plasma Cell		1 (2%)		1 (2%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Atrophy		2 (4%)	2 (4%)	5 (10%)
Fibrosis, Focal	1 (2%)			
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	1 (2%)	
Infiltration Cellular, Plasma Cell			1 (2%)	
Inflammation	1 (2%)			
Spleen	(50)	(50)	(50)	(50)
Hematopoietic Cell Proliferation	37 (74%)	40 (80%)	38 (76%)	39 (78%)
Pigmentation, Hemosiderin	42 (84%)	39 (78%)	38 (76%)	39 (78%)
Capsule, Thrombosis		1 (2%)		
Lymphoid Follicle, Atrophy	12 (24%)	6 (12%)	5 (10%)	7 (14%)
Lymphoid Follicle, Hyperplasia		1 (2%)		
Thymus	(49)	(50)	(49)	(50)
Atrophy	45 (92%)	42 (84%)	45 (92%)	49 (98%)
Cyst			1 (2%)	
Hyperplasia, Lymphoid		2 (4%)		

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Galactocele	4 (8%)	4 (8%)	2 (4%)	1 (2%)
Hyperplasia	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Inflammation				1 (2%)
Duct, Dilatation			1 (2%)	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	1 (2%)	1 (2%)		
Dermis, Thrombosis	1 (2%)			
Dorsal, Inflammation, Acute				1 (2%)
Ear, Inflammation, Acute	1 (2%)	2 (4%)		
Ear, Inflammation, Chronic Active		1 (2%)		

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Experiment Number: 20725 - 03
 Test Type: CHRONIC
 Route: RESPIRATORY EXPOSURE WHOLE BODY
 Species/Strain: RATS/Wistar Han

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMICAL SITE(a)
 2,3-Butanedione
 CAS Number: 431-03-8

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 Lab: BNW

Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Ear, Ulcer, Multifocal		1 (2%)		
Ear, Epidermis, Hyperplasia		1 (2%)		
Epidermis, Hyperplasia		1 (2%)		1 (2%)
Epidermis, Ulcer, Multifocal	1 (2%)			1 (2%)
Foot, Inflammation, Chronic Active				4 (8%)
Foot, Ulcer, Focal				4 (8%)
Inguinal, Inflammation, Pyogranulomatous		1 (2%)		2 (4%)
Inguinal, Inflammation, Acute				1 (2%)
Lateral, Inflammation, Acute		1 (2%)		
Lateral, Ulcer, Focal		1 (2%)		
Neck, Inflammation, Chronic Active	1 (2%)			
Neck, Ulcer, Diffuse	1 (2%)			
Other, Inflammation, Multifocal	1 (2%)			
Subcutaneous Tissue, Abscess		1 (2%)		
Tail, Inflammation, Chronic Active		1 (2%)		
Tail, Ulcer, Multifocal		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosclerosis			1 (2%)	1 (2%)
Tarsal, Tendon, Inflammation			1 (2%)	
Skeletal Muscle	(3)	(7)	(5)	(5)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Compression		1 (2%)		
Hemorrhage		1 (2%)		
Choroid Plexus, Hyperplasia			1 (2%)	
Peripheral Nerve	(3)	(5)	(5)	(5)
Spinal Cord	(3)	(5)	(5)	(5)
Gliosis		1 (20%)		

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Experiment Number: 20725 - 03
 Test Type: CHRONIC
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P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
RESPIRATORY SYSTEM				
Larynx	(50)	(50)	(50)	(50)
Foreign Body			1 (2%)	
Inflammation, Chronic Active	4 (8%)	2 (4%)	4 (8%)	25 (50%)
Respiratory Epithelium, Hyperplasia				2 (4%)
Respiratory Epithelium, Metaplasia, Squamous				35 (70%)
Respiratory Epithelium, Regeneration				2 (4%)
Squamous Epithelium, Hyperplasia	1 (2%)	1 (2%)	6 (12%)	48 (96%)
Squamous Epithelium, Ulcer, Focal				5 (10%)
Squamous Epithelium, Ulcer, Multifocal				1 (2%)
Lung	(50)	(50)	(50)	(50)
Inflammation, Suppurative				3 (6%)
Inflammation, Granulomatous	2 (4%)	1 (2%)	3 (6%)	13 (26%)
Inflammation, Chronic Active	2 (4%)			
Thrombus				1 (2%)
Alveolar Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Alveolar Epithelium, Hyperplasia, Focal	1 (2%)	1 (2%)		1 (2%)
Alveolus, Infiltration Cellular, Histiocyte	13 (26%)	11 (22%)	10 (20%)	32 (64%)
Bronchiole, Epithelium, Hyperplasia			8 (16%)	39 (78%)
Bronchus, Epithelium, Atrophy				7 (14%)
Bronchus, Epithelium, Hyperplasia				46 (92%)
Bronchus, Epithelium, Metaplasia, Squamous				1 (2%)
Bronchus, Epithelium, Necrosis				1 (2%)
Bronchus, Epithelium, Regeneration			1 (2%)	2 (4%)
Bronchus, Submucosa, Inflammation, Suppurative				1 (2%)
Bronchus, Submucosa, Necrosis				1 (2%)
Interstitialium, Fibrosis	1 (2%)	1 (2%)	1 (2%)	9 (18%)
Peribronchial, Inflammation, Chronic Active	1 (2%)	2 (4%)		27 (54%)
Pleura, Fibrosis				1 (2%)
Nose	(50)	(50)	(50)	(50)
Foreign Body				1 (2%)
Inflammation, Suppurative	4 (8%)	3 (6%)	11 (22%)	49 (98%)
Lamina Propria, Fibrosis	1 (2%)	1 (2%)	17 (34%)	46 (92%)

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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Olfactory Epithelium, Accumulation, Hyaline Droplet	5 (10%)	10 (20%)	3 (6%)	1 (2%)
Olfactory Epithelium, Atrophy	1 (2%)	1 (2%)	14 (28%)	24 (48%)
Olfactory Epithelium, Metaplasia, Respiratory	1 (2%)		18 (36%)	46 (92%)
Olfactory Epithelium, Necrosis				4 (8%)
Respiratory Epithelium, Hyperplasia	1 (2%)		2 (4%)	44 (88%)
Respiratory Epithelium, Metaplasia, Squamous	1 (2%)		1 (2%)	44 (88%)
Respiratory Epithelium, Necrosis				3 (6%)
Turbinates, Hyperostosis				8 (16%)
Trachea	(50)	(50)	(50)	(50)
Inflammation, Suppurative				1 (2%)
Inflammation, Chronic Active				20 (40%)
Epithelium, Atrophy				4 (8%)
Epithelium, Hyperplasia				30 (60%)
Epithelium, Metaplasia, Squamous				3 (6%)
Epithelium, Necrosis				1 (2%)
Epithelium, Regeneration				3 (6%)
Epithelium, Ulcer				1 (2%)
Submucosa, Fibrosis				19 (38%)
Submucosa, Necrosis				1 (2%)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Inflammation, Chronic Active		1 (2%)	1 (2%)	
Retinal Detachment			1 (2%)	
Anterior Chamber, Inflammation, Suppurative	1 (2%)		6 (12%)	5 (10%)
Cornea, Inflammation, Chronic Active	2 (4%)	6 (12%)	23 (46%)	31 (62%)
Cornea, Mineralization		1 (2%)		2 (4%)
Cornea, Necrosis			1 (2%)	
Cornea, Endothelium, Rupture		1 (2%)		1 (2%)
Cornea, Epithelium, Hyperplasia		3 (6%)	8 (16%)	5 (10%)
Cornea, Epithelium, Ulcer		1 (2%)	2 (4%)	13 (26%)
Iris, Inflammation, Acute			5 (10%)	4 (8%)
Lens, Cataract	1 (2%)	1 (2%)	6 (12%)	9 (18%)

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Wistar Han RATS FEMALE	Control	12.5 ppm	25 ppm	50 ppm
Retina, Degeneration	10 (20%)	7 (14%)	11 (22%)	15 (30%)
Unilateral, Phthisis Bulbi		1 (2%)		8 (16%)
Harderian Gland	(50)	(50)	(50)	(50)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Accumulation, Hyaline Droplet		1 (2%)	2 (4%)	
Calculus Gross Observation		1 (2%)	1 (2%)	
Calculus Micro Observation Only	27 (54%)	29 (58%)	35 (70%)	27 (54%)
Infarct	1 (2%)		2 (4%)	
Nephropathy	12 (24%)	11 (22%)	10 (20%)	11 (22%)
Thrombosis		1 (2%)		
Cortex, Cyst	1 (2%)		2 (4%)	
Papilla, Necrosis		1 (2%)		
Pelvis, Dilatation		2 (4%)		2 (4%)
Pelvis, Inflammation	5 (10%)	8 (16%)	6 (12%)	6 (12%)
Renal Tubule, Dilatation		1 (2%)		
Renal Tubule, Necrosis				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
Calculus Gross Observation		1 (2%)		
Hemorrhage		1 (2%)		
Hyperplasia		1 (2%)		
Inflammation		1 (2%)		

*** END OF REPORT ***

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