

Experiment Number: 20725 - 01
Test Type: 90-DAY
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: 01/12/2017
Time Report Requested: 15:54:18
First Dose M/F: 07/28/08 / 07/29/08
Lab: BNW

F1_Rev.2_RE

NTP Study Number: C20725
Lock Date: 02/27/2009
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: NONE

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS MALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
----------------------	---------	----------	----------	--------	--------	---------

Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Natural Death						2
Survivors						
Terminal Sacrifice	10	10	10	10	10	8
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(8)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(8)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(8)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(9)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(8)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(8)
Liver	(10)	(0)	(1)	(2)	(0)	(10)
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy	3 (30%)					
Basophilic Focus						1 (10%)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(8)

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
Cardiomyopathy	1 (10%)					1 (10%)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
----------------	------	-----	-----	-----	-----	------

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS MALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(7)
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(10)	(0)	(0)	(0)	(0)	(10)
Preputial Gland	(10)	(0)	(0)	(0)	(0)	(9)
Inflammation, Chronic Active	3 (30%)					3 (33%)
Prostate	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	2 (20%)					6 (60%)
Seminal Vesicle	(10)	(0)	(0)	(0)	(0)	(10)
Testes	(10)	(0)	(0)	(0)	(0)	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Bronchial	(8)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(1)	(10)
Atrophy, Lymphoid						1 (10%)
Hemorrhage					1 (100%)	
Lymph Node, Mediastinal	(10)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy, Lymphoid						1 (10%)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy, Lymphoid						1 (10%)
Thymus	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy, Lymphoid						1 (10%)

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS MALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
INTEGUMENTARY SYSTEM						
Mammary Gland	(2)	(0)	(0)	(0)	(0)	(3)
Skin	(10)	(0)	(0)	(0)	(1)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active						2 (20%)
Epithelium, Necrosis						2 (20%)
Respiratory Epithelium, Hyperplasia					3 (30%)	1 (10%)
Respiratory Epithelium, Metaplasia, Squamous					8 (80%)	10 (100%)
Squamous Epithelium, Hyperplasia						5 (50%)
Squamous Epithelium, Hyperplasia, Atypical						2 (20%)
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Congestion						2 (20%)
Infiltration Cellular, Histiocyte	1 (10%)		1 (10%)			7 (70%)
Inflammation, Eosinophil	2 (20%)		3 (30%)	1 (10%)		6 (60%)
Inflammation, Acute						1 (10%)
Metaplasia, Osseous	1 (10%)					1 (10%)
Bronchiole, Epithelium, Hyperplasia						5 (50%)
Bronchus, Inflammation, Chronic						1 (10%)
Bronchus, Epithelium, Hyperplasia						4 (40%)
Bronchus, Epithelium, Hyperplasia, Atypical						3 (30%)

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS MALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Bronchus, Epithelium, Necrosis						4 (40%)
Bronchus, Epithelium, Regeneration						5 (50%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative				1 (10%)	10 (100%)	10 (100%)
Lymphoid Tissue, Hyperplasia				3 (30%)	9 (90%)	6 (60%)
Olfactory Epithelium, Atrophy						1 (10%)
Olfactory Epithelium, Degeneration				3 (30%)	9 (90%)	
Olfactory Epithelium, Metaplasia, Respiratory				2 (20%)	7 (70%)	9 (90%)
Olfactory Epithelium, Necrosis						9 (90%)
Respiratory Epithelium, Hyperplasia				2 (20%)	10 (100%)	9 (90%)
Respiratory Epithelium, Metaplasia, Squamous				8 (80%)	10 (100%)	10 (100%)
Respiratory Epithelium, Necrosis					2 (20%)	10 (100%)
Respiratory Epithelium, Regeneration					4 (40%)	10 (100%)
Septum, Necrosis						1 (10%)
Turbinate, Atrophy					3 (30%)	10 (100%)
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active						2 (20%)
Epithelium, Hyperplasia					2 (20%)	2 (20%)
Epithelium, Metaplasia, Squamous						4 (40%)
Epithelium, Necrosis						10 (100%)
Epithelium, Regeneration						9 (90%)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Cornea, Inflammation, Acute						2 (20%)
Cornea, Mineralization					1 (10%)	
Cornea, Neovascularization						1 (10%)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(2)	(0)	(10)
Cyst				1 (50%)		
Nephropathy				1 (50%)		1 (10%)

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

Experiment Number: 20725 - 01
Test Type: 90-DAY
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: 01/12/2017
Time Report Requested: 15:54:18
First Dose M/F: 07/28/08 / 07/29/08
Lab: BNW

Wistar Han RATS MALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Pelvis, Dilatation				1 (50%)		
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

*** END OF MALE ***

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS FEMALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(0)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(0)	(10)
Liver	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 (10%)					
Pancreas	(10)	(0)	(0)	(0)	(0)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(0)	(10)
Stomach, Glandular	(10)	(0)	(0)	(0)	(0)	(10)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(0)	(10)
Heart	(10)	(0)	(0)	(0)	(0)	(10)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(0)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(0)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(0)	(10)
Parathyroid Gland	(10)	(0)	(0)	(0)	(0)	(7)

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS FEMALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Pituitary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Pars Distalis, Cyst	1 (10%)					1 (10%)
Thyroid Gland	(10)	(0)	(0)	(0)	(0)	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(0)	(0)	(1)	(10)
Inflammation, Chronic Active	3 (30%)				1 (100%)	2 (20%)
Ovary	(10)	(0)	(0)	(0)	(0)	(10)
Cyst						1 (10%)
Uterus	(10)	(0)	(0)	(0)	(0)	(10)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(0)	(10)
Lymph Node	(0)	(0)	(0)	(0)	(0)	(1)
Deep Cervical, Hyperplasia, Lymphoid						1 (100%)
Lymph Node, Bronchial	(10)	(0)	(0)	(0)	(0)	(8)
Lymph Node, Mandibular	(10)	(0)	(0)	(1)	(0)	(9)
Lymph Node, Mediastinal	(10)	(0)	(0)	(0)	(0)	(9)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(0)	(10)
Spleen	(10)	(0)	(0)	(0)	(0)	(10)
Atrophy, Lymphoid						2 (20%)
Thymus	(10)	(0)	(0)	(1)	(0)	(9)
Atrophy, Lymphoid						1 (11%)
Hemorrhage				1 (100%)		

INTEGUMENTARY SYSTEM

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS FEMALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Mammary Gland	(10)	(0)	(0)	(0)	(0)	(10)
Skin	(10)	(0)	(0)	(0)	(0)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(0)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(0)	(10)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active						5 (50%)
Epithelium, Necrosis						6 (60%)
Respiratory Epithelium, Hyperplasia						2 (20%)
Respiratory Epithelium, Metaplasia, Squamous					8 (80%)	10 (100%)
Respiratory Epithelium, Regeneration						1 (10%)
Squamous Epithelium, Hyperplasia						9 (90%)
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Foreign Body						2 (20%)
Infiltration Cellular, Histiocyte						3 (30%)
Inflammation, Eosinophil	4 (40%)	3 (30%)		1 (10%)	1 (10%)	7 (70%)
Inflammation, Acute						1 (10%)
Alveolar Epithelium, Inflammation, Focal, Acute		1 (10%)				
Bronchiole, Epithelium, Hyperplasia						8 (80%)
Bronchus, Epithelium, Hyperplasia						5 (50%)
Bronchus, Epithelium, Hyperplasia, Atypical						4 (40%)
Bronchus, Epithelium, Metaplasia, Squamous						2 (20%)
Bronchus, Epithelium, Necrosis						2 (20%)
Bronchus, Epithelium, Regeneration						4 (40%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative					10 (100%)	10 (100%)

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

Experiment Number: 20725 - 01
 Test Type: 90-DAY
 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: 01/12/2017
 Time Report Requested: 15:54:18
 First Dose M/F: 07/28/08 / 07/29/08
 Lab: BNW

Wistar Han RATS FEMALE	CONTROL	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
Lymphoid Tissue, Hyperplasia		1 (10%)		2 (20%)	8 (80%)	6 (60%)
Olfactory Epithelium, Atrophy						4 (40%)
Olfactory Epithelium, Degeneration				4 (40%)	9 (90%)	4 (40%)
Olfactory Epithelium, Metaplasia, Respiratory					10 (100%)	10 (100%)
Olfactory Epithelium, Necrosis						4 (40%)
Respiratory Epithelium, Hyperplasia					10 (100%)	10 (100%)
Respiratory Epithelium, Metaplasia, Squamous				5 (50%)	10 (100%)	10 (100%)
Respiratory Epithelium, Necrosis					3 (30%)	10 (100%)
Respiratory Epithelium, Regeneration					3 (30%)	9 (90%)
Septum, Necrosis						2 (20%)
Turbinate, Atrophy					4 (40%)	10 (100%)
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active						1 (10%)
Epithelium, Hyperplasia						9 (90%)
Epithelium, Necrosis					1 (10%)	10 (100%)
Epithelium, Regeneration					2 (20%)	10 (100%)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Cornea, Inflammation, Acute					1 (10%)	3 (30%)
Cornea, Neovascularization						1 (10%)
Cornea, Epithelium, Vacuolation						1 (10%)
Harderian Gland	(10)	(0)	(0)	(0)	(0)	(10)
Inflammation, Chronic Active	1 (10%)					
URINARY SYSTEM						
Kidney	(10)	(0)	(0)	(0)	(0)	(10)
Nephropathy	1 (10%)					
Urinary Bladder	(10)	(0)	(0)	(0)	(0)	(10)

*** END OF REPORT ***

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