

Experiment Number: 20727 - 01

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Date Report Requested: 10/16/2015

Test Type: 90-DAY

ortho-Phthalaldehyde

Time Report Requested: 12:31:33

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/20/09

Species/Strain: RATS/HSD

Lab: BNW

F1_Rev.1_HSD

NTP Study Number: C20727
Lock Date: 08/21/2009
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: 11/01/2011

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Species/Strain: RATS/HSD

Lab: BNW

Harlan Sprague Dawley RATS MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					3	2
Natural Death					4	8
Survivors						
Terminal Sacrifice	10	10	10	10	3	
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(9)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(10)	(10)	(8)
Intestine Large, Colon	(10)	(0)	(0)	(10)	(10)	(8)
Intestine Large, Rectum	(10)	(0)	(0)	(10)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(10)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(10)	(10)	(8)
Diverticulum						1 [1.0]
Intestine Small, Jejunum	(10)	(0)	(0)	(10)	(10)	(7)
Liver	(10)	(1)	(0)	(10)	(10)	(10)
Fibrosis					1 [2.0]	
Hepatodiaphragmatic Nodule		1 [1.0]				
Hepatocyte, Degeneration, Focal	1 [2.0]					
Pancreas	(10)	(0)	(0)	(10)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(10)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(10)	(10)	(10)
Cyst, Squamous						1 [2.0]
Hyperplasia, Squamous				1 [2.0]		
Stomach, Glandular	(10)	(0)	(0)	(10)	(10)	(10)

CARDIOVASCULAR SYSTEM

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

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)

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Harlan Sprague Dawley RATS MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Cardiomyopathy Congestion	1 [1.0]		1 [1.0]	1 [1.0]		
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(10)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(10)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(10)	(10)	(10)
Parathyroid Gland	(10)	(0)	(0)	(8)	(10)	(9)
Pituitary Gland	(10)	(0)	(0)	(10)	(10)	(10)
Thyroid Gland	(10)	(0)	(0)	(10)	(10)	(10)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(10)	(10)	(10)	(10)	(10)
Hypospermia			1 [4.0]		1 [3.0]	
Infiltration Cellular, Mononuclear Cell						1 [1.0]
Duct, Exfoliated Germ Cell Epithelium, Apoptosis			1 [2.0]	1 [2.0]	5 [1.6] 3 [1.3]	4 [2.5] 5 [1.2]
Penis	(0)	(0)	(0)	(0)	(1)	(0)
Inflammation, Suppurative					1 [3.0]	
Preputial Gland	(10)	(0)	(0)	(9)	(10)	(10)
Inflammation, Chronic Active	1 [2.0]				1 [1.0]	
Prostate	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active				1 [1.0]		
Seminal Vesicle	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy					1 [1.0]	
Testes	(10)	(10)	(10)	(10)	(10)	(10)
Exfoliated Germ Cell, Focal Immature					1 [2.0] 4	2 [2.0] 10

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Species/Strain: RATS/HSD

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Harlan Sprague Dawley RATS MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Elongated Spermatid, Degeneration					4 [1.3]	
Germinal Epithelium, Apoptosis					4 [1.3]	6 [1.0]
Germinal Epithelium, Atrophy, Multifocal			1 [4.0]			
Germinal Epithelium, Degeneration, Focal	1 [1.0]					
Germinal Epithelium, Degeneration, Multifocal				1 [2.0]		
Interstitial Cell, Atrophy					7 [2.9]	10 [2.9]
Round Spermatid, Degeneration						2 [2.5]
Seminiferous Tubule, Vacuolation					3 [1.3]	
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(0)	(0)	(10)	(10)	(10)
Lymph Node	(0)	(1)	(0)	(0)	(0)	(0)
Pigmentation		1 [1.0]				
Lymph Node, Bronchial	(7)	(0)	(0)	(6)	(7)	(6)
Lymph Node, Mandibular	(9)	(0)	(0)	(10)	(10)	(10)
Lymph Node, Mediastinal	(8)	(0)	(0)	(4)	(9)	(7)
Lymph Node, Mesenteric	(10)	(0)	(0)	(10)	(10)	(10)
Spleen	(10)	(9)	(10)	(10)	(10)	(10)
Atrophy, Lymphoid					6 [1.5]	10 [2.7]
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy, Lymphoid					8 [1.5]	7 [2.7]
INTEGUMENTARY SYSTEM						
Mammary Gland	(6)	(0)	(0)	(7)	(6)	(2)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous					1 [1.0]	1 [1.0]
Inflammation, Suppurative					1 [3.0]	
Adnexa, Degeneration					4 [1.3]	10 [1.2]
Epithelium, Hair Follicle, Parakeratosis		7 [1.0]	4 [1.0]	7 [1.0]	3 [1.3]	10 [1.7]
MUSCULOSKELETAL SYSTEM						

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Species/Strain: RATS/HSD

Lab: BNW

Harlan Sprague Dawley RATS MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Bone	(10)	(0)	(0)	(10)	(10)	(10)
Maxilla, Inflammation, Chronic Active						1 [3.0]
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(10)	(10)	(10)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	1 [1.0]	2 [1.0]	8 [1.4]	10 [1.6]	10 [2.5]	10 [3.0]
Metaplasia, Squamous		1 [1.0]	8 [1.0]	10 [1.9]	10 [2.5]	10 [2.7]
Necrosis			1 [1.0]	5 [1.0]	9 [1.9]	10 [2.6]
Regeneration			3 [1.7]	2 [1.5]	2 [2.0]	6 [2.0]
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte		1 [1.0]		3 [1.3]	9 [1.4]	1 [1.0]
Alveolus, Inflammation, Suppurative					3 [1.0]	6 [1.0]
Bronchus, Fibrosis				1 [1.0]	2 [1.5]	1 [2.0]
Bronchus, Hyperplasia				2 [1.0]	5 [1.8]	1 [1.0]
Bronchus, Inflammation, Chronic Active				3 [1.3]	9 [1.7]	8 [2.4]
Bronchus, Metaplasia, Squamous				7 [1.0]	6 [1.5]	1 [1.0]
Bronchus, Necrosis					5 [1.6]	7 [2.7]
Bronchus, Regeneration					3 [1.0]	1 [2.0]
Bronchus, Goblet Cell, Hyperplasia					1 [2.0]	
Perivascular, Inflammation, Chronic Active					2 [2.5]	
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 [1.6]	10 [2.0]	10 [2.3]	10 [2.7]	10 [2.3]
Glands, Olfactory Epithelium, Hyperplasia				1 [1.0]	2 [1.0]	3 [1.7]
Goblet Cell, Respiratory Epithelium, Hyperplasia		4 [1.0]	6 [1.7]	2 [2.0]		1 [1.0]
Olfactory Epithelium, Accumulation, Hyaline Droplet	9 [1.3]	10 [2.8]	9 [1.7]	1 [2.0]		
Olfactory Epithelium, Atrophy	2 [1.0]	10 [1.9]	10 [2.0]	10 [2.0]	7 [2.0]	6 [1.3]
Olfactory Epithelium, Metaplasia, Respiratory	1 [1.0]	1 [1.0]	6 [1.0]	6 [1.0]	2 [2.0]	
Olfactory Epithelium, Metaplasia, Squamous				1 [1.0]	1 [2.0]	1 [1.0]

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Lab: BNW

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Olfactory Epithelium, Necrosis				1 [2.0]	3 [2.0]	
Olfactory Epithelium, Regeneration			1 [1.0]		4 [1.8]	
Respiratory Epithelium, Accumulation, Hyaline Droplet	1 [1.0]		1 [1.0]			
Respiratory Epithelium, Hyperplasia	3 [1.0]	9 [1.0]	9 [1.2]	7 [1.0]	3 [1.0]	
Respiratory Epithelium, Metaplasia, Squamous		10 [1.9]	10 [2.0]	10 [2.0]	10 [1.7]	8 [1.8]
Respiratory Epithelium, Necrosis			3 [1.3]	5 [1.4]	10 [2.3]	10 [2.9]
Respiratory Epithelium, Regeneration			1 [1.0]		3 [1.3]	6 [1.5]
Respiratory Epithelium, Ulcer		1 [1.0]				
Turbinate, Atrophy			7 [1.0]	10 [1.0]		
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis				5 [1.0]	3 [1.7]	
Inflammation, Chronic Active			4 [1.0]	8 [1.8]	9 [1.9]	10 [2.7]
Metaplasia, Squamous			4 [1.0]	10 [1.0]	6 [2.0]	6 [1.8]
Necrosis				3 [1.3]	8 [1.8]	8 [2.6]
Regeneration				7 [2.9]	7 [2.3]	6 [2.2]
Ulcer					1 [1.0]	2 [2.5]
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Anterior Chamber, Inflammation, Suppurative					4 [1.0]	5 [1.0]
Cornea, Hyperplasia						2 [1.5]
Cornea, Inflammation, Suppurative	1 [1.0]	1 [1.0]	1 [2.0]	1 [2.0]	5 [2.0]	6 [2.3]
Cornea, Necrosis			1 [1.0]		2 [1.5]	4 [2.5]
Harderian Gland	(10)	(0)	(0)	(10)	(10)	(10)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Nephropathy	10 [1.4]	10 [1.3]	9 [1.2]	7 [1.3]	1 [1.0]	2 [1.0]
Urinary Bladder	(10)	(0)	(0)	(10)	(10)	(10)

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Species/Strain: RATS/HSD

Lab: BNW

Harlan Sprague Dawley RATS MALE

CONTROL

0.44 ppm

0.88 ppm

1.75 ppm

3.5 ppm

7.0 ppm

*** END OF MALE ***

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

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Harlan Sprague Dawley RATS FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice					2	1
Natural Death						9
Survivors						
Terminal Sacrifice	10	10	10	10	8	
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(6)
Liver	(10)	(0)	(0)	(0)	(10)	(10)
Mesentery	(0)	(0)	(1)	(0)	(0)	(0)
Fat, Degeneration			1 [1.0]			
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(0)	(0)	(0)	(10)	(10)
Cyst, Squamous	1 [2.0]					
Stomach, Glandular	(10)	(9)	(9)	(10)	(10)	(10)
Ulcer						2 [2.0]

CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(10)	(0)
Heart	(10)	(0)	(0)	(0)	(10)	(10)
Cardiomyopathy						2 [1.5]
Congestion						1 [1.0]

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ENDOCRINE SYSTEM

Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(10)
Parathyroid Gland	(8)	(0)	(0)	(0)	(9)	(9)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(10)	(0)	(0)	(0)	(10)	(10)
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Uterus	(10)	(0)	(0)	(1)	(10)	(10)
Decidual Reaction				1 [4.0]		

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(0)	(0)	(0)	(10)	(10)
Lymph Node, Bronchial	(8)	(0)	(0)	(0)	(7)	(5)
Lymph Node, Mandibular	(9)	(0)	(0)	(0)	(10)	(10)
Lymph Node, Mediastinal	(8)	(0)	(0)	(0)	(6)	(10)
Lymph Node, Mesenteric	(10)	(0)	(0)	(0)	(10)	(9)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy, Lymphoid				1 [1.0]	4 [1.3]	10 [3.5]
Thymus	(10)	(10)	(10)	(10)	(9)	(10)
Atrophy, Lymphoid					6 [1.0]	10 [3.0]

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INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous						1 [1.0]
Adnexa, Degeneration		1 [1.0]			1 [1.0]	10 [1.7]
Epithelium, Hair Follicle, Parakeratosis		1 [1.0]	1 [1.0]	3 [1.0]	3 [1.0]	6 [1.5]
Hair Follicle, Atrophy					1 [1.0]	
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active		1 [1.0]	1 [2.0]	9 [1.4]	10 [1.8]	10 [2.6]
Metaplasia, Squamous		1 [1.0]	4 [1.0]	10 [1.9]	10 [3.0]	10 [3.0]
Necrosis				1 [2.0]	7 [1.3]	8 [2.5]
Regeneration			1 [2.0]	3 [2.0]	1 [2.0]	2 [1.0]
Ulcer			1 [1.0]	1 [1.0]		
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte		2 [1.0]	1 [1.0]	3 [1.3]	9 [2.0]	3 [1.0]
Alveolus, Inflammation, Suppurative					2 [1.5]	4 [1.5]
Bronchus, Fibrosis				1 [1.0]	1 [1.0]	3 [2.3]
Bronchus, Hyperplasia				1 [2.0]	6 [2.0]	1 [2.0]
Bronchus, Inflammation, Chronic Active				2 [1.5]	10 [1.6]	10 [2.0]
Bronchus, Metaplasia, Squamous				2 [1.0]	9 [1.6]	
Bronchus, Necrosis					2 [1.0]	10 [2.3]
Bronchus, Regeneration					1 [1.0]	5 [1.6]

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Harlan Sprague Dawley RATS FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Interstitial, Fibrosis			1 [1.0]		2 [2.0]	
Interstitial, Inflammation, Granulomatous Perivascular, Inflammation, Chronic Active			1 [1.0]	1 [2.0]	6 [1.7]	2 [1.5]
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Foreign Body						1 [2.0]
Inflammation, Suppurative		9 [1.1]	10 [1.5]	10 [2.4]	10 [2.9]	10 [2.4]
Synechia				1 [1.0]		
Glands, Olfactory Epithelium, Hyperplasia		2 [1.0]		2 [1.0]	2 [1.0]	2 [1.0]
Goblet Cell, Respiratory Epithelium, Hyperplasia				1 [1.0]		1 [1.0]
Olfactory Epithelium, Accumulation, Hyaline Droplet	9 [1.2]	10 [2.6]	8 [2.5]	4 [1.5]		
Olfactory Epithelium, Atrophy		9 [1.8]	10 [2.0]	10 [2.0]	10 [1.9]	7 [1.6]
Olfactory Epithelium, Metaplasia, Respiratory		1 [1.0]	2 [1.0]	5 [1.2]	7 [1.4]	1 [1.0]
Olfactory Epithelium, Metaplasia, Squamous				1 [1.0]		
Olfactory Epithelium, Necrosis			1 [1.0]		1 [1.0]	
Olfactory Epithelium, Regeneration					1 [1.0]	
Respiratory Epithelium, Accumulation, Hyaline Droplet		4 [1.3]				
Respiratory Epithelium, Hyperplasia		9 [1.0]	7 [1.1]	4 [1.3]	3 [1.0]	3 [1.0]
Respiratory Epithelium, Metaplasia, Squamous		10 [1.9]	10 [2.0]	10 [1.9]	10 [2.1]	10 [1.7]
Respiratory Epithelium, Necrosis		2 [1.0]	6 [1.2]	9 [1.1]	10 [1.8]	10 [2.3]
Respiratory Epithelium, Regeneration			2 [1.5]		1 [2.0]	3 [1.7]
Respiratory Epithelium, Ulcer				1 [1.0]		1 [1.0]
Turbinate, Atrophy		2 [1.0]	4 [1.0]	10 [1.0]	10 [1.0]	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis				2 [1.0]	6 [1.2]	
Inflammation, Chronic Active			3 [1.0]	5 [1.2]	10 [1.8]	10 [2.9]
Metaplasia, Squamous			3 [1.0]	10 [1.0]	7 [1.7]	7 [1.4]
Necrosis				3 [1.0]	3 [1.0]	8 [2.0]
Regeneration			1 [2.0]	7 [2.6]	10 [2.9]	9 [1.8]
Ulcer					1 [2.0]	2 [2.0]

SPECIAL SENSES SYSTEM

Eye	(10)	(10)	(10)	(10)	(10)	(10)
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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: 20727 - 01

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/16/2015

Test Type: 90-DAY

ortho-Phthalaldehyde

Time Report Requested: 12:31:33

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 643-79-8

First Dose M/F: 01/19/09 / 01/20/09

Species/Strain: RATS/HSD

Lab: BNW

Harlan Sprague Dawley RATS FEMALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Anterior Chamber, Inflammation, Suppurative					1 [1.0]	5 [1.6]
Cornea, Hyperplasia						1 [2.0]
Cornea, Inflammation, Suppurative			1 [1.0]		1 [1.0]	8 [2.5]
Cornea, Necrosis						7 [2.4]
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
URINARY SYSTEM						
Kidney	(10)	(10)	(9)	(10)	(10)	(10)
Nephropathy	6 [1.0]	5 [1.2]	4 [1.3]	5 [1.0]	1 [1.0]	2 [1.0]
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(10)

*** 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)