

**Experiment Number:** 20727 - 01

**Test Type:** 90-DAY

**Route:** RESPIRATORY EXPOSURE WHOLE BODY

**Species/Strain:** RATS/HSD

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

ortho-Phthalaldehyde

**CAS Number:** 643-79-8

**Date Report Requested:** 02/10/2012

**Time Report Requested:** 11:42:10

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

**Lab:** BNW

F1\_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:** 2.6.0.0\_007  
**PWG Approval Date:** NONE

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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
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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 (13%)
Intestine Small, Jejunum	(10)	(0)	(0)	(10)	(10)	(7)
Liver	(10)	(1)	(0)	(10)	(10)	(10)
Fibrosis					1 (10%)	
Hepatodiaphragmatic Nodule		1 (100%)				
Hepatocyte, Degeneration, Focal	1 (10%)					
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 (10%)
Hyperplasia, Squamous				1 (10%)		
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

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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 (10%)		1 (100%)	1 (10%)		
<b>ENDOCRINE SYSTEM</b>						
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)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
Epididymis	(10)	(0)	(0)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell						1 (10%)
Penis	(0)	(0)	(0)	(0)	(1)	(0)
Inflammation, Suppurative					1 (100%)	
Preputial Gland	(10)	(0)	(0)	(9)	(10)	(10)
Inflammation, Chronic Active	1 (10%)				1 (10%)	
Prostate	(10)	(0)	(0)	(10)	(10)	(10)
Inflammation, Chronic Active				1 (10%)		
Seminal Vesicle	(10)	(0)	(0)	(10)	(10)	(10)
Atrophy					1 (10%)	
Testes	(10)	(0)	(1)	(10)	(10)	(10)
Germinal Epithelium, Atrophy			1 (100%)	1 (10%)		
<b>HEMATOPOIETIC SYSTEM</b>						

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

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**Lab:** BNW

Harlan Sprague Dawley RATS MALE	CONTROL	0.44 ppm	0.88 ppm	1.75 ppm	3.5 ppm	7.0 ppm
Bone Marrow	(10)	(0)	(0)	(10)	(10)	(10)
Lymph Node	(0)	(1)	(0)	(0)	(0)	(0)
Pigmentation		1 (100%)				
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 (60%)	10 (100%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy, Lymphoid					8 (80%)	7 (70%)
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(6)	(0)	(0)	(7)	(6)	(2)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous					1 (10%)	1 (10%)
Inflammation, Suppurative					1 (10%)	
Adnexa, Degeneration					4 (40%)	10 (100%)
Epithelium, Hair Follicle, Parakeratosis		7 (70%)	4 (40%)	7 (70%)	3 (30%)	10 (100%)
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(10)	(10)	(10)
Maxilla, Inflammation, Chronic Active						1 (10%)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(10)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)

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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
Inflammation, Chronic Active	1 (10%)	2 (20%)	8 (80%)	10 (100%)	10 (100%)	10 (100%)
Metaplasia, Squamous		1 (10%)	8 (80%)	10 (100%)	10 (100%)	10 (100%)
Necrosis			1 (10%)	5 (50%)	9 (90%)	10 (100%)
Regeneration			3 (30%)	2 (20%)	2 (20%)	6 (60%)
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte		1 (10%)		3 (30%)	9 (90%)	1 (10%)
Alveolus, Inflammation, Suppurative					3 (30%)	6 (60%)
Bronchus, Fibrosis				1 (10%)	2 (20%)	1 (10%)
Bronchus, Hyperplasia				2 (20%)	5 (50%)	1 (10%)
Bronchus, Inflammation, Chronic Active				3 (30%)	9 (90%)	8 (80%)
Bronchus, Metaplasia, Squamous				7 (70%)	6 (60%)	1 (10%)
Bronchus, Necrosis					5 (50%)	7 (70%)
Bronchus, Regeneration					3 (30%)	1 (10%)
Bronchus, Goblet Cell, Hyperplasia					1 (10%)	
Perivascular, Inflammation, Chronic Active					2 (20%)	
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Suppurative		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Glands, Olfactory Epithelium, Hyperplasia				1 (10%)	2 (20%)	3 (30%)
Goblet Cell, Respiratory Epithelium, Hyperplasia		4 (40%)	6 (60%)	2 (20%)		1 (10%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	9 (90%)	10 (100%)	9 (90%)	1 (10%)		
Olfactory Epithelium, Atrophy	2 (20%)	10 (100%)	10 (100%)	10 (100%)	7 (70%)	6 (60%)
Olfactory Epithelium, Metaplasia, Respiratory	1 (10%)	1 (10%)	6 (60%)	6 (60%)	2 (20%)	
Olfactory Epithelium, Metaplasia, Squamous				1 (10%)	1 (10%)	1 (10%)
Olfactory Epithelium, Necrosis				1 (10%)	3 (30%)	
Olfactory Epithelium, Regeneration			1 (10%)		4 (40%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet	1 (10%)		1 (10%)			
Respiratory Epithelium, Hyperplasia	3 (30%)	9 (90%)	9 (90%)	7 (70%)	3 (30%)	
Respiratory Epithelium, Metaplasia, Squamous		10 (100%)	10 (100%)	10 (100%)	10 (100%)	8 (80%)
Respiratory Epithelium, Necrosis			3 (30%)	5 (50%)	10 (100%)	10 (100%)
Respiratory Epithelium, Regeneration			1 (10%)		3 (30%)	6 (60%)
Respiratory Epithelium, Ulcer		1 (10%)				
Turbinate, Atrophy			7 (70%)	10 (100%)		
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis				5 (50%)	3 (30%)	

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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
Inflammation, Chronic Active			4 (40%)	8 (80%)	9 (90%)	10 (100%)
Metaplasia, Squamous			4 (40%)	10 (100%)	6 (60%)	6 (60%)
Necrosis				3 (30%)	8 (80%)	8 (80%)
Regeneration				7 (70%)	7 (70%)	6 (60%)
Ulcer					1 (10%)	2 (20%)
<b>SPECIAL SENSES SYSTEM</b>						
Eye	(10)	(10)	(10)	(10)	(10)	(10)
Anterior Chamber, Inflammation, Suppurative					4 (40%)	5 (50%)
Cornea, Hyperplasia						2 (20%)
Cornea, Inflammation, Suppurative	1 (10%)	1 (10%)	1 (10%)	1 (10%)	5 (50%)	6 (60%)
Cornea, Necrosis			1 (10%)		2 (20%)	4 (40%)
Harderian Gland	(10)	(0)	(0)	(10)	(10)	(10)
<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Nephropathy	10 (100%)	10 (100%)	9 (90%)	7 (70%)	1 (10%)	2 (20%)
Urinary Bladder	(10)	(0)	(0)	(10)	(10)	(10)

\*\*\* END OF MALE \*\*\*

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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 (100%)			
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 (10%)					
Stomach, Glandular	(10)	(9)	(9)	(10)	(10)	(10)
Ulcer						2 (20%)

### CARDIOVASCULAR SYSTEM

Blood Vessel	(10)	(0)	(0)	(0)	(10)	(0)
Heart	(10)	(0)	(0)	(0)	(10)	(10)
Cardiomyopathy						2 (20%)
Congestion						1 (10%)

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Species/Strain: RATS/HSD

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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
<b>ENDOCRINE SYSTEM</b>						
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)
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
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 (100%)		
<b>HEMATOPOIETIC SYSTEM</b>						
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 (10%)	4 (40%)	10 (100%)
Thymus	(10)	(10)	(10)	(10)	(9)	(10)
Atrophy, Lymphoid					6 (67%)	10 (100%)

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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
<b>INTEGUMENTARY SYSTEM</b>						
Mammary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia, Squamous						1 (10%)
Adnexa, Degeneration		1 (10%)			1 (10%)	10 (100%)
Epithelium, Hair Follicle, Parakeratosis		1 (10%)	1 (10%)	3 (30%)	3 (30%)	6 (60%)
Hair Follicle, Atrophy					1 (10%)	
<b>MUSCULOSKELETAL SYSTEM</b>						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
<b>NERVOUS SYSTEM</b>						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
<b>RESPIRATORY SYSTEM</b>						
Larynx	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active		1 (10%)	1 (10%)	9 (90%)	10 (100%)	10 (100%)
Metaplasia, Squamous		1 (10%)	4 (40%)	10 (100%)	10 (100%)	10 (100%)
Necrosis				1 (10%)	7 (70%)	8 (80%)
Regeneration			1 (10%)	3 (30%)	1 (10%)	2 (20%)
Ulcer			1 (10%)	1 (10%)		
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte		2 (20%)	1 (10%)	3 (30%)	9 (90%)	3 (30%)
Alveolus, Inflammation, Suppurative					2 (20%)	4 (40%)
Bronchus, Fibrosis				1 (10%)	1 (10%)	3 (30%)
Bronchus, Hyperplasia				1 (10%)	6 (60%)	1 (10%)
Bronchus, Inflammation, Chronic Active				2 (20%)	10 (100%)	10 (100%)
Bronchus, Metaplasia, Squamous				2 (20%)	9 (90%)	
Bronchus, Necrosis					2 (20%)	10 (100%)
Bronchus, Regeneration					1 (10%)	5 (50%)

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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 (10%)		2 (20%)	
Interstitial, Inflammation, Granulomatous Perivascular, Inflammation, Chronic Active			1 (10%)	1 (10%)	6 (60%)	2 (20%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Foreign Body						1 (10%)
Inflammation, Suppurative		9 (90%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Synechia				1 (10%)		
Glands, Olfactory Epithelium, Hyperplasia		2 (20%)		2 (20%)	2 (20%)	2 (20%)
Goblet Cell, Respiratory Epithelium, Hyperplasia				1 (10%)		1 (10%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	9 (90%)	10 (100%)	8 (80%)	4 (40%)		
Olfactory Epithelium, Atrophy		9 (90%)	10 (100%)	10 (100%)	10 (100%)	7 (70%)
Olfactory Epithelium, Metaplasia, Respiratory		1 (10%)	2 (20%)	5 (50%)	7 (70%)	1 (10%)
Olfactory Epithelium, Metaplasia, Squamous				1 (10%)		
Olfactory Epithelium, Necrosis			1 (10%)		1 (10%)	
Olfactory Epithelium, Regeneration					1 (10%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet		4 (40%)				
Respiratory Epithelium, Hyperplasia		9 (90%)	7 (70%)	4 (40%)	3 (30%)	3 (30%)
Respiratory Epithelium, Metaplasia, Squamous		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Respiratory Epithelium, Necrosis		2 (20%)	6 (60%)	9 (90%)	10 (100%)	10 (100%)
Respiratory Epithelium, Regeneration			2 (20%)		1 (10%)	3 (30%)
Respiratory Epithelium, Ulcer				1 (10%)		1 (10%)
Turbinate, Atrophy		2 (20%)	4 (40%)	10 (100%)	10 (100%)	
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Fibrosis				2 (20%)	6 (60%)	
Inflammation, Chronic Active			3 (30%)	5 (50%)	10 (100%)	10 (100%)
Metaplasia, Squamous			3 (30%)	10 (100%)	7 (70%)	7 (70%)
Necrosis				3 (30%)	3 (30%)	8 (80%)
Regeneration			1 (10%)	7 (70%)	10 (100%)	9 (90%)
Ulcer					1 (10%)	2 (20%)

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

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 ortho-Phthalaldehyde  
**CAS Number:** 643-79-8

**Date Report Requested:** 02/10/2012  
**Time Report Requested:** 11:42:10  
**First Dose M/F:** 01/19/09 / 01/20/09  
**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 (10%)	5 (50%)
Cornea, Hyperplasia						1 (10%)
Cornea, Inflammation, Suppurative			1 (10%)		1 (10%)	8 (80%)
Cornea, Necrosis						7 (70%)
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
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<b>URINARY SYSTEM</b>						
Kidney	(10)	(10)	(9)	(10)	(10)	(10)
Nephropathy	6 (60%)	5 (50%)	4 (44%)	5 (50%)	1 (10%)	2 (20%)
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