

Experiment Number: 10987 - 01

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

Date Report Requested: 08/20/2019

Test Type: Chronic PN

Dibutyl Phthalate

Time Report Requested: 12:03:41

Route: DOSED FEED

CAS Number: 84-74-2

First Dose M/F: 08/30/10 / 08/31/10

Species/Strain: RATS/HSD

Lab: BAT

NTP Study Number: C10987
Lock Date: 01/15/2015
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

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Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50	50
Early Deaths					
Moribund Sacrifice	9	4	10	9	10
Natural Death	13	8	9	7	7
Survivors					
Natural Death	1				1
Terminal Sacrifice	26	38	31	34	32
Animals Examined Microscopically	49	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(49)	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(50)	(49)	(50)	(50)
Lymphoid Tissue, Hyperplasia			1 [2.0]		1 [2.0]
Intestine Large, Colon	(49)	(50)	(50)	(50)	(50)
Parasite Metazoan	2	1	1	1	
Lymphoid Tissue, Hyperplasia					1 [2.0]
Intestine Large, Rectum	(49)	(50)	(50)	(50)	(50)
Parasite Metazoan	4	6	8	4	6
Polyarteritis Nodosa	1 [2.0]				
Intestine Small, Duodenum	(49)	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(49)	(49)	(50)	(49)	(50)
Intestine Small, Jejunum	(49)	(49)	(50)	(50)	(50)
Necrosis			1 [1.0]		
Liver	(49)	(50)	(50)	(50)	(50)
Angiectasis, Focal	2 [1.0]	1 [2.0]			
Basophilic Focus	4	2	2	3	3
Cholangiofibrosis	1 [2.0]	1 [2.0]		1 [3.0]	1 [3.0]
Clear Cell Focus	24	29	23	32	24
Congestion	1 [3.0]				
Degeneration, Cystic	1 [1.0]		1 [1.0]	1 [1.0]	2 [1.0]
Fatty Change	1 [1.0]	1 [1.0]	1 [1.0]		
Fatty Change, Focal	2 [1.0]	1 [1.0]	1 [1.0]	2 [1.0]	3 [1.0]
Hepatodiaphragmatic Nodule		2	3		

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Inflammation, Chronic Active				1 [1.0]	1 [1.0]
Mixed Cell Focus	5	8	2	3	2
Polyarteritis Nodosa	1 [1.0]	3 [1.0]	3 [1.0]	2 [1.0]	2 [1.0]
Bile Duct, Cyst	2	1			1
Bile Duct, Hyperplasia	15 [1.1]	14 [1.1]	14 [1.0]	9 [1.0]	9 [1.0]
Hepatocyte, Cytoplasmic Alteration					39 [1.0]
Hepatocyte, Necrosis		2 [1.5]			1 [1.0]
Periportal, Fibrosis, Focal				1 [1.0]	
Mesentery	(0)	(1)	(0)	(0)	(2)
Fat, Necrosis		1 [3.0]			2 [2.5]
Oral Mucosa	(1)	(0)	(0)	(0)	(0)
Pancreas	(49)	(50)	(50)	(50)	(49)
Basophilic Focus	3		1		
Fibrosis		1 [3.0]			
Polyarteritis Nodosa	1 [1.0]	3 [1.7]	4 [2.3]	1 [2.0]	1 [2.0]
Acinus, Atrophy	2 [1.5]	3 [1.7]	2 [2.0]	3 [2.0]	1 [1.0]
Acinus, Hyperplasia	19 [2.3]	21 [2.1]	18 [2.1]	23 [2.0]	18 [2.1]
Duct, Cyst	1				
Duct, Inflammation, Acute				1 [1.0]	
Salivary Glands	(49)	(50)	(50)	(49)	(50)
Basophilic Focus	1				
Hyperplasia					1 [2.0]
Infiltration Cellular, Mononuclear Cell	1 [2.0]				
Mineral				1 [2.0]	
Stomach, Forestomach	(49)	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 [2.0]				
Inflammation, Chronic Active	1 [3.0]		1 [2.0]		
Mineral			1 [3.0]		
Ulcer	6 [2.3]		1 [3.0]	3 [3.0]	1 [3.0]
Epithelium, Hyperplasia	1 [4.0]	1 [1.0]		2 [1.5]	1 [1.0]
Stomach, Glandular	(49)	(50)	(50)	(50)	(50)
Erosion				1 [1.0]	
Inflammation, Chronic Active				1 [1.0]	
Mineral	1 [2.0]	1 [2.0]	5 [2.4]	5 [1.6]	
Glands, Ectasia				1 [1.0]	

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CARDIOVASCULAR SYSTEM					
Blood Vessel	(49)	(50)	(50)	(50)	(50)
Mineral	1 [3.0]	1 [3.0]	4 [2.5]	2 [2.0]	1 [2.0]
Heart	(49)	(50)	(50)	(50)	(50)
Cardiomyopathy	44 [1.5]	47 [1.7]	47 [1.9]	45 [1.6]	44 [1.5]
Hemorrhage				1 [1.0]	1 [2.0]
Mineral			2 [2.0]		
Polyarteritis Nodosa	1 [2.0]			1 [1.0]	
Aortic Valve, Endothelium, Hyperplasia	1 [1.0]				
Artery, Hyperplasia	1 [3.0]				
Artery, Mineral		1 [2.0]	1 [2.0]	1 [2.0]	
Atrium, Thrombus	2 [4.0]		1 [4.0]		
Endocardium, Hyperplasia, Schwann Cell	1 [2.0]				
Epicardium, Inflammation, Chronic					1 [1.0]
Myocardium, Fibrosis, Focal	1 [2.0]				
Myocardium, Inflammation, Acute	1 [3.0]				
Myocardium, Necrosis, Multifocal	1 [3.0]				1 [3.0]
ENDOCRINE SYSTEM					
Adrenal Cortex	(49)	(50)	(50)	(50)	(50)
Degeneration, Cystic			2 [1.0]	3 [1.3]	
Hemorrhage		1 [3.0]			1 [2.0]
Hyperplasia, Focal	30 [1.8]	32 [1.6]	27 [1.4]	14 [1.5]	15 [1.3]
Hypertrophy, Focal	18 [1.4]	24 [1.2]	23 [1.2]	23 [1.3]	14 [1.5]
Metaplasia, Osseous		1 [2.0]		1 [3.0]	
Nuclear Alteration		1 [1.0]			
Vacuolization Cytoplasmic				1 [2.0]	
Vacuolization Cytoplasmic, Focal	8 [1.1]	9 [1.3]	8 [1.0]	3 [1.0]	5 [1.4]
Adrenal Medulla	(49)	(50)	(50)	(50)	(50)
Atypia Cellular		1 [1.0]			
Degeneration, Cystic					1 [2.0]
Hemorrhage				1 [3.0]	

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Hyperplasia	11 [2.2]	11 [2.5]	9 [2.6]	7 [1.9]	3 [1.7]
Islets, Pancreatic	(49)	(50)	(50)	(50)	(50)
Hyperplasia	1 [3.0]		2 [2.0]		
Parathyroid Gland	(48)	(48)	(42)	(47)	(47)
Hyperplasia	4 [2.3]	3 [2.0]	3 [2.0]	1 [2.0]	3 [2.0]
Hyperplasia, Focal	1 [1.0]				
Pituitary Gland	(48)	(50)	(50)	(50)	(50)
Inflammation, Pyogranulomatous, Focal			1 [3.0]		
Pars Distalis, Cyst, Multiple	1				
Pars Distalis, Cyst Multilocular			1		
Pars Distalis, Hyperplasia	15 [1.8]	13 [2.1]	13 [1.7]	18 [1.6]	22 [1.7]
Pars Distalis, Hypertrophy					29 [1.0]
Pars Intermedia, Hyperplasia	3 [2.0]	1 [1.0]		1 [4.0]	2 [1.0]
Rathke's Cleft, Cyst		2			
Thyroid Gland	(49)	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	5 [2.4]	3 [1.3]	5 [1.8]	10 [1.7]	4 [1.8]
Follicle, Dilation	1 [2.0]				
Follicular Cell, Hyperplasia	2 [1.0]	1 [4.0]	1 [1.0]		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland	(0)	(1)	(0)	(0)	(0)
Inflammation, Chronic Active		1 [4.0]			
Epididymis	(49)	(50)	(50)	(50)	(50)
Granuloma Sperm		2 [4.0]			1 [4.0]
Hypospermia	3 [3.3]		1 [4.0]	5 [3.4]	13 [3.8]
Bilateral, Hypospermia	1 [4.0]	7 [3.1]	9 [2.9]	4 [3.0]	27 [3.9]
Bilateral, Polyarteritis Nodosa		1 [1.0]		1 [3.0]	
Bilateral, Duct, Exfoliated Germ Cell	3 [1.0]	5 [2.2]	4 [2.5]	5 [2.6]	2 [2.5]
Bilateral, Interstitium, Inflammation, Chronic Active			1 [1.0]		

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Duct, Exfoliated Germ Cell	4 [1.3]	1 [2.0]	2 [2.5]	2 [1.0]	1 [4.0]
Preputial Gland	(49)	(49)	(50)	(49)	(50)
Hyperplasia, Squamous				1 [2.0]	
Inflammation, Chronic	7 [1.1]	10 [1.2]	2 [2.0]		
Inflammation, Chronic Active	27 [1.3]	8 [1.5]	1 [2.0]	1 [1.0]	2 [2.5]
Bilateral, Polyarteritis Nodosa				1 [1.0]	
Bilateral, Duct, Dilation	35 [2.1]	16 [2.1]	3 [2.7]	2 [2.0]	3 [3.3]
Duct, Hyperplasia, Focal	1 [3.0]			1 [2.0]	
Duct, Inflammation, Suppurative	4 [1.3]				
Prostate	(49)	(50)	(50)	(50)	(50)
Decreased Secretory Fluid	5	8	5	5	18
Inflammation, Chronic Active					1 [4.0]
Polyarteritis Nodosa		1 [1.0]			
Acinus, Dilation		1 [3.0]			
Acinus, Inflammation, Suppurative, Focal	1 [1.0]				
Epithelium, Hyperplasia, Regenerative, Focal	1 [1.0]				
Epithelium, Ventral, Hyperplasia, Focal	5 [1.6]		1 [2.0]	1 [3.0]	
Seminal Vesicle	(49)	(50)	(50)	(50)	(49)
Decreased Secretory Fluid	6	7	9	6	15
Inflammation, Chronic					2 [2.0]
Inflammation, Chronic Active		1 [3.0]			2 [2.5]
Testis	(49)	(50)	(50)	(47)	(50)
Edema	1 [3.0]	1 [2.0]	2 [2.5]	2 [3.0]	11 [3.6]
Hemorrhage					1 [3.0]
Mineral			1 [1.0]		
Sperm Granuloma	1				
Bilateral, Edema	1 [3.0]	2 [2.0]			7 [3.3]
Bilateral, Polyarteritis Nodosa	16 [1.8]	21 [1.6]	15 [2.0]	11 [2.0]	14 [2.3]
Bilateral, Germinal Epithelium, Atrophy	5 [2.4]	21 [1.8]	10 [2.6]	9 [3.1]	40 [4.0]
Bilateral, Germinal Epithelium, Degeneration	8 [1.1]	7 [2.6]	12 [2.2]	7 [2.0]	2 [2.5]
Bilateral, Interstitial Cell, Hyperplasia, Focal		1 [3.0]			3 [1.7]
Bilateral, Interstitial Cell, Hyperplasia, Diffuse			1 [2.0]		9 [2.2]
Bilateral, Rete Testis, Fibrosis					1 [3.0]
Bilateral, Rete Testis, Sperm Granuloma					1
Bilateral, Seminiferous Tubule, Dysgenesis					2 [1.5]
Germinal Epithelium, Atrophy	3 [2.0]		1 [1.0]	1 [1.0]	2 [2.5]

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Germinal Epithelium, Degeneration					1 [1.0]
Interstitial Cell, Hyperplasia, Focal	1 [3.0]	6 [1.3]	5 [1.2]	3 [1.7]	8 [1.5]
Rete Testis, Dilation		1 [2.0]	1 [2.0]	2 [2.5]	
Rete Testis, Fibrosis					10 [2.4]
Rete Testis, Sperm Granuloma					1
Seminiferous Tubule, Dilation	1 [2.0]	1 [2.0]			
Seminiferous Tubule, Dysgenesis				1 [2.0]	7 [2.0]
HEMATOPOIETIC SYSTEM					
Bone Marrow	(49)	(50)	(50)	(50)	(50)
Hypercellularity	14 [2.5]	5 [2.8]	12 [2.5]	10 [2.3]	10 [2.4]
Lymph Node	(5)	(0)	(3)	(2)	(2)
Lumbar, Hyperplasia, Plasma Cell			1 [2.0]		
Mediastinal, Hemorrhage				1 [3.0]	
Mediastinal, Hyperplasia, Plasma Cell	1 [3.0]				
Pancreatic, Hemorrhage	1 [2.0]				
Popliteal, Fibrosis	1 [4.0]				
Renal, Infiltration Cellular, Histiocyte	2 [3.0]				
Lymph Node, Mandibular	(49)	(49)	(50)	(48)	(50)
Degeneration, Cystic	3 [2.0]	2 [2.5]	6 [2.0]	9 [1.7]	6 [1.7]
Hyperplasia, Lymphoid	1 [3.0]	1 [2.0]	2 [2.0]		
Hyperplasia, Plasma Cell	5 [3.0]	1 [3.0]	1 [2.0]		
Inflammation, Chronic		1 [1.0]			
Lymph Node, Mesenteric	(49)	(49)	(50)	(50)	(50)
Hemorrhage	1 [3.0]		1 [3.0]		
Hyperplasia, Lymphoid	1 [2.0]				
Infiltration Cellular, Histiocyte	1 [1.0]				
Spleen	(49)	(50)	(50)	(50)	(50)
Extramedullary Hematopoiesis	38 [1.7]	40 [1.7]	36 [1.8]	39 [1.7]	42 [1.8]
Hemorrhage				1 [4.0]	
Hyperplasia, Lymphoid	3 [2.0]	2 [1.5]	1 [2.0]		
Inflammation, Chronic Active	1 [2.0]				
Pigment	45 [2.3]	44 [1.8]	42 [1.8]	44 [2.4]	43 [2.3]
Lymphoid Follicle, Atrophy	5 [2.6]	2 [2.5]	4 [3.0]	5 [2.6]	2 [2.5]

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Thymus	(48)	(46)	(45)	(49)	(49)
Atrophy	9 [3.0]			3 [2.7]	1 [4.0]
Ectopic Parathyroid Gland	1 [2.0]				
Hemorrhage	1 [3.0]			1 [2.0]	
Epithelial Cell, Hyperplasia	1 [1.0]				
INTEGUMENTARY SYSTEM					
Mammary Gland	(49)	(49)	(50)	(50)	(50)
Skin	(49)	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	3	6	2	3	1
Fibrosis			1 [2.0]		
Inflammation, Chronic Active	1 [3.0]				1 [4.0]
Ulcer	1 [4.0]	4 [3.5]		3 [2.7]	3 [4.0]
Epidermis, Hyperplasia		2 [3.0]			1 [2.0]
Eyelid, Cyst			1		
Sebaceous Gland, Cyst			1		
Subcutaneous Tissue, Hemorrhage				1 [4.0]	
Subcutaneous Tissue, Inflammation, Chronic Active	1 [4.0]			1 [3.0]	
MUSCULOSKELETAL SYSTEM					
Bone	(49)	(50)	(50)	(50)	(50)
Femur, Osteopetrosis				1 [3.0]	
Skeletal Muscle	(0)	(0)	(0)	(2)	(1)
Inflammation, Pyogranulomatous					1 [4.0]
NERVOUS SYSTEM					
Brain	(49)	(50)	(50)	(50)	(50)
Hemorrhage		1 [2.0]	1 [3.0]	1 [4.0]	2 [2.5]
Cerebrum, Inflammation, Suppurative			1 [3.0]		
Peripheral Nerve	(2)	(0)	(2)	(1)	(2)

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Sciatic, Degeneration					1 [4.0]
Trigeminal, Degeneration			1 [2.0]		
Spinal Cord	(0)	(0)	(1)	(1)	(0)
Hemorrhage			1 [3.0]	1 [4.0]	
RESPIRATORY SYSTEM					
Lung	(49)	(50)	(50)	(50)	(50)
Congestion				1 [3.0]	
Granuloma	2 [1.0]			2 [1.0]	1 [1.0]
Hemorrhage		1 [2.0]	1 [3.0]	1 [1.0]	
Mineral	2 [1.0]		2 [1.5]	3 [1.3]	
Alveolar Epithelium, Hyperplasia		1 [2.0]	1 [2.0]	1 [1.0]	
Alveolar Epithelium, Hyperplasia, Focal				2 [1.5]	
Alveolus, Infiltration Cellular, Histiocyte	22 [1.5]	24 [1.6]	24 [1.4]	25 [1.5]	29 [1.4]
Alveolus, Inflammation, Chronic	7 [1.1]	6 [1.0]	10 [1.1]	5 [1.0]	14 [1.0]
Alveolus, Inflammation, Chronic Active	6 [1.5]	1 [1.0]	1 [1.0]	2 [1.0]	4 [1.5]
Artery, Hyperplasia	1 [3.0]				
Interstitial, Fibrosis, Focal					1 [1.0]
Interstitial, Inflammation, Chronic Active	1 [2.0]				
Nose	(49)	(50)	(50)	(50)	(50)
Foreign Body	1	2		4	1
Inflammation, Suppurative	2 [2.0]	6 [1.2]	1 [2.0]	7 [1.0]	3 [2.0]
Inflammation, Acute	1 [2.0]				
Goblet Cell, Hyperplasia	2 [1.5]	1 [1.0]	1 [1.0]	5 [1.2]	1 [1.0]
Olfactory Epithelium, Inflammation, Acute				1 [1.0]	
Respiratory Epithelium, Hyperplasia	1 [1.0]				
Squamous Epithelium, Degeneration				1 [1.0]	
Submucosa, Granuloma		1 [1.0]			
Submucosa, Inflammation, Chronic	1 [1.0]	1 [2.0]			
Pleura	(0)	(0)	(0)	(0)	(1)
Infiltration Cellular, Mast Cell					1 [2.0]
Trachea	(49)	(50)	(50)	(50)	(50)

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SPECIAL SENSES SYSTEM					
Eye	(49)	(50)	(50)	(50)	(50)
Hemorrhage				1 [4.0]	
Phthisis Bulbi				1	
Anterior Chamber, Inflammation, Suppurative				1 [2.0]	
Cornea, Erosion, Multifocal				1 [1.0]	
Cornea, Inflammation, Acute			1 [3.0]	1 [3.0]	
Cornea, Ulcer, Focal				1 [3.0]	
Harderian Gland	(49)	(50)	(50)	(50)	(50)
Hyperplasia	1 [2.0]				
Infiltration Cellular, Mast Cell	1 [2.0]				
Karyomegaly				1 [1.0]	
Zymbal's Gland	(1)	(0)	(0)	(0)	(1)
URINARY SYSTEM					
Kidney	(49)	(50)	(50)	(50)	(50)
Inflammation, Suppurative	1 [3.0]				
Mineral				3 [1.7]	
Nephropathy, Chronic Progressive	47 [2.8]	48 [2.7]	48 [2.8]	50 [2.5]	47 [2.1]
Bilateral, Inflammation, Suppurative					2 [2.5]
Bilateral, Pelvis, Dilation				1 [3.0]	1 [2.0]
Bilateral, Renal Tubule, Inflammation, Acute	1 [2.0]				
Epithelium, Renal Tubule, Pigment				1 [2.0]	
Pelvis, Dilation	1 [2.0]		2 [2.5]	3 [1.3]	3 [2.3]
Pelvis, Inflammation, Chronic Active					3 [2.0]
Renal Tubule, Cyst		2		4	1
Renal Tubule, Inflammation, Acute	2 [1.5]				
Renal Tubule, Inflammation, Chronic Active	1 [1.0]				
Ureter	(0)	(0)	(0)	(1)	(2)
Cyst				1	
Dilation					1 [2.0]
Inflammation, Chronic Active					1 [2.0]
Urinary Bladder	(49)	(50)	(50)	(50)	(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)

Experiment Number: 10987 - 01

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

Date Report Requested: 08/20/2019

Test Type: Chronic PN

Dibutyl Phthalate

Time Report Requested: 12:03:41

Route: DOSED FEED

CAS Number: 84-74-2

First Dose M/F: 08/30/10 / 08/31/10

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Hemorrhage	1 [1.0]				
Lumen, Calculus Micro Observation Only		1 [1.0]			
Urothelium, Hyperplasia			1 [4.0]		1 [2.0]
Urothelium, Inflammation, Acute	1 [2.0]				
Urothelium, Inflammation, Chronic Active				1 [2.0]	2 [3.0]

*** END OF MALE ***

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Test Type: Chronic PN

Dibutyl Phthalate

Time Report Requested: 12:03:41

Route: DOSED FEED

CAS Number: 84-74-2

First Dose M/F: 08/30/10 / 08/31/10

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
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Disposition Summary

Animals Initially In Study	50	50	50	50	50
Early Deaths					
Moribund Sacrifice	9	8	14	11	13
Natural Death	12	5	9	7	8
Survivors					
Moribund Sacrifice	1				
Natural Death			1		
Terminal Sacrifice	28	37	26	32	29
Animals Examined Microscopically	50	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)	(50)
Muscularis, Atrophy	1 [2.0]				
Intestine Large, Cecum	(48)	(50)	(50)	(49)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(49)	(50)
Parasite Metazoan	2	1	1		
Intestine Large, Rectum	(50)	(50)	(50)	(49)	(50)
Inflammation, Chronic Active			1 [1.0]		
Parasite Metazoan	6	9	3	6	3
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Epithelium, Necrosis		1 [2.0]			
Intestine Small, Ileum	(50)	(50)	(50)	(49)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(49)	(50)
Liver	(50)	(50)	(50)	(50)	(50)
Angiectasis, Focal		3 [1.3]		1 [4.0]	3 [2.0]
Basophilic Focus	4	3	2	4	1
Clear Cell Focus	11	8	8	10	4
Congestion				1 [2.0]	
Eosinophilic Focus	2	2	4	3	3
Extramedullary Hematopoiesis	2 [1.0]		3 [1.0]	3 [1.0]	3 [1.0]
Fatty Change, Focal		1 [2.0]	1 [1.0]	5 [1.0]	
Fatty Change, Multifocal			1 [1.0]		
Hemorrhage, Focal		1 [1.0]			1 [2.0]

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CAS Number: 84-74-2

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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Hepatodiaphragmatic Nodule		1	1	2	1
Inflammation, Chronic Active	3 [1.0]	3 [1.0]	2 [1.0]	3 [1.0]	4 [1.3]
Mixed Cell Focus	3	5	4	8	
Polyarteritis Nodosa				2 [1.0]	
Bile Duct, Cyst	5	2	2	5	
Bile Duct, Cyst, Multiple	1				1
Bile Duct, Hyperplasia	5 [1.0]	11 [1.1]	6 [1.2]	6 [1.2]	12 [1.3]
Centrilobular, Hepatocyte, Hypertrophy				1 [1.0]	
Centrilobular, Hepatocyte, Vacuolization Cytoplasmic			1 [1.0]		
Hepatocyte, Cytoplasmic Alteration				1 [1.0]	40 [1.0]
Hepatocyte, Hypertrophy			1 [2.0]		
Hepatocyte, Necrosis	4 [1.5]	6 [1.3]	3 [2.0]	1 [2.0]	5 [1.8]
Mesentery	(0)	(0)	(0)	(1)	(1)
Pancreas	(50)	(49)	(50)	(49)	(50)
Basophilic Focus					1
Infiltration Cellular, Lipocyte	1 [1.0]				
Polyarteritis Nodosa		1 [2.0]		1 [1.0]	1 [2.0]
Acinus, Atrophy	1 [1.0]	2 [2.5]	2 [1.0]		
Acinus, Atypia Cellular				1 [2.0]	
Salivary Glands	(49)	(50)	(50)	(49)	(49)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)
Inflammation, Focal, Chronic Active			1 [2.0]		1 [2.0]
Inflammation, Chronic				1 [1.0]	
Mineral		1 [1.0]			
Ulcer		1 [3.0]	1 [3.0]		2 [3.0]
Epithelium, Hyperplasia					2 [2.0]
Epithelium, Hyperplasia, Focal			1 [3.0]		1 [1.0]
Epithelium, Hyperplasia, Multifocal					1 [4.0]
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Erosion		2 [2.0]			
Inflammation, Focal, Chronic Active			1 [2.0]		
Mineral		1 [1.0]	1 [1.0]		1 [1.0]
Glands, Ectasia		1 [1.0]			

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Test Type: Chronic PN

Dibutyl Phthalate

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Route: DOSED FEED

CAS Number: 84-74-2

First Dose M/F: 08/30/10 / 08/31/10

Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	(50)
Mineral					1 [2.0]
Heart	(50)	(50)	(50)	(50)	(50)
Cardiomyopathy	42 [1.1]	33 [1.2]	42 [1.4]	32 [1.2]	27 [1.1]
Hemorrhage	1 [3.0]				1 [3.0]
Endocardium, Fibrosis	1 [1.0]				
Myocardium, Hyperplasia, Schwann Cell	1 [3.0]				
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	(50)
Angiectasis	1 [2.0]		1 [2.0]	1 [2.0]	1 [2.0]
Degeneration, Cystic	1 [2.0]	2 [3.5]	4 [2.0]	5 [1.6]	3 [1.3]
Extramedullary Hematopoiesis	4 [1.0]				
Hemorrhage				2 [3.0]	
Hyperplasia, Focal	26 [1.5]	27 [1.6]	23 [1.5]	23 [1.1]	25 [1.4]
Hypertrophy, Focal	23 [1.1]	34 [1.5]	29 [1.7]	27 [1.4]	24 [1.3]
Karyomegaly		2 [1.0]	4 [1.0]	2 [1.0]	
Mineral			1 [2.0]		
Necrosis	1 [3.0]			2 [3.0]	2 [1.0]
Nuclear Alteration	2 [1.0]				
Thrombus				1 [2.0]	2 [1.0]
Vacuolization Cytoplasmic	2 [2.0]	6 [1.3]		2 [1.0]	3 [1.0]
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Hyperplasia	3 [1.7]	3 [1.7]	7 [1.7]	7 [1.7]	2 [1.5]
Infiltration Cellular, Mononuclear Cell			1 [1.0]		
Bilateral, Hyperplasia		1 [2.0]			
Islets, Pancreatic	(50)	(50)	(50)	(50)	(50)
Hyperplasia	1 [2.0]			1 [2.0]	
Parathyroid Gland	(45)	(45)	(37)	(47)	(43)
Hyperplasia		1 [2.0]		1 [3.0]	
Pituitary Gland	(50)	(50)	(50)	(50)	(50)
Angiectasis			1 [3.0]		

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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Infiltration Cellular, Mononuclear Cell	1 [1.0]				
Pars Distalis, Atypia Cellular					1 [1.0]
Pars Distalis, Cyst					1
Pars Distalis, Hyperplasia	24 [2.3]	15 [2.2]	14 [2.6]	15 [2.5]	18 [1.9]
Pars Distalis, Hypertrophy	1 [1.0]			1 [1.0]	1 [1.0]
Pars Distalis, Karyomegaly			1 [1.0]	1 [1.0]	
Thyroid Gland	(50)	(50)	(49)	(50)	(50)
C-cell, Hyperplasia	4 [2.0]	8 [2.3]	6 [2.8]	3 [2.7]	5 [1.4]
Follicular Cell, Hyperplasia			2 [2.0]		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(49)	(50)	(50)	(49)	(50)
Inflammation, Chronic					1 [3.0]
Duct, Dilation	1 [4.0]				
Ovary	(50)	(50)	(50)	(49)	(50)
Cyst					1
Cyst, Epithelial		1			
Inflammation, Chronic			1 [2.0]		
Bursa, Cyst	2	2	3	2	5
Follicle, Cyst	3	5	2	3	5
Paraovarian Tissue, Cyst	1				
Rete Ovarii, Cyst			1		
Uterus	(50)	(50)	(50)	(49)	(50)
Adenomyosis				1 [2.0]	
Dilation	2 [3.0]	6 [2.7]	1 [3.0]	3 [2.7]	3 [3.3]
Hemorrhage	2 [2.0]				1 [1.0]
Inflammation, Suppurative	1 [4.0]		1 [4.0]		
Inflammation, Chronic Active				1 [4.0]	
Thrombus			1 [4.0]		1 [1.0]
Cervix, Dilation					1 [4.0]

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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Cervix, Metaplasia, Squamous					1 [3.0]
Cervix, Myometrium, Hyperplasia			1 [3.0]	1 [4.0]	
Endometrium, Hyperplasia, Cystic	26 [2.0]	29 [2.0]	20 [1.9]	21 [2.0]	30 [2.5]
Endometrium, Metaplasia, Squamous	22 [1.7]	22 [1.8]	19 [2.3]	22 [1.9]	25 [1.7]
Vagina	(0)	(0)	(1)	(2)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)	(50)
Hypercellularity	30 [3.1]	21 [3.0]	18 [3.0]	23 [3.1]	33 [2.7]
Lymph Node	(0)	(0)	(0)	(5)	(1)
Lumbar, Hyperplasia, Plasma Cell				1 [3.0]	
Mediastinal, Hemorrhage				1 [2.0]	
Mediastinal, Hyperplasia, Plasma Cell				1 [2.0]	
Lymph Node, Mandibular	(49)	(50)	(50)	(48)	(49)
Hyperplasia, Lymphoid			1 [2.0]	1 [2.0]	1 [2.0]
Hyperplasia, Plasma Cell			2 [2.5]	1 [1.0]	
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	(50)
Hemorrhage					1 [3.0]
Hyperplasia, Lymphoid				1 [3.0]	1 [3.0]
Infiltration Cellular, Mast Cell					1 [2.0]
Spleen	(50)	(50)	(50)	(50)	(50)
Extramedullary Hematopoiesis	45 [2.2]	41 [1.6]	30 [1.8]	44 [1.8]	40 [2.2]
Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]	2 [2.0]	2 [2.0]	2 [2.0]
Pigment	37 [1.9]	46 [2.0]	36 [2.3]	37 [1.8]	46 [2.3]
Lymphoid Follicle, Atrophy		1 [4.0]	5 [2.4]	1 [2.0]	3 [2.7]
Red Pulp, Atypia Cellular	1 [4.0]				
Thymus	(49)	(48)	(50)	(48)	(48)
Atrophy				1 [2.0]	
Cyst					1
Ectopic Parathyroid Gland		1			
Epithelial Cell, Hyperplasia	1 [1.0]				1 [2.0]

INTEGUMENTARY SYSTEM

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Dibutyl Phthalate

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CAS Number: 84-74-2

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Species/Strain: RATS/HSD

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Mammary Gland	(50)	(50)	(50)	(49)	(50)
Inflammation, Focal, Chronic		1 [2.0]			
Inflammation, Chronic			2 [1.5]		
Duct, Dilatation, Focal	3 [2.3]	8 [2.3]	8 [2.0]	7 [2.6]	5 [2.4]
Duct, Galactocele			1 [2.0]		
Epithelium, Hyperplasia			3 [3.0]		
Epithelium, Hyperplasia, Lobular, Focal			1 [3.0]		1 [1.0]
Skin	(50)	(50)	(50)	(49)	(50)
Cyst Epithelial Inclusion		1			
Inflammation, Chronic Active		1 [4.0]	1 [2.0]		
Ulcer		1 [4.0]			
Ulcer, Multifocal			1 [2.0]		
Epidermis, Hyperplasia			1 [2.0]		
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	(50)
Metaplasia, Cartilagenous	1 [2.0]				
Joint, Inflammation, Chronic				1 [1.0]	
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)
NERVOUS SYSTEM					
Brain	(50)	(49)	(50)	(50)	(50)
Hemorrhage	1 [2.0]	1 [4.0]	1 [2.0]		1 [3.0]
Neuron, Necrosis	1 [3.0]				
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	(50)
Granuloma	1 [1.0]				
Keratin Cyst					1
Alveolar Epithelium, Hyperplasia			2 [2.0]		
Alveolus, Infiltration Cellular, Histiocyte	43 [1.9]	47 [2.3]	44 [2.2]	41 [2.1]	47 [2.1]

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Alveolus, Inflammation, Suppurative					2 [2.5]
Alveolus, Inflammation, Chronic	32 [1.3]	38 [1.7]	32 [1.8]	35 [1.5]	39 [1.5]
Alveolus, Inflammation, Chronic Active	2 [1.0]	3 [1.3]	1 [3.0]	1 [3.0]	
Nose	(50)	(50)	(50)	(50)	(50)
Foreign Body					2
Inflammation, Suppurative			1 [1.0]	2 [1.0]	2 [2.5]
Glands, Dilation					1 [1.0]
Goblet Cell, Hyperplasia	1 [1.0]				
Goblet Cell, Respiratory Epithelium, Hyperplasia				1 [1.0]	2 [1.5]
Respiratory Epithelium, Erosion, Multifocal					1 [1.0]
Respiratory Epithelium, Inflammation, Acute		1 [1.0]			
Respiratory Epithelium, Inflammation, Chronic Active	1 [2.0]		1 [1.0]		
Respiratory Epithelium, Metaplasia, Squamous		1 [3.0]			1 [1.0]
Respiratory Epithelium, Ulcer, Multifocal		1 [1.0]	2 [1.0]		
Respiratory Epithelium, Submucosa, Inflammation, Acute					1 [2.0]
Respiratory Epithelium, Submucosa, Inflammation, Chronic Active				1 [1.0]	
Trachea	(50)	(50)	(50)	(50)	(50)
Glands, Dilation, Focal	1 [1.0]				1 [1.0]
Glands, Inflammation, Suppurative					1 [1.0]
Submucosa, Inflammation, Chronic	1 [1.0]				1 [1.0]
Submucosa, Inflammation, Chronic Active					1 [2.0]

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)	(50)
Cornea, Hyperplasia, Squamous					1 [1.0]
Harderian Gland	(50)	(50)	(50)	(50)	(50)
Atrophy	3 [1.0]	4 [1.0]	2 [2.0]	2 [1.0]	3 [1.0]
Zymbal's Gland	(0)	(1)	(0)	(0)	(0)

URINARY SYSTEM

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Kidney	(50)	(50)	(50)	(50)	(50)
Calculus Micro Observation Only			1		
Hydronephrosis	1 [1.0]	1 [2.0]	1 [1.0]		1 [1.0]
Hyperplasia, Tubular		1 [1.0]			
Mineral					1 [2.0]
Nephropathy, Chronic Progressive	49 [1.3]	46 [1.5]	48 [1.6]	46 [1.4]	49 [1.5]
Pelvis, Dilation			1 [2.0]		
Pelvis, Inflammation, Suppurative				1 [1.0]	
Renal Tubule, Cyst		1			
Renal Tubule, Pigment				1 [2.0]	
Transitional Epithelium, Hyperplasia	1 [1.0]				
Urinary Bladder	(50)	(49)	(50)	(49)	(49)
Inflammation, Acute		1 [2.0]			
Urothelium, Hyperplasia	1 [1.0]	1 [1.0]		1 [1.0]	

*** END OF REPORT ***

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b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)