

Experiment Number: 10188 - 01
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/HSD

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

Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

Time Report Requested: 10:43:08

First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Final 2_HSD Rats

NTP Study Number: C10188B
Lock Date: 04/01/2015
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 Male

300 ppm Male

1000 ppm Male

3000 ppm Male

10000 ppm Male

Disposition Summary

	0 ppm Male	300 ppm Male	1000 ppm Male	3000 ppm Male	10000 ppm Male
Animals Initially In Study	50	50	50	50	50
Early Deaths					
Moribund Sacrifice	4	8	2	8	4
Natural Death	14	8	9	7	4
Survivors					
Natural Death		1			
Terminal Sacrifice	32	33	39	35	42
Animals Examined Microscopically	50	50	50	50	50

ALIMENTARY SYSTEM

	0 ppm Male	300 ppm Male	1000 ppm Male	3000 ppm Male	10000 ppm Male
Esophagus	(50)	(50)	(49)	(50)	(50)
Foreign Body		1 (2%)			
Inflammation, Chronic Active		1 (2%)			
Intestine Large, Cecum	(49)	(50)	(50)	(50)	(50)
Erosion			1 (2%)		
Inflammation, Acute	1 (2%)				
Inflammation, Chronic Active			1 (2%)		
Mineral			1 (2%)		
Polyarteritis Nodosa	5 (10%)	1 (2%)			
Intestine Large, Colon	(49)	(50)	(50)	(50)	(50)
Hyperplasia, Lymphocyte	2 (4%)				
Inflammation, Chronic Active			1 (2%)		
Parasite Metazoan	1 (2%)	1 (2%)	3 (6%)		1 (2%)
Polyarteritis Nodosa	1 (2%)	1 (2%)			1 (2%)
Serosa, Hemorrhage			1 (2%)		
Intestine Large, Rectum	(50)	(50)	(50)	(50)	(50)
Parasite Metazoan	8 (16%)	11 (22%)	8 (16%)	6 (12%)	16 (32%)
Polyarteritis Nodosa	2 (4%)	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(48)	(50)	(50)	(50)	(50)
Infiltration Cellular, Mononuclear Cell	1 (2%)				
Intestine Small, Jejunum	(49)	(50)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia	1 (2%)				

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Liver	(50)	(50)	(50)	(50)	(50)
Angiectasis	1 (2%)	1 (2%)			
Basophilic Focus	6 (12%)	1 (2%)	6 (12%)	4 (8%)	3 (6%)
Cholangiofibrosis				1 (2%)	
Clear Cell Focus	29 (58%)	31 (62%)	33 (66%)	35 (70%)	39 (78%)
Degeneration, Cystic	2 (4%)	1 (2%)		4 (8%)	1 (2%)
Eosinophilic Focus	1 (2%)		4 (8%)	2 (4%)	24 (48%)
Extramedullary Hematopoiesis	1 (2%)	1 (2%)			
Fibrosis	1 (2%)				
Hepatodiaphragmatic Nodule				1 (2%)	
Infiltration Cellular, Lymphoid				1 (2%)	
Inflammation, Focal	2 (4%)				
Mixed Cell Focus	1 (2%)	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Necrosis		2 (4%)	4 (8%)	7 (14%)	8 (16%)
Pigment			7 (14%)	45 (90%)	50 (100%)
Polyarteritis Nodosa	1 (2%)	1 (2%)			
Bile Duct, Cyst	2 (4%)		1 (2%)		
Bile Duct, Dilation		2 (4%)	1 (2%)	2 (4%)	
Bile Duct, Hyperplasia	9 (18%)	14 (28%)	11 (22%)	8 (16%)	11 (22%)
Bile Duct, Inflammation, Chronic Active		1 (2%)			
Hepatocyte, Cytoplasmic Alteration		1 (2%)		38 (76%)	49 (98%)
Hepatocyte, Fatty Change, Diffuse		1 (2%)			
Hepatocyte, Hypertrophy				2 (4%)	6 (12%)
Mesentery	(2)	(5)	(1)	(3)	(4)
Hemorrhage			1 (100%)	1 (33%)	
Polyarteritis Nodosa	2 (100%)	3 (60%)	1 (100%)	1 (33%)	1 (25%)
Arteriole, Mineral			1 (100%)		
Fat, Necrosis		1 (20%)			1 (25%)
Oral Mucosa	(0)	(1)	(0)	(1)	(1)
Gingival, Cyst					1 (100%)
Pancreas	(49)	(50)	(50)	(50)	(50)
Basophilic Focus	1 (2%)				
Cholangiofibrosis		1 (2%)			
Edema		1 (2%)			
Fatty Infiltration		1 (2%)			
Fibrosis					1 (2%)

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Harlan Sprague Dawley RATS MALE	0 ppm Male	300 ppm Male	1000 ppm Male	3000 ppm Male	10000 ppm Male
Infiltration Cellular, Lymphoid Inflammation, Chronic Active	1 (2%)	1 (2%)		1 (2%)	1 (2%)
Polyarteritis Nodosa	6 (12%)	4 (8%)	7 (14%)	2 (4%)	2 (4%)
Acinus, Atrophy	3 (6%)	3 (6%)	4 (8%)	2 (4%)	5 (10%)
Acinus, Hyperplasia	7 (14%)	8 (16%)	9 (18%)	24 (48%)	26 (52%)
Bile Duct, Dilation		1 (2%)			2 (4%)
Duct, Inflammation, Chronic Active	1 (2%)				
Salivary Glands	(50)	(50)	(50)	(50)	(50)
Fibrosis					1 (2%)
Inflammation, Chronic Active					1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)
Inflammation, Granulomatous					1 (2%)
Inflammation, Chronic				1 (2%)	
Inflammation, Chronic Active	1 (2%)	1 (2%)			2 (4%)
Mineral	1 (2%)			1 (2%)	
Polyarteritis Nodosa					1 (2%)
Ulcer		1 (2%)			
Epithelium, Dysplasia				1 (2%)	
Epithelium, Hyperplasia	3 (6%)	3 (6%)	1 (2%)	1 (2%)	3 (6%)
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Cyst, Squamous	1 (2%)				
Inflammation, Acute				1 (2%)	
Inflammation, Chronic Active		1 (2%)			
Mineral	3 (6%)	1 (2%)	1 (2%)	3 (6%)	
Polyarteritis Nodosa		1 (2%)			
Thrombus				1 (2%)	
Glands, Amyloid			1 (2%)		
Tooth	(0)	(1)	(0)	(0)	(0)
Inflammation, Suppurative		1 (100%)			
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	(50)
Aneurysm		1 (2%)			1 (2%)
Infiltration Cellular, Histiocyte		1 (2%)			

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Mineral	1 (2%)				
Aorta, Mineral	2 (4%)	1 (2%)	1 (2%)	2 (4%)	5 (10%)
Aorta, Polyarteritis Nodosa		1 (2%)			
Pulmonary Artery, Mineral				1 (2%)	
Pulmonary Vein, Mineral				1 (2%)	1 (2%)
Heart	(50)	(50)	(50)	(50)	(50)
Angiectasis			1 (2%)		
Cardiomyopathy	42 (84%)	41 (82%)	47 (94%)	37 (74%)	30 (60%)
Inflammation, Acute				1 (2%)	
Mineral				1 (2%)	
Polyarteritis Nodosa	2 (4%)				
Thrombus				1 (2%)	
Artery, Mineral				1 (2%)	
Artery, Polyarteritis Nodosa				1 (2%)	
Myocardium, Necrosis				1 (2%)	
Valve, Degeneration					1 (2%)
Valve, Fibrosis	2 (4%)			1 (2%)	9 (18%)
Valve, Thrombus				2 (4%)	6 (12%)
Vein, Mineral				1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(49)	(50)	(50)	(50)
Atypia Cellular	1 (2%)				
Degeneration, Cystic			1 (2%)		2 (4%)
Hyperplasia	5 (10%)	4 (8%)	10 (20%)	4 (8%)	3 (6%)
Hypertrophy, Focal	3 (6%)	6 (12%)	10 (20%)	6 (12%)	5 (10%)
Mineral	1 (2%)				
Necrosis	1 (2%)		1 (2%)		
Pigment			1 (2%)		
Thrombus		1 (2%)			
Bilateral, Hypertrophy, Focal				3 (6%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Hyperplasia, Focal	7 (14%)	9 (18%)	8 (16%)	4 (8%)	2 (4%)
Bilateral, Hyperplasia, Focal		1 (2%)			

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Islets, Pancreatic	(49)	(50)	(50)	(50)	(50)
Atrophy				1 (2%)	
Hyperplasia	4 (8%)		1 (2%)	6 (12%)	2 (4%)
Pigment	1 (2%)			1 (2%)	
Parathyroid Gland	(43)	(43)	(45)	(50)	(40)
Hyperplasia, Focal		2 (5%)	1 (2%)		
Hyperplasia, Diffuse	5 (12%)		2 (4%)		
Bilateral, Hyperplasia, Diffuse	2 (5%)			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)	(50)
Cyst					1 (2%)
Pigment, Cholesterol	1 (2%)				
Pars Distalis, Hyperplasia	28 (56%)	23 (46%)	26 (52%)	24 (48%)	23 (46%)
Pars Distalis, Hypertrophy	8 (16%)	10 (20%)	11 (22%)	14 (28%)	37 (74%)
Pars Distalis, Necrosis				1 (2%)	
Pars Intermedia, Hyperplasia		1 (2%)	4 (8%)	1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)	(50)
Inflammation, Acute				1 (2%)	
Inflammation, Chronic			1 (2%)		
C-cell, Hyperplasia	10 (20%)	8 (16%)	4 (8%)	6 (12%)	11 (22%)
Follicle, Cyst	1 (2%)				
Follicular Cell, Hyperplasia		1 (2%)	1 (2%)		

GENERAL BODY SYSTEM

Peritoneum	(1)	(0)	(0)	(0)	(0)
Tissue NOS	(0)	(0)	(1)	(0)	(0)

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)	(50)
Hypospermia		1 (2%)			
Necrosis		1 (2%)			
Polyarteritis Nodosa	1 (2%)	1 (2%)			
Bilateral, Hypospermia	4 (8%)	3 (6%)	4 (8%)	3 (6%)	43 (86%)
Bilateral, Inflammation, Suppurative	1 (2%)				

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Bilateral, Inflammation, Chronic	1 (2%)				
Bilateral, Inflammation, Chronic Active			1 (2%)		1 (2%)
Bilateral, Polyarteritis Nodosa	1 (2%)	1 (2%)			1 (2%)
Bilateral, Duct, Exfoliated Germ Cell	2 (4%)	3 (6%)	4 (8%)	4 (8%)	36 (72%)
Penis	(0)	(0)	(1)	(0)	(0)
Prolapse			1 (100%)		
Ulcer			1 (100%)		
Preputial Gland	(49)	(50)	(50)	(50)	(50)
Inflammation, Chronic					1 (2%)
Inflammation, Chronic Active	1 (2%)	1 (2%)	1 (2%)		1 (2%)
Metaplasia, Squamous	1 (2%)				1 (2%)
Mineral	1 (2%)				
Duct, Hyperplasia, Squamous			1 (2%)	1 (2%)	1 (2%)
Prostate	(50)	(50)	(50)	(50)	(50)
Edema		1 (2%)			
Hyperplasia	1 (2%)				
Inflammation, Suppurative	1 (2%)				
Inflammation, Chronic Active				1 (2%)	
Polyarteritis Nodosa		1 (2%)			1 (2%)
Dorsal, Epithelium, Lateral, Hyperplasia	1 (2%)				
Dorsal, Lateral, Inflammation, Granulomatous			1 (2%)		1 (2%)
Dorsal, Lateral, Inflammation, Acute	1 (2%)				
Dorsal, Lateral, Inflammation, Chronic	1 (2%)				
Dorsal, Lateral, Inflammation, Chronic Active	1 (2%)	2 (4%)	3 (6%)	2 (4%)	2 (4%)
Epithelium, Ventral, Hyperplasia	3 (6%)	4 (8%)	5 (10%)	1 (2%)	5 (10%)
Ventral, Inflammation, Acute			1 (2%)		
Ventral, Inflammation, Chronic	1 (2%)				
Ventral, Inflammation, Chronic Active		2 (4%)			
Seminal Vesicle	(50)	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)			
Infiltration Cellular, Lymphoid				1 (2%)	
Inflammation, Suppurative	1 (2%)				
Inflammation, Chronic Active				2 (4%)	
Mineral				1 (2%)	
Polyarteritis Nodosa		1 (2%)			
Testis	(50)	(50)	(50)	(50)	(50)

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Harlan Sprague Dawley RATS MALE	0 ppm Male	300 ppm Male	1000 ppm Male	3000 ppm Male	10000 ppm Male
Edema	5 (10%)	8 (16%)	7 (14%)	10 (20%)	6 (12%)
Granuloma Sperm	1 (2%)		1 (2%)		
Polyarteritis Nodosa	1 (2%)	1 (2%)	1 (2%)		
Bilateral, Edema	22 (44%)	15 (30%)	22 (44%)	14 (28%)	39 (78%)
Bilateral, Polyarteritis Nodosa	24 (48%)	20 (40%)	14 (28%)	4 (8%)	5 (10%)
Bilateral, Germinal Epithelium, Degeneration	29 (58%)	18 (36%)	19 (38%)	19 (38%)	48 (96%)
Bilateral, Interstitial Cell, Hyperplasia					1 (2%)
Germinal Epithelium, Degeneration	2 (4%)	7 (14%)	2 (4%)	3 (6%)	2 (4%)
Interstitial Cell, Hyperplasia	1 (2%)	1 (2%)		4 (8%)	3 (6%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)	(50)
Congestion		1 (2%)	1 (2%)	1 (2%)	2 (4%)
Hypercellularity	18 (36%)	22 (44%)	30 (60%)	25 (50%)	34 (68%)
Myelofibrosis				1 (2%)	
Lymph Node	(1)	(2)	(2)	(4)	(0)
Lumbar, Hyperplasia, Lymphocyte			1 (50%)		
Mediastinal, Hemorrhage				1 (25%)	
Renal, Dilation			1 (50%)		
Renal, Inflammation, Chronic			1 (50%)		
Renal, Pigment			1 (50%)		
Lymph Node, Mandibular	(49)	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	1 (2%)			
Dilation	3 (6%)				1 (2%)
Hyperplasia, Lymphocyte				1 (2%)	
Infiltration Cellular, Plasma Cell	3 (6%)	1 (2%)	1 (2%)		
Inflammation, Chronic	1 (2%)				
Inflammation, Chronic Active				1 (2%)	
Necrosis	1 (2%)				
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)	(50)
Atrophy	1 (2%)	1 (2%)			
Dilation	2 (4%)				
Fibrosis		1 (2%)			
Hyperplasia, Lymphocyte	1 (2%)	1 (2%)			1 (2%)

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Infiltration Cellular, Plasma Cell	2 (4%)				
Inflammation, Acute	1 (2%)				
Spleen	(50)	(50)	(50)	(50)	(50)
Accessory Spleen				1 (2%)	
Extramedullary Hematopoiesis	45 (90%)	45 (90%)	44 (88%)	45 (90%)	44 (88%)
Fibrosis				1 (2%)	
Hemorrhage				2 (4%)	
Infiltration Cellular, Lipocyte			1 (2%)		
Necrosis			1 (2%)		
Pigment	45 (90%)	44 (88%)	47 (94%)	42 (84%)	43 (86%)
White Pulp, Atrophy	1 (2%)	7 (14%)	4 (8%)	3 (6%)	1 (2%)
White Pulp, Hyperplasia	1 (2%)				
Thymus	(48)	(47)	(49)	(50)	(46)
Atrophy	41 (85%)	43 (91%)	49 (100%)	48 (96%)	44 (96%)
Ectopic Parathyroid Gland	1 (2%)				1 (2%)
Hyperplasia, Lymphocyte	1 (2%)	1 (2%)			
Infiltration Cellular, Lipocyte	1 (2%)				
Polyarteritis Nodosa	1 (2%)	1 (2%)			
Epithelial Cell, Hyperplasia		1 (2%)			

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(49)	(50)	(50)
Fibrosis			1 (2%)		
Inflammation, Chronic Active			1 (2%)		
Skin	(49)	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	5 (10%)		1 (2%)		2 (4%)
Fibrosis					1 (2%)
Hyperkeratosis	1 (2%)	1 (2%)			
Inflammation, Suppurative			1 (2%)		
Inflammation, Chronic					1 (2%)
Inflammation, Chronic Active	1 (2%)	2 (4%)	1 (2%)		
Ulcer		1 (2%)	1 (2%)		
Hair Follicle, Atrophy		1 (2%)			
Hair Follicle, Inflammation, Chronic		1 (2%)			

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Sebacous Gland, Hyperplasia		1 (2%)			
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	(50)
Cartilage, Joint, Degeneration		3 (6%)	2 (4%)	2 (4%)	
Skeletal Muscle	(0)	(1)	(0)	(0)	(0)
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	(50)
Hemorrhage				3 (6%)	
Inflammation, Acute				1 (2%)	
Necrosis		1 (2%)		1 (2%)	
Cerebrum, Gliosis					1 (2%)
Glial Cell, Hypertrophy		1 (2%)			
Meninges, Venule, Developmental Malformation					1 (2%)
Neuron, Necrosis	1 (2%)				
Nerve Trigeminal	(0)	(1)	(0)	(0)	(0)
Peripheral Nerve	(1)	(1)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	1 (100%)				
Axon, Tibial, Degeneration		1 (100%)			
Spinal Cord	(0)	(1)	(0)	(0)	(0)
Axon, Degeneration		1 (100%)			
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	(50)
Fibrosis		1 (2%)	1 (2%)		
Hyperplasia, Lymphocyte			1 (2%)	1 (2%)	
Infiltration Cellular, Histiocyte	30 (60%)	31 (62%)	39 (78%)	38 (76%)	40 (80%)
Infiltration Cellular, Lymphoid				1 (2%)	
Inflammation, Granulomatous	6 (12%)	6 (12%)	7 (14%)	10 (20%)	8 (16%)

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Inflammation, Acute	1 (2%)	1 (2%)		1 (2%)	1 (2%)
Inflammation, Chronic Active	2 (4%)	5 (10%)	5 (10%)	5 (10%)	4 (8%)
Mineral	1 (2%)				
Polyarteritis Nodosa			1 (2%)		
Alveolar Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Alveolus, Infiltration Cellular, Histiocyte		5 (10%)			1 (2%)
Serosa, Fibrosis	1 (2%)				
Nose	(50)	(50)	(50)	(50)	(50)
Amyloid					1 (2%)
Foreign Body		1 (2%)			
Inflammation, Suppurative				1 (2%)	
Inflammation, Granulomatous		1 (2%)			
Inflammation, Acute		1 (2%)	1 (2%)	1 (2%)	
Inflammation, Chronic			1 (2%)		
Inflammation, Chronic Active	1 (2%)	8 (16%)	2 (4%)	6 (12%)	6 (12%)
Glands, Dilation		1 (2%)		1 (2%)	3 (6%)
Olfactory Epithelium, Accumulation, Hyaline Droplet	34 (68%)	33 (66%)	40 (80%)	40 (80%)	42 (84%)
Olfactory Epithelium, Metaplasia, Respiratory		4 (8%)		4 (8%)	
Respiratory Epithelium, Accumulation, Hyaline Droplet	1 (2%)				
Respiratory Epithelium, Hyperplasia	1 (2%)			1 (2%)	
Respiratory Epithelium, Metaplasia, Squamous		1 (2%)		1 (2%)	
Respiratory Epithelium, Necrosis				1 (2%)	
Trachea	(50)	(50)	(50)	(50)	(50)
Inflammation, Chronic	1 (2%)				
Inflammation, Chronic Active	2 (4%)	1 (2%)			
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	(50)
Cataract					1 (2%)
Hemorrhage					1 (2%)
Choroid, Hyperplasia			1 (2%)		
Cornea, Inflammation, Chronic	2 (4%)	1 (2%)	2 (4%)	1 (2%)	
Cornea, Inflammation, Chronic Active	2 (4%)	1 (2%)	2 (4%)	2 (4%)	

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

Experiment Number: 10188 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

Time Report Requested: 10:43:08

First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm Male	300 ppm Male	1000 ppm Male	3000 ppm Male	10000 ppm Male
Cornea, Necrosis				1 (2%)	
Optic Nerve, Degeneration					1 (2%)
Retina, Degeneration	1 (2%)			1 (2%)	1 (2%)
Retina, Dysplasia				1 (2%)	1 (2%)
Retina, Fibrosis					1 (2%)
Harderian Gland	(50)	(50)	(50)	(50)	(50)
Atrophy				1 (2%)	1 (2%)
Fibrosis					1 (2%)
Hyperplasia	1 (2%)		1 (2%)		1 (2%)
Inflammation, Chronic Active				2 (4%)	
Metaplasia	1 (2%)				1 (2%)
Necrosis					1 (2%)
Duct, Metaplasia, Squamous				1 (2%)	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)	(50)
Infarct	3 (6%)		1 (2%)	1 (2%)	2 (4%)
Inflammation, Suppurative	1 (2%)				
Inflammation, Chronic				1 (2%)	
Inflammation, Chronic Active				1 (2%)	
Mineral	1 (2%)				
Nephropathy, Chronic Progressive	49 (98%)	50 (100%)	50 (100%)	49 (98%)	50 (100%)
Polyarteritis Nodosa	1 (2%)				
Pelvis, Dilation		2 (4%)			
Renal Tubule, Accumulation, Hyaline Droplet		1 (2%)			
Renal Tubule, Cyst	1 (2%)				
Renal Tubule, Hyperplasia	1 (2%)	1 (2%)			
Renal Tubule, Hyperplasia, Atypical					1 (2%)
Renal Tubule, Necrosis				1 (2%)	
Ureter	(0)	(1)	(0)	(0)	(0)
Polyarteritis Nodosa		1 (100%)			
Urethra	(0)	(1)	(0)	(0)	(0)
Urinary Bladder	(50)	(50)	(50)	(50)	(50)

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Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

Time Report Requested: 10:43:08

First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS MALE

0 ppm Male

300 ppm Male

1000 ppm Male

3000 ppm Male

10000 ppm Male

*** END OF MALE ***

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

Experiment Number: 10188 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Di(2-ethylhexyl) Phthalate

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Lab: BAT

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

Animals Initially In Study	50	50	50	50	50
Early Deaths					
Moribund Sacrifice	9	10	13	9	6
Natural Death	8	6	4	7	12
Survivors					
Moribund Sacrifice			1		
Natural Death			1		1
Terminal Sacrifice	33	34	31	34	31
Animals Examined Microscopically	50	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)	(49)
Intestine Large, Cecum	(50)	(50)	(50)	(49)	(48)
Polyarteritis Nodosa			2 (4%)		
Intestine Large, Colon	(50)	(50)	(50)	(50)	(48)
Hyperplasia, Lymphocyte Infiltration Cellular, Histiocyte					1 (2%)
Parasite Metazoan	2 (4%)		1 (2%)	2 (4%)	
Polyarteritis Nodosa			1 (2%)		
Intestine Large, Rectum	(50)	(49)	(50)	(50)	(50)
Parasite Metazoan	6 (12%)	6 (12%)	7 (14%)	9 (18%)	7 (14%)
Polyarteritis Nodosa			2 (4%)		
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(48)
Polyarteritis Nodosa			1 (2%)		
Intestine Small, Ileum	(50)	(50)	(49)	(50)	(48)
Parasite Metazoan	1 (2%)		1 (2%)		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)	(48)
Liver	(50)	(50)	(50)	(50)	(49)
Angiectasis	1 (2%)			1 (2%)	
Basophilic Focus	6 (12%)	7 (14%)		1 (2%)	4 (8%)
Cholangiofibrosis	1 (2%)				
Clear Cell Focus	8 (16%)	10 (20%)	14 (28%)	7 (14%)	5 (10%)
Degeneration, Cystic					1 (2%)

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Experiment Number: 10188 - 01

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Di(2-ethylhexyl) Phthalate

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First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Eosinophilic Focus	7 (14%)	6 (12%)	6 (12%)	3 (6%)	7 (14%)
Extramedullary Hematopoiesis	9 (18%)	4 (8%)	1 (2%)	5 (10%)	5 (10%)
Hepatodiaphragmatic Nodule	1 (2%)	1 (2%)	2 (4%)	1 (2%)	
Inflammation, Focal	1 (2%)	2 (4%)			
Inflammation, Chronic			1 (2%)		
Inflammation, Chronic Active				2 (4%)	1 (2%)
Mixed Cell Focus	3 (6%)	2 (4%)	1 (2%)		
Necrosis	2 (4%)	5 (10%)	4 (8%)	2 (4%)	4 (8%)
Pigment	3 (6%)		18 (36%)	30 (60%)	48 (98%)
Polyarteritis Nodosa			1 (2%)		
Vacuolization Cytoplasmic			1 (2%)		
Bile Duct, Cyst	4 (8%)	3 (6%)	2 (4%)	1 (2%)	
Bile Duct, Fibrosis					1 (2%)
Bile Duct, Hyperplasia	6 (12%)	2 (4%)	4 (8%)	7 (14%)	1 (2%)
Centrilobular, Degeneration	1 (2%)		1 (2%)		
Hepatocyte, Cytoplasmic Alteration		2 (4%)	15 (30%)	38 (76%)	45 (92%)
Hepatocyte, Fatty Change, Diffuse	1 (2%)		1 (2%)		
Hepatocyte, Hypertrophy			6 (12%)	14 (28%)	28 (57%)
Oval Cell, Hyperplasia			1 (2%)		
Serosa, Fibrosis	1 (2%)		1 (2%)		
Mesentery	(0)	(1)	(1)	(2)	(2)
Polyarteritis Nodosa			1 (100%)		
Oral Mucosa	(1)	(0)	(0)	(0)	(0)
Cyst, Squamous	1 (100%)				
Pancreas	(50)	(50)	(50)	(50)	(47)
Polyarteritis Nodosa	1 (2%)		2 (4%)	1 (2%)	
Acinus, Atrophy	1 (2%)			1 (2%)	1 (2%)
Acinus, Hyperplasia		1 (2%)	1 (2%)	1 (2%)	5 (11%)
Salivary Glands	(49)	(50)	(50)	(47)	(49)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)
Inflammation, Acute			1 (2%)		2 (4%)
Inflammation, Chronic	1 (2%)				1 (2%)
Inflammation, Chronic Active	2 (4%)	2 (4%)	2 (4%)	4 (8%)	3 (6%)
Mineral		1 (2%)			
Polyarteritis Nodosa			1 (2%)		
Ulcer	2 (4%)		2 (4%)	2 (4%)	2 (4%)

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Experiment Number: 10188 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

Time Report Requested: 10:43:08

First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Epithelium, Hyperplasia	2 (4%)	5 (10%)	3 (6%)	6 (12%)	6 (12%)
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Mineral	1 (2%)	3 (6%)	2 (4%)	1 (2%)	1 (2%)
Necrosis					1 (2%)
Artery, Mineral			1 (2%)		
Artery, Polyarteritis Nodosa		1 (2%)			

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)	(49)
Adventitia, Aorta, Inflammation, Chronic				1 (2%)	
Aorta, Mineral	1 (2%)			1 (2%)	
Heart	(50)	(50)	(50)	(49)	(49)
Cardiomyopathy	14 (28%)	12 (24%)	16 (32%)	13 (27%)	8 (16%)
Inflammation, Chronic Active	1 (2%)				
Polyarteritis Nodosa			1 (2%)		
Myocardium, Mineral	1 (2%)				
Schwann Cell, Hyperplasia	1 (2%)				

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)	3 (6%)	1 (2%)	1 (2%)
Atrophy		1 (2%)			
Degeneration, Cystic	12 (24%)	7 (14%)	10 (20%)	11 (22%)	10 (20%)
Hemorrhage			1 (2%)		1 (2%)
Hyperplasia		3 (6%)	1 (2%)	4 (8%)	
Hypertrophy		2 (4%)		1 (2%)	
Metaplasia, Osseous	1 (2%)				
Necrosis	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Thrombus		2 (4%)	5 (10%)	2 (4%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Hyperplasia	4 (8%)	3 (6%)	2 (4%)	9 (18%)	1 (2%)
Infiltration Cellular, Lymphocyte				1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)	(48)

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First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Hyperplasia	1 (2%)	1 (2%)			
Parathyroid Gland	(42)	(48)	(47)	(41)	(43)
Fibrosis			1 (2%)		
Hyperplasia		1 (2%)	1 (2%)		
Pituitary Gland	(49)	(50)	(50)	(50)	(50)
Angiectasis		1 (2%)			
Cyst	1 (2%)		1 (2%)		1 (2%)
Pars Distalis, Hyperplasia	20 (41%)	17 (34%)	21 (42%)	19 (38%)	10 (20%)
Pars Intermedia, Hyperplasia		1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(48)	(49)
Cyst				1 (2%)	
Infiltration Cellular, Lymphocyte			1 (2%)		
Necrosis		1 (2%)			
Artery, Degeneration, Hyaline		1 (2%)			
C-cell, Hyperplasia	12 (24%)	5 (10%)	5 (10%)	4 (8%)	5 (10%)
Follicle, Cyst	1 (2%)				
Follicular Cell, Degeneration			1 (2%)		
Follicular Cell, Hyperplasia					1 (2%)
GENERAL BODY SYSTEM					
Peritoneum	(1)	(1)	(0)	(1)	(1)
Inflammation, Acute					1 (100%)
Inflammation, Chronic Active	1 (100%)				
GENITAL SYSTEM					
Clitoral Gland	(49)	(49)	(47)	(49)	(48)
Inflammation, Chronic Active	1 (2%)	1 (2%)			
Metaplasia, Squamous		1 (2%)			
Duct, Hyperplasia			1 (2%)		
Duct, Hyperplasia, Squamous		1 (2%)			
Ovary	(50)	(50)	(50)	(49)	(48)
Atrophy		1 (2%)			
Cyst	4 (8%)	2 (4%)	1 (2%)	7 (14%)	5 (10%)

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Experiment Number: 10188 - 01

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

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CAS Number: 117-81-7

Date Report Requested: 12/17/2019

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First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Bilateral, Atrophy	36 (72%)	32 (64%)	37 (74%)	34 (69%)	29 (60%)
Bursa, Cyst		2 (4%)	1 (2%)	3 (6%)	2 (4%)
Follicle, Cyst	5 (10%)	4 (8%)	8 (16%)	6 (12%)	10 (21%)
Granulosa Cell, Hyperplasia	1 (2%)				
Paraovarian Tissue, Cyst	2 (4%)	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Rete Ovarii, Cyst		1 (2%)			
Rete Ovarii, Hyperplasia					2 (4%)
Oviduct	(0)	(1)	(0)	(0)	(0)
Cyst		1 (100%)			
Uterus	(50)	(50)	(50)	(50)	(49)
Adenomyosis	3 (6%)	2 (4%)	2 (4%)	2 (4%)	
Cyst, Squamous	1 (2%)				
Dilation		5 (10%)	2 (4%)	2 (4%)	1 (2%)
Hemorrhage	2 (4%)	2 (4%)		1 (2%)	2 (4%)
Hyperplasia, Adenomatous	1 (2%)				
Inflammation, Suppurative	3 (6%)	2 (4%)			1 (2%)
Inflammation, Chronic			3 (6%)		
Inflammation, Chronic Active	2 (4%)	9 (18%)	6 (12%)	8 (16%)	8 (16%)
Thrombus	1 (2%)				1 (2%)
Ulcer			1 (2%)		
Cervix, Cyst, Squamous	1 (2%)				
Cervix, Hyperplasia, Squamous					1 (2%)
Cervix, Hypertrophy	1 (2%)	1 (2%)	1 (2%)	1 (2%)	
Cervix, Inflammation, Chronic Active	1 (2%)				
Cervix, Metaplasia, Squamous		1 (2%)			
Cervix, Polyarteritis Nodosa			1 (2%)		
Endometrium, Atypical Hyperplasia	4 (8%)	5 (10%)	3 (6%)	6 (12%)	3 (6%)
Endometrium, Hyperplasia, Cystic	31 (62%)	22 (44%)	25 (50%)	27 (54%)	26 (53%)
Endometrium, Inflammation, Chronic Active			1 (2%)		
Endometrium, Metaplasia, Squamous	34 (68%)	27 (54%)	28 (56%)	25 (50%)	12 (24%)
Vagina	(1)	(1)	(1)	(1)	(0)
Inflammation	1 (100%)		1 (100%)		

HEMATOPOIETIC SYSTEM

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

Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

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First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Bone Marrow	(50)	(50)	(50)	(50)	(50)
Congestion	3 (6%)				1 (2%)
Hypercellularity	43 (86%)	39 (78%)	43 (86%)	43 (86%)	47 (94%)
Necrosis			1 (2%)		
Pigment	1 (2%)				1 (2%)
Lymph Node	(2)	(1)	(2)	(2)	(4)
Axillary, Infiltration Cellular, Plasma Cell		1 (100%)			
Lumbar, Hyperplasia, Lymphocyte			1 (50%)		
Lumbar, Infiltration Cellular, Plasma Cell		1 (100%)			1 (25%)
Lumbar, Pigment				1 (50%)	
Mediastinal, Hemorrhage	1 (50%)				
Mediastinal, Pigment	1 (50%)				
Lymph Node, Mandibular	(48)	(50)	(50)	(47)	(49)
Atrophy					1 (2%)
Dilation	1 (2%)				
Infiltration Cellular, Plasma Cell			1 (2%)		
Lymph Node, Mediastinal	(0)	(1)	(0)	(0)	(0)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)	(48)
Atrophy	2 (4%)				1 (2%)
Hyperplasia, Lymphocyte				1 (2%)	
Spleen	(50)	(50)	(50)	(50)	(47)
Accessory Spleen	1 (2%)	1 (2%)			
Extramedullary Hematopoiesis	47 (94%)	45 (90%)	45 (90%)	43 (86%)	39 (83%)
Hemorrhage					1 (2%)
Pigment	38 (76%)	38 (76%)	42 (84%)	40 (80%)	36 (77%)
White Pulp, Atrophy	5 (10%)	5 (10%)	2 (4%)	6 (12%)	7 (15%)
White Pulp, Hyperplasia			1 (2%)	1 (2%)	
Thymus	(49)	(49)	(50)	(47)	(48)
Atrophy	47 (96%)	45 (92%)	47 (94%)	45 (96%)	42 (88%)
Cyst			1 (2%)		
Hyperplasia, Lymphocyte			1 (2%)	1 (2%)	1 (2%)
Epithelial Cell, Hyperplasia		1 (2%)			

INTEGUMENTARY SYSTEM

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Experiment Number: 10188 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Mammary Gland	(50)	(50)	(50)	(50)	(50)
Galactocele			3 (6%)	3 (6%)	
Hyperplasia	13 (26%)	20 (40%)	13 (26%)	15 (30%)	9 (18%)
Inflammation, Chronic	1 (2%)				
Inflammation, Chronic Active	1 (2%)				
Skin	(50)	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion		1 (2%)			
Inflammation, Acute			1 (2%)		
Inflammation, Chronic Active				1 (2%)	
Ulcer				1 (2%)	
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	(50)
Osteopetrosis			1 (2%)	1 (2%)	
Cartilage, Joint, Degeneration		1 (2%)	3 (6%)	1 (2%)	
Skeletal Muscle	(0)	(0)	(0)	(0)	(3)
NERVOUS SYSTEM					
Brain	(50)	(50)	(50)	(50)	(50)
Hemorrhage			2 (4%)	1 (2%)	1 (2%)
Hydrocephalus				1 (2%)	
Necrosis		1 (2%)	1 (2%)	1 (2%)	
Peripheral Nerve	(0)	(0)	(0)	(0)	(1)
Spinal Cord	(0)	(0)	(0)	(0)	(1)
Hemorrhage					1 (100%)
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	(49)
Infiltration Cellular, Histiocyte	47 (94%)	45 (90%)	46 (92%)	49 (98%)	48 (98%)
Inflammation, Granulomatous	6 (12%)	11 (22%)	18 (36%)	7 (14%)	10 (20%)
Inflammation, Chronic Active	16 (32%)		2 (4%)	6 (12%)	18 (37%)

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Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Pigment	1 (2%)				
Thrombus	1 (2%)				
Alveolar Epithelium, Hyperplasia	2 (4%)	1 (2%)	2 (4%)	3 (6%)	
Alveolus, Metaplasia, Squamous	1 (2%)				
Nose	(50)	(50)	(50)	(50)	(50)
Cyst, Squamous	1 (2%)				
Foreign Body				1 (2%)	
Inflammation, Acute				1 (2%)	
Inflammation, Chronic Active	3 (6%)	4 (8%)	2 (4%)	1 (2%)	
Olfactory Epithelium, Accumulation, Hyaline Droplet	48 (96%)	49 (98%)	50 (100%)	48 (96%)	33 (66%)
Olfactory Epithelium, Metaplasia, Respiratory		2 (4%)			1 (2%)
Respiratory Epithelium, Metaplasia, Squamous	2 (4%)				
Trachea	(50)	(50)	(50)	(49)	(49)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(49)	(50)
Phthisis Bulbi					1 (2%)
Retinal Detachment			1 (2%)		
Choroid, Hyperplasia			2 (4%)		
Choroid, Inflammation, Chronic Active				1 (2%)	
Cornea, Inflammation, Chronic Active	1 (2%)			1 (2%)	
Retina, Degeneration		2 (4%)	1 (2%)		
Retina, Dysplasia			1 (2%)		
Harderian Gland	(50)	(50)	(50)	(49)	(49)
Atrophy				1 (2%)	

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)	(50)
Atrophy				2 (4%)	
Cyst			1 (2%)		
Hydronephrosis				1 (2%)	
Infarct	3 (6%)				2 (4%)

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

Experiment Number: 10188 - 01

Test Type: CHRONIC

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Di(2-ethylhexyl) Phthalate

CAS Number: 117-81-7

Date Report Requested: 12/17/2019

Time Report Requested: 10:43:08

First Dose M/F: 02/17/11 / 02/18/11

Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm Female	300 ppm Female	1000 ppm Female	3000 ppm Female	10000 ppm Female
Inflammation, Chronic Active Mineral	1 (2%)			1 (2%)	
Nephropathy, Chronic Progressive	40 (80%)	34 (68%)	43 (86%)	36 (72%)	36 (72%)
Polyarteritis Nodosa			1 (2%)		
Pelvis, Dilation		1 (2%)		2 (4%)	3 (6%)
Pelvis, Inflammation, Suppurative					1 (2%)
Renal Tubule, Accumulation, Hyaline Droplet			1 (2%)	1 (2%)	
Renal Tubule, Cyst	1 (2%)				
Renal Tubule, Hypertrophy					1 (2%)
Ureter	(0)	(0)	(0)	(1)	(0)
Dilation				1 (100%)	
Urinary Bladder	(50)	(50)	(49)	(50)	(47)
Inflammation, Chronic Active				1 (2%)	

*** END OF REPORT ***

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