Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD

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

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 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

Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
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%)		1 (2%)
Intestine Large, Colon	(49)	(50)	(50)	(50)	(50)
Parasite Metazoan	2 (4%)	1 (2%)	1 (2%)	1 (2%)	
Lymphoid Tissue, Hyperplasia		· · ·	· · /	· · ·	1 (2%)
Intestine Large, Rectum	(49)	(50)	(50)	(50)	(50)
Parasite Metazoan	4 (8%)	6 (12%)	8 (16%)	4 (8%)	6 (12%)
Polyarteritis Nodosa	1 (2%)			. ,	. ,
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 (2%)		
Liver	(49)	(50)	(50)	(50)	(50)
Angiectasis, Focal	2 (4%)	1 (2%)			
Basophilic Focus	4 (8%)	2 (4%)	2 (4%)	3 (6%)	3 (6%)
Cholangiofibrosis	1 (2%)	1 (2%)		1 (2%)	1 (2%)
Clear Cell Focus	24 (49%)	29 (58%)	23 (46%)	32 (64%)	24 (48%)
Congestion	1 (2%)				
Degeneration, Cystic	1 (2%)		1 (2%)	1 (2%)	2 (4%)
Fatty Change	1 (2%)	1 (2%)	1 (2%)		
Fatty Change, Focal	2 (4%)	1 (2%)	1 (2%)	2 (4%)	3 (6%)
Hepatodiaphragmatic Nodule		2 (4%)	3 (6%)		

Test Type: Chronic PN

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

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Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Inflammation, Chronic Active				1 (2%)	1 (2%)	
Mixed Cell Focus	5 (10%)	8 (16%)	2 (4%)	3 (6%)	2 (4%)	
Polyarteritis Nodosa	1 (2%)	3 (6%)	3 (6%)	2 (4%)	2 (4%)	
Bile Duct, Cyst	2 (4%)	1 (2%)			1 (2%)	
Bile Duct, Hyperplasia	15 (31%)	14 (28%)	14 (28%)	9 (18%)	9 (18%)	
Hepatocyte, Cytoplasmic Alteration			· · · ·		39 (78%)	
Hepatocyte, Necrosis		2 (4%)			1 (2%)	
Periportal, Fibrosis, Focal				1 (2%)		
Mesentery	(0)	(1)	(0)	(0)	(2)	
Fat, Necrosis		1 (100%)			2 (100%)	
Oral Mucosa	(1)	(0)	(0)	(0)	(0)	
Pancreas	(49)	(50)	(50)	(50)	(49)	
Basophilic Focus	3 (6%)	()	1 (2%)	()	(-)	
Fibrosis	- ()	1 (2%)	()			
Polyarteritis Nodosa	1 (2%)	3 (6%)	4 (8%)	1 (2%)	1 (2%)	
Acinus, Atrophy	2 (4%)	3 (6%)	2 (4%)	3 (6%)	1 (2%)	
Acinus, Hyperplasia	19 (39%)	21 (42%)	18 (36%)	23 (46%)	18 (37%)	
Duct, Cyst	1 (2%)		- ()			
Duct, Inflammation, Acute	()			1 (2%)		
Salivary Glands	(49)	(50)	(50)	(49)	(50)	
Basophilic Focus	1 (2%)	()	()	(-)	()	
Hyperplasia	()				1 (2%)	
Infiltration Cellular, Mononuclear Cell	1 (2%)				(_/-)	
Mineral	(_,,,)			1 (2%)		
Stomach, Forestomach	(49)	(50)	(50)	(50)	(50)	
Inflammation, Chronic	1 (2%)	()	()	()	()	
Inflammation, Chronic Active	1 (2%)		1 (2%)			
Mineral	(_,,)		1 (2%)			
Ulcer	6 (12%)		1 (2%)	3 (6%)	1 (2%)	
Epithelium, Hyperplasia	1 (2%)	1 (2%)	- (- / -)	2 (4%)	1 (2%)	
Stomach, Glandular	(49)	(50)	(50)	(50)	(50)	
Erosion	()	()	()	1 (2%)	(/	
Inflammation, Chronic Active				1 (2%)		
Mineral	1 (2%)	1 (2%)	5 (10%)	5 (10%)		
Glands, Ectasia	. (=,**)	. (=/0)		1 (2%)		

Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
CARDIOVASCULAR SYSTEM						
Blood Vessel	(49)	(50)	(50)	(50)	(50)	
Mineral	1 (2%)	1 (2%)	4 (8%)	2 (4%)	1 (2%)	
Heart	(49)	(50)	(50)	(50)	(50)	
Cardiomyopathy	44 (90%)	47 (94%)	47 (94%)	45 (90%)	44 (88%)	
Hemorrhage	((, , , , , , , , , , , , , , , , , , ,	(, , , , , , , , , , , , , , , , , , ,	1 (2%)	1 (2%)	
Mineral			2 (4%)			
Polyarteritis Nodosa	1 (2%)			1 (2%)		
Aortic Valve, Endothelium, Hyperplasia	1 (2%)			. (_,.,)		
Artery, Hyperplasia	1 (2%)					
Artery, Mineral	. (= /0)	1 (2%)	1 (2%)	1 (2%)		
Atrium, Thrombus	2 (4%)	1 (270)	1 (2%)	1 (270)		
Endocardium, Hyperplasia, Schwann Cell	1 (2%)		1 (270)			
Epicardium, Inflammation, Chronic	1 (270)				1 (2%)	
Myocardium, Fibrosis, Focal	1 (2%)				1 (270)	
Myocardium, Inflammation, Acute	1 (2%)					
Myocardium, Necrosis, Multifocal	1 (2%)				1 (2%)	
	1 (276)				1 (270)	
ENDOCRINE SYSTEM						
Adrenal Cortex	(49)	(50)	(50)	(50)	(50)	
Degeneration, Cystic			2 (4%)	3 (6%)		
Hemorrhage		1 (2%)			1 (2%)	
Hyperplasia, Focal	30 (61%)	32 (64%)	27 (54%)	14 (28%)	15 (30%)	
Hypertrophy, Focal	18 (37%)	24 (48%)	23 (46%)	23 (46%)	14 (28%)	
Metaplasia, Osseous	(1 (2%)	(, , , , , , , , , , , , , , , , , , ,	1 (2%)	× ,	
Nuclear Alteration		1 (2%)				
Vacuolization Cytoplasmic		(1 (2%)		
Vacuolization Cytoplasmic, Focal	8 (16%)	9 (18%)	8 (16%)	3 (6%)	5 (10%)	
Adrenal Medulla	(49)	(50)	(50)	(50)	(50)	
Atypia Cellular	x - /	1 (2%)	x - /		X /	
Degeneration, Cystic		x <i>y</i>			1 (2%)	
Hemorrhage				1 (2%)	x · · · · /	

Test Type: Chronic PN

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

larlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Hyperplasia	11 (22%)	11 (22%)	9 (18%)	7 (14%)	3 (6%)
Islets, Pancreatic	(49)	(50)	(50)	(50)	(50)
Hyperplasia	1 (2%)		2 (4%)		
Parathyroid Gland	(48)	(48)	(42)	(47)	(47)
Hyperplasia	4 (8%)	3 (6%)	3 (7%)	1 (2%)	3 (6%)
Hyperplasia, Focal	1 (2%)				
Pituitary Gland	(48)	(50)	(50)	(50)	(50)
Inflammation, Pyogranulomatous, Focal			1 (2%)		
Pars Distalis, Cyst, Multiple	1 (2%)				
Pars Distalis, Cyst Multilocular			1 (2%)		
Pars Distalis, Hyperplasia	15 (31%)	13 (26%)	13 (26%)	18 (36%)	22 (44%)
Pars Distalis, Hypertrophy					29 (58%)
Pars Intermedia, Hyperplasia	3 (6%)	1 (2%)		1 (2%)	2 (4%)
Rathke's Cleft, Cyst		2 (4%)			
Thyroid Gland	(49)	(50)	(50)	(50)	(50)
C-cell, Hyperplasia	5 (10%)	3 (6%)	5 (10%)	10 (20%)	4 (8%)
Follicle, Dilation	1 (2%)				
Follicular Cell, Hyperplasia	2 (4%)	1 (2%)	1 (2%)		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Coagulating Gland Inflammation, Chronic Active	(0)	(1) 1 (100%)	(0)	(0)	(0)
Epididymis	(49)	(50)	(50)	(50)	(50)
Granuloma Sperm		2 (4%)			1 (2%)
Hypospermia	3 (6%)		1 (2%)	5 (10%)	13 (26%)
Bilateral, Hypospermia	1 (2%)	7 (14%)	9 (18%)	4 (8%)	27 (54%)
Bilateral, Polyarteritis Nodosa		1 (2%)		1 (2%)	
Bilateral, Duct, Exfoliated Germ Cell	3 (6%)	5 (10%)	4 (8%)	5 (10%)	2 (4%)
Bilateral, Interstitium, Inflammation, Chronic Active			1 (2%)		

Experiment Number: 10987 - 01 Test Type: Chronic PN

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Duct, Exfoliated Germ Cell	4 (8%)	1 (2%)	2 (4%)	2 (4%)	1 (2%)	
Preputial Gland	(49)	(49)	(50)	(49)	(50)	
Hyperplasia, Squamous	(),	((),	1 (2%)		
Inflammation, Chronic	7 (14%)	10 (20%)	2 (4%)	(),		
Inflammation, Chronic Active	27 (55%)	8 (16%)	1 (2%)	1 (2%)	2 (4%)	
Bilateral, Polyarteritis Nodosa	(),	(),	(),	1 (2%)	· · ·	
Bilateral, Duct, Dilation	35 (71%)	16 (33%)	3 (6%)	2 (4%)	3 (6%)	
Duct, Hyperplasia, Focal	1 (2%)	(, , , , , , , , , , , , , , , , , , ,	(),	1 (2%)	· · ·	
Duct, Inflammation, Suppurative	4 (8%)			(),		
Prostate	(49)	(50)	(50)	(50)	(50)	
Decreased Secretory Fluid	5 (10%)	8 (16%)	5 (10%)	5 (10%)	18 (36%)	
Inflammation, Chronic Active		(),	· · · · ·	· · · · ·	1 (2%)	
Polyarteritis Nodosa		1 (2%)			· · · ·	
Acinus, Dilation		1 (2%)				
Acinus, Inflammation, Suppurative, Focal	1 (2%)					
Epithelium, Hyperplasia, Regenerative, Focal	1 (2%)					
Epithelium, Ventral, Hyperplasia, Focal	5 (10%)		1 (2%)	1 (2%)		
Seminal Vesicle	(49)	(50)	(50)	(50)	(49)	
Decreased Secretory Fluid	6 (12%)	7 (14%)	9 (18%)	6 (12%)	15 (31%)	
Inflammation, Chronic	. ,	· · ·	· · ·	· · ·	2 (4%)	
Inflammation, Chronic Active		1 (2%)			2 (4%)	
Testis	(49)	(50)	(50)	(47)	(50)	
Edema	1 (2%)	1 (2%)	2 (4%)	2 (4%)	11 (22%)	
Hemorrhage	(),		(),	(),	1 (2%)	
Mineral			1 (2%)		· · ·	
Sperm Granuloma	1 (2%)		(),			
Bilateral, Edema	1 (2%)	2 (4%)			7 (14%)	
Bilateral, Polyarteritis Nodosa	16 (33%)	21 (42%)	15 (30%)	11 (23%)	14 (28%)	
Bilateral, Germinal Epithelium, Atrophy	5 (10%)	21 (42%)	10 (20%)	9 (19%)	40 (80%)	
Bilateral, Germinal Epithelium, Degeneration	8 (16%)	7 (14%)	12 (24%)	7 (15%)	2 (4%)	
Bilateral, Interstitial Cell, Hyperplasia, Focal	· /	1 (2%)	· · /		3 (6%)	
Bilateral, Interstitial Cell, Hyperplasia, Diffuse			1 (2%)		9 (18%)	
Bilateral, Rete Testis, Fibrosis			· · /		1 (2%)	
Bilateral, Rete Testis, Sperm Granuloma					1 (2%)	
Bilateral, Seminiferous Tubule, Dysgenesis					2 (4%)	
Germinal Epithelium, Atrophy	3 (6%)		1 (2%)	1 (2%)	2 (4%)	

Experiment Number: 10987 - 01 Fest Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD	P03: INCIDENCE R	P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) Dibutyl Phthalate CAS Number: 84-74-2				
Iarlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Germinal Epithelium, Degeneration					1 (2%)	
Interstitial Cell, Hyperplasia, Focal	1 (2%)	6 (12%)	5 (10%)	3 (6%)	8 (16%)	
Rete Testis, Dilation		1 (2%)	1 (2%)	2 (4%)		
Rete Testis, Fibrosis					10 (20%)	
Rete Testis, Sperm Granuloma					1 (2%)	
Seminiferous Tubule, Dilation	1 (2%)	1 (2%)				
Seminiferous Tubule, Dysgenesis	· · /			1 (2%)	7 (14%)	
HEMATOPOIETIC SYSTEM				<u> </u>		
Bone Marrow	(49)	(50)	(50)	(50)	(50)	
Hypercellularity	14 (29%)	5 (10%)	12 (24%)	10 (20%)	10 (20%)	
Lymph Node	(5)	(0)	(3)	(2)	(2)	
Lumbar, Hyperplasia, Plasma Cell			1 (33%)			
Mediastinal, Hemorrhage				1 (50%)		
Mediastinal, Hyperplasia, Plasma Cell	1 (20%)					
Pancreatic, Hemorrhage	1 (20%)					
Popliteal, Fibrosis	1 (20%)					
Renal, Infiltration Cellular, Histiocyte	2 (40%)					
Lymph Node, Mandibular	(49)	(49)	(50)	(48)	(50)	
Degeneration, Cystic	3 (6%)	2 (4%)	6 (12%)	9 (19%)	6 (12%)	
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	2 (4%)		, , , , , , , , , , , , , , , , , , ,	
Hyperplasia, Plasma Cell	5 (10%)	1 (2%)	1 (2%)			
Inflammation, Chronic		1 (2%)				
Lymph Node, Mesenteric	(49)	(49)	(50)	(50)	(50)	
Hemorrhage	1 (2%)	(- /	1 (2%)	()	()	
Hyperplasia, Lymphoid	1 (2%)		\			
Infiltration Cellular, Histiocyte	1 (2%)					
Spleen	(49)	(50)	(50)	(50)	(50)	
Extramedullary Hematopoiesis	38 (78%)	40 (80%)	36 (72%)	39 (78%)	42 (84%)	
Hemorrhage	(,-,	- ()		1 (2%)	<u> </u>	
Hyperplasia, Lymphoid	3 (6%)	2 (4%)	1 (2%)	()		
Inflammation, Chronic Active	1 (2%)	- (,	. ()			
Pigment	45 (92%)	44 (88%)	42 (84%)	44 (88%)	43 (86%)	
Lymphoid Follicle, Atrophy	5 (10%)	2 (4%)	4 (8%)	5 (10%)	2 (4%)	

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD	P03: INCIDENCE F	ATES OF NON-NEOP Dibutyl I CAS Numl	Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT			
Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Thymus Atrophy Ectopic Parathyroid Gland Hemorrhage	(48) 9 (19%) 1 (2%) 1 (2%)	(46)	(45)	(49) 3 (6%) 1 (2%)	(49) 1 (2%)	
Epithelial Cell, Hyperplasia	1 (2%)					
INTEGUMENTARY SYSTEM						
Mammary Gland	(49)	(49)	(50)	(50)	(50)	
Skin	(49)	(50)	(50)	(50)	(50)	
Cyst Epithelial Inclusion	3 (6%)	6 (12%)	2 (4%)	3 (6%)	1 (2%)	
Fibrosis	1 (20/)		1 (2%)		1 (20/)	
Inflammation, Chronic Active Ulcer	1 (2%)	4 (8%)		2 (60/)	1 (2%)	
Epidermis, Hyperplasia	1 (2%)	4 (8%) 2 (4%)		3 (6%)	3 (6%) 1 (2%)	
Eyelid, Cyst		2 (470)	1 (2%)		1 (278)	
Sebaceous Gland, Cyst			1 (2%)			
Subcutaneous Tissue, Hemorrhage			1 (270)	1 (2%)		
Subcutaneous Tissue, Inflammation, Chronic Active	1 (2%)			1 (2%)		
MUSCULOSKELETAL SYSTEM						
Bone	(49)	(50)	(50)	(50)	(50)	
Femur, Osteopetrosis				1 (2%)		
Skeletal Muscle	(0)	(0)	(0)	(2)	(1)	
Inflammation, Pyogranulomatous					1 (100%)	
NERVOUS SYSTEM						
Brain	(49)	(50)	(50)	(50)	(50)	
Hemorrhage	(10)	1 (2%)	1 (2%)	1 (2%)	2 (4%)	
Cerebrum, Inflammation, Suppurative		. (_,;;)	1 (2%)	. (=,0)	_ (,	
Peripheral Nerve	(2)	(0)	(2)	(1)	(2)	

Test Type: Chronic PN

Species/Strain: RATS/HSD

Route: DOSED FEED

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Sciatic, Degeneration					1 (50%)	
Trigeminal, Degeneration			1 (50%)			
Spinal Cord	(0)	(0)	(1)	(1)	(0)	
Hemorrhage			1 (100%)	1 (100%)		
RESPIRATORY SYSTEM						
Lung	(49)	(50)	(50)	(50)	(50)	
Congestion				1 (2%)		
Granuloma	2 (4%)			2 (4%)	1 (2%)	
Hemorrhage		1 (2%)	1 (2%)	1 (2%)		
Mineral	2 (4%)		2 (4%)	3 (6%)		
Alveolar Epithelium, Hyperplasia		1 (2%)	1 (2%)	1 (2%)		
Alveolar Epithelium, Hyperplasia, Focal				2 (4%)		
Alveolus, Infiltration Cellular, Histiocyte	22 (45%)	24 (48%)	24 (48%)	25 (50%)	29 (58%)	
Alveolus, Inflammation, Chronic	7 (14%)	6 (12%)	10 (20%)	5 (10%)	14 (28%)	
Alveolus, Inflammation, Chronic Active	6 (12%)	1 (2%)	1 (2%)	2 (4%)	4 (8%)	
Artery, Hyperplasia	1 (2%)					
Interstitium, Fibrosis, Focal					1 (2%)	
Interstitium, Inflammation, Chronic Active	1 (2%)					
Nose	(49)	(50)	(50)	(50)	(50)	
Foreign Body	1 (2%)	2 (4%)		4 (8%)	1 (2%)	
Inflammation, Suppurative	2 (4%)	6 (12%)	1 (2%)	7 (14%)	3 (6%)	
Inflammation, Acute	1 (2%)					
Goblet Cell, Hyperplasia	2 (4%)	1 (2%)	1 (2%)	5 (10%)	1 (2%)	
Olfactory Epithelium, Inflammation, Acute				1 (2%)		
Respiratory Epithelium, Hyperplasia	1 (2%)					
Squamous Epithelium, Degeneration				1 (2%)		
Submucosa, Granuloma		1 (2%)				
Submucosa, Inflammation, Chronic	1 (2%)	1 (2%)				
Pleura	(0)	(0)	(0)	(0)	(1)	
Infiltration Cellular, Mast Cell					1 (100%)	
Trachea	(49)	(50)	(50)	(50)	(50)	

Test Type: Chronic PN

Route: DOSED FEED

Species/Strain: RATS/HSD

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Dibutyl Phthalate

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Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
SPECIAL SENSES SYSTEM						
Еуе	(49)	(50)	(50)	(50)	(50)	
Hemorrhage				1 (2%)		
Phthisis Bulbi				1 (2%)		
Anterior Chamber, Inflammation, Suppurative				1 (2%)		
Cornea, Erosion, Multifocal				1 (2%)		
Cornea, Inflammation, Acute			1 (2%)	1 (2%)		
Cornea, Ulcer, Focal				1 (2%)		
Harderian Gland	(49)	(50)	(50)	(50)	(50)	
Hyperplasia	1 (2%)					
Infiltration Cellular, Mast Cell	1 (2%)					
Karyomegaly				1 (2%)		
Zymbal's Gland	(1)	(0)	(0)	(0)	(1)	
URINARY SYSTEM				·	· · · · · · · · · · · · · · · · · · ·	
Kidney	(49)	(50)	(50)	(50)	(50)	
Inflammation, Suppurative	1 (2%)					
Mineral				3 (6%)		
Nephropathy, Chronic Progressive	47 (96%)	48 (96%)	48 (96%)	50 (100%)	47 (94%)	
Bilateral, Inflammation, Suppurative					2 (4%)	
Bilateral, Pelvis, Dilation				1 (2%)	1 (2%)	
Bilateral, Renal Tubule, Inflammation, Acute	1 (2%)					
Epithelium, Renal Tubule, Pigment				1 (2%)		
Pelvis, Dilation	1 (2%)		2 (4%)	3 (6%)	3 (6%)	
Pelvis, Inflammation, Chronic Active					3 (6%)	
Renal Tubule, Cyst		2 (4%)		4 (8%)	1 (2%)	
Renal Tubule, Inflammation, Acute	2 (4%)					
Renal Tubule, Inflammation, Chronic Active	1 (2%)					
Ureter	(0)	(0)	(0)	(1)	(2)	
Cyst		. ,		1 (100%)	· ·	
Dilation				· · /	1 (50%)	
Inflammation, Chronic Active					1 (50%)	
Urinary Bladder	(49)	(50)	(50)	(50)	(50)	

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD	P03: INCIDENCE R	Dibutyl PhthalateTiCAS Number: 84-74-2Fi			Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT	
Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Hemorrhage Lumen, Calculus Micro Observation Only Urothelium, Hyperplasia Urothelium, Inflammation, Acute Urothelium, Inflammation, Chronic Active	1 (2%) 1 (2%)	1 (2%)	1 (2%)	1 (2%)	1 (2%) 2 (4%)	

*** END OF MALE ***

Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
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%)	. ,		- *	. ,
Intestine Large, Cecum	(48)	(50)	(50)	(49)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(49)	(50)
Parasite Metazoan	2 (4%)	1 (2%)	1 (2%)	. /	. ,
Intestine Large, Rectum	(50)	(50)	(50)	(49)	(50)
Inflammation, Chronic Active		. ,	1 (2%)	. /	. ,
Parasite Metazoan	6 (12%)	9 (18%)	3 (6%)	6 (12%)	3 (6%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Epithelium, Necrosis		1 (2%)			
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 (6%)		1 (2%)	3 (6%)
Basophilic Focus	4 (8%)	3 (6%)	2 (4%)	4 (8%)	1 (2%)
Clear Cell Focus	11 (22%)	8 (16%)	8 (16%)	10 (20%)	4 (8%)
Congestion				1 (2%)	
Eosinophilic Focus	2 (4%)	2 (4%)	4 (8%)	3 (6%)	3 (6%)
Extramedullary Hematopoiesis	2 (4%)		3 (6%)	3 (6%)	3 (6%)
Fatty Change, Focal		1 (2%)	1 (2%)	5 (10%)	
Fatty Change, Multifocal			1 (2%)		
Hemorrhage, Focal		1 (2%)			1 (2%)

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

larlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Hepatodiaphragmatic Nodule		1 (2%)	1 (2%)	2 (4%)	1 (2%)	
Inflammation, Chronic Active	3 (6%)	3 (6%)	2 (4%)	3 (6%)	4 (8%)	
Mixed Cell Focus	3 (6%)	5 (10%)	4 (8%)	8 (16%)		
Polyarteritis Nodosa				2 (4%)		
Bile Duct, Cyst	5 (10%)	2 (4%)	2 (4%)	5 (10%)		
Bile Duct, Cyst, Multiple	1 (2%)				1 (2%)	
Bile Duct, Hyperplasia	5 (10%)	11 (22%)	6 (12%)	6 (12%)	12 (24%)	
Centrilobular, Hepatocyte, Hypertrophy				1 (2%)		
Centrilobular, Hepatocyte, Vacuolization Cytoplasmic			1 (2%)			
Hepatocyte, Cytoplasmic Alteration				1 (2%)	40 (80%)	
Hepatocyte, Hypertrophy			1 (2%)			
Hepatocyte, Necrosis	4 (8%)	6 (12%)	3 (6%)	1 (2%)	5 (10%)	
Mesentery	(0)	(0)	(0)	(1)	(1)	
Pancreas	(50)	(49)	(50)	(49)	(50)	
Basophilic Focus					1 (2%)	
Infiltration Cellular, Lipocyte	1 (2%)					
Polyarteritis Nodosa		1 (2%)		1 (2%)	1 (2%)	
Acinus, Atrophy	1 (2%)	2 (4%)	2 (4%)	. ,		
Acinus, Atypia Cellular				1 (2%)		
Salivary Glands	(49)	(50)	(50)	(49)	(49)	
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)	
Inflammation, Focal, Chronic Active			1 (2%)	(),	1 (2%)	
Inflammation, Chronic			(),	1 (2%)	. ,	
Mineral		1 (2%)		. ,		
Ulcer		1 (2%)	1 (2%)		2 (4%)	
Epithelium, Hyperplasia		. ,	. /		2 (4%)	
Epithelium, Hyperplasia, Focal			1 (2%)		1 (2%)	
Epithelium, Hyperplasia, Multifocal			. /		1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)	
Erosion		2 (4%)				
Inflammation, Focal, Chronic Active		· /	1 (2%)			
Mineral		1 (2%)	1 (2%)		1 (2%)	
Glands, Ectasia		1 (2%)				

Experiment Number: 10987 - 01 P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a) Date Report Requested: 08/20/2019 Test Type: Chronic PN Time Report Requested: 12:03:41 **Dibutyl Phthalate** CAS Number: 84-74-2 Route: DOSED FEED 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%) Heart (50) (50)(50) (50) (50)27 (54%) Cardiomyopathy 42 (84%) 33 (66%) 42 (84%) 32 (64%) Hemorrhage 1 (2%) 1 (2%) 1 (2%) Endocardium, Fibrosis Myocardium, Hyperplasia, Schwann Cell 1 (2%) ENDOCRINE SYSTEM Adrenal Cortex (50) (50)(50) (50) (50)Angiectasis 1 (2%) 1 (2%) 1 (2%) 1 (2%) Degeneration, Cystic 1 (2%) 2 (4%) 4 (8%) 5 (10%) 3 (6%) Extramedullary Hematopoiesis 4 (8%) Hemorrhage 2 (4%) Hyperplasia, Focal 26 (52%) 27 (54%) 23 (46%) 23 (46%) 25 (50%) Hypertrophy, Focal 23 (46%) 34 (68%) 29 (58%) 27 (54%) 24 (48%) Karyomegaly 2 (4%) 4 (8%) 2 (4%) Mineral 1 (2%) Necrosis 1 (2%) 2 (4%) 2 (4%) Nuclear Alteration 2 (4%) Thrombus 1 (2%) 2 (4%) 2 (4%) Vacuolization Cytoplasmic 2 (4%) 6 (12%) 3 (6%) Adrenal Medulla (50) (50) (50) (50) (50)Hyperplasia 3 (6%) 7 (14%) 7 (14%) 2 (4%) 3 (6%) Infiltration Cellular, Mononuclear Cell 1 (2%) Bilateral, Hyperplasia 1 (2%) Islets, Pancreatic (50) (50) (50) (50) (50)Hyperplasia 1 (2%) 1 (2%) Parathyroid Gland (47) (45) (45)(37) (43)Hyperplasia 1 (2%) 1 (2%) Pituitary Gland (50) (50)(50) (50) (50)Angiectasis 1 (2%)

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

larlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Infiltration Cellular, Mononuclear Cell	1 (2%)				
Pars Distalis, Atypia Cellular					1 (2%)
Pars Distalis, Cyst					1 (2%)
Pars Distalis, Hyperplasia	24 (48%)	15 (30%)	14 (28%)	15 (30%)	18 (36%)
Pars Distalis, Hypertrophy	1 (2%)			1 (2%)	1 (2%)
Pars Distalis, Karyomegaly			1 (2%)	1 (2%)	
Thyroid Gland	(50)	(50)	(49)	(50)	(50)
C-cell, Hyperplasia	4 (8%)	8 (16%)	6 (12%)	3 (6%)	5 (10%)
Follicular Cell, Hyperplasia		. ,	2 (4%)	· · /	

GENERAL BODY SYSTEM

None

Clitoral Gland	(49)	(50)	(50)	(49)	(50)
Inflammation, Chronic					1 (2%)
Duct, Dilation	1 (2%)				
Ovary	(50)	(50)	(50)	(49)	(50)
Cyst					1 (2%)
Cyst, Epithelial		1 (2%)			
Inflammation, Chronic			1 (2%)		
Bursa, Cyst	2 (4%)	2 (4%)	3 (6%)	2 (4%)	5 (10%)
Follicle, Cyst	3 (6%)	5 (10%)	2 (4%)	3 (6%)	5 (10%)
Paraovarian Tissue, Cyst	1 (2%)				
Rete Ovarii, Cyst			1 (2%)		
Uterus	(50)	(50)	(50)	(49)	(50)
Adenomyosis				1 (2%)	
Dilation	2 (4%)	6 (12%)	1 (2%)	3 (6%)	3 (6%)
Hemorrhage	2 (4%)				1 (2%)
Inflammation, Suppurative	1 (2%)		1 (2%)		
Inflammation, Chronic Active				1 (2%)	
Thrombus			1 (2%)		1 (2%)
Cervix, Dilation					1 (2%)

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD	P03: INCIDENCE R	Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT			
Harlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
Cervix, Metaplasia, Squamous					1 (2%)
Cervix, Myometrium, Hyperplasia			1 (2%)	1 (2%)	
Endometrium, Hyperplasia, Cystic	26 (52%)	29 (58%)	20 (40%)	21 (43%)	30 (60%)
Endometrium, Metaplasia, Squamous	22 (44%)	22 (44%)	19 (38%)	22 (45%)	25 (50%)
Vagina	(0)	(0)	(1)	(2)	(0)
HEMATOPOIETIC SYSTEM					· · · · · · · · · · · · · · · · · · ·
Bone Marrow	(50)	(50)	(50)	(50)	(50)
Hypercellularity	30 (60%)	21 (42%)	18 (36%)	23 (46%)	33 (66%)
Lymph Node	(0)	(0)	(0)	(5)	(1)
Lumbar, Hyperplasia, Plasma Cell				1 (20%)	
Mediastinal, Hemorrhage				1 (20%)	
Mediastinal, Hyperplasia, Plasma Cell				1 (20%)	
Lymph Node, Mandibular	(49)	(50)	(50)	(48)	(49)
Hyperplasia, Lymphoid			1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Plasma Cell			2 (4%)	1 (2%)	
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	(50)
Hemorrhage					1 (2%)
Hyperplasia, Lymphoid				1 (2%)	1 (2%)
Infiltration Cellular, Mast Cell					1 (2%)
Spleen	(50)	(50)	(50)	(50)	(50)
Extramedullary Hematopoiesis	45 (90%)	41 (82%)	30 (60%)	44 (88%)	40 (80%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Pigment	37 (74%)	46 (92%)	36 (72%)	37 (74%)	46 (92%)
Lymphoid Follicle, Atrophy		1 (2%)	5 (10%)	1 (2%)	3 (6%)
Red Pulp, Atypia Cellular	1 (2%)				
Thymus	(49)	(48)	(50)	(48)	(48)
Atrophy				1 (2%)	
Cyst					1 (2%)
Ectopic Parathyroid Gland		1 (2%)			
Epithelial Cell, Hyperplasia	1 (2%)	. ,			1 (2%)

INTEGUMENTARY SYSTEM

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

rlan 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%)				
Inflammation, Chronic			2 (4%)			
Duct, Dilation, Focal	3 (6%)	8 (16%)	8 (16%)	7 (14%)	5 (10%)	
Duct, Galactocele			1 (2%)			
Epithelium, Hyperplasia			3 (6%)			
Epithelium, Hyperplasia, Lobular, Focal			1 (2%)		1 (2%)	
Skin	(50)	(50)	(50)	(49)	(50)	
Cyst Epithelial Inclusion		1 (2%)				
Inflammation, Chronic Active		1 (2%)	1 (2%)			
Ulcer		1 (2%)				
Ulcer, Multifocal			1 (2%)			
Epidermis, Hyperplasia			1 (2%)			
USCULOSKELETAL SYSTEM						
Bone	(50)	(50)	(50)	(50)	(50)	
Metaplasia, Cartilagenous	1 (2%)					
Joint, Inflammation, Chronic				1 (2%)		
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)	
ERVOUS SYSTEM						
Brain	(50)	(49)	(50)	(50)	(50)	
Hemorrhage	1 (2%)	1 (2%)	1 (2%)	(00)	1 (2%)	
Neuron, Necrosis	1 (2%)	. (_/)	. (_/)		. (= //)	
ESPIRATORY SYSTEM						
Lung	(50)	(50)	(50)	(50)	(50)	
Granuloma	(50) 1 (2%)	(00)	(00)	(50)	(00)	
Keratin Cyst	I (∠70)				1 (2%)	
Alveolar Epithelium, Hyperplasia			2 (4%)		I (∠ /0)	
Alveolar Epinelium, hyperplasia Alveolus, Infiltration Cellular, Histiocyte	43 (86%)	47 (94%)	44 (88%)	41 (82%)	47 (94%)	
		71 (3470)	(00 00) דד	TI (0270)	(0/דט) וד	

Experiment Number: 10987 - 01	
Test Type: Chronic PN	

Route: DOSED FEED

Species/Strain: RATS/HSD

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

Dibutyl Phthalate

CAS Number: 84-74-2

Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 Lab: BAT

Iarlan Sprague Dawley RATS FEMALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm	
Alveolus, Inflammation, Suppurative					2 (4%)	
Alveolus, Inflammation, Chronic	32 (64%)	38 (76%)	32 (64%)	35 (70%)	39 (78%)	
Alveolus, Inflammation, Chronic Active	2 (4%)	3 (6%)	1 (2%)	1 (2%)		
Nose	(50)	(50)	(50)	(50)	(50)	
Foreign Body					2 (4%)	
Inflammation, Suppurative			1 (2%)	2 (4%)	2 (4%)	
Glands, Dilation					1 (2%)	
Goblet Cell, Hyperplasia	1 (2%)					
Goblet Cell, Respiratory Epithelium, Hyperplasia				1 (2%)	2 (4%)	
Respiratory Epithelium, Erosion, Multifocal					1 (2%)	
Respiratory Epithelium, Inflammation, Acute		1 (2%)				
Respiratory Epithelium, Inflammation, Chronic Active	1 (2%)		1 (2%)			
Respiratory Epithelium, Metaplasia, Squamous		1 (2%)			1 (2%)	
Respiratory Epithelium, Ulcer, Multifocal		1 (2%)	2 (4%)			
Respiratory Epithelium, Submucosa, Inflammation, Acute					1 (2%)	
Respiratory Epithelium, Submucosa, Inflammation, Chronic Active				1 (2%)		
Trachea	(50)	(50)	(50)	(50)	(50)	
Glands, Dilation, Focal	1 (2%)				1 (2%)	
Glands, Inflammation, Suppurative					1 (2%)	
Submucosa, Inflammation, Chronic	1 (2%)				1 (2%)	
Submucosa, Inflammation, Chronic Active					1 (2%)	
PECIAL SENSES SYSTEM		·				
Eye	(50)	(50)	(50)	(50)	(50)	
Cornea, Hyperplasia, Squamous					1 (2%)	
Harderian Gland	(50)	(50)	(50)	(50)	(50)	
Atrophy	3 (6%)	4 (8%)	2 (4%)	2 (4%)	3 (6%)	
Zymbal's Gland	(0)	(1)	(0)	(0)	(0)	

URINARY SYSTEM

Experiment Number: 10987 - 01 Test Type: Chronic PN Route: DOSED FEED Species/Strain: RATS/HSD	P03: INCIDENCE R	Date Report Requested: 08/20/2019 Time Report Requested: 12:03:41 First Dose M/F: 08/30/10 / 08/31/10 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 (2%)		
Hydronephrosis	1 (2%)	1 (2%)	1 (2%)		1 (2%)
Hyperplasia, Tubular		1 (2%)			
Mineral					1 (2%)
Nephropathy, Chronic Progressive	49 (98%)	46 (92%)	48 (96%)	46 (92%)	49 (98%)
Pelvis, Dilation			1 (2%)		
Pelvis, Inflammation, Suppurative				1 (2%)	
Renal Tubule, Cyst		1 (2%)			
Renal Tubule, Pigment				1 (2%)	
Transitional Epithelium, Hyperplasia	1 (2%)				
Urinary Bladder	(50)	(49)	(50)	(49)	(49)
Inflammation, Acute		1 (2%)			· · · ·
Urothelium, Hyperplasia	1 (2%)	1 (2%)		1 (2%)	

*** END OF REPORT ***