

Experiment Number: 10987 - 01

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS
ABRIDGED) (a)**

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

Test Type: Chronic PN

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Species/Strain: RATS/HSD

Lab: BAT

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)
Intestine Large, Colon	(49)	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(49)	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(49)	(49)	(50)	(49)	(50)
Intestine Small, Jejunum	(49)	(49)	(50)	(50)	(50)
Adenocarcinoma			1 (2%)		
Liver	(49)	(50)	(50)	(50)	(50)
Cholangiocarcinoma					1 (2%)
Cholangioma		1 (2%)			
Hepatocellular Adenoma			1 (2%)		
Hepatocellular Carcinoma	1 (2%)				
Mesentery	(0)	(1)	(0)	(0)	(2)
Oral Mucosa	(1)	(0)	(0)	(0)	(0)
Pharyngeal, Squamous Cell Carcinoma	1 (100%)				
Pancreas	(49)	(50)	(50)	(50)	(49)
Acinus, Adenoma	2 (4%)	3 (6%)	3 (6%)	1 (2%)	8 (16%)
Acinus, Adenoma, Multiple	2 (4%)	1 (2%)			2 (4%)
Acinus, Carcinoma	2 (4%)				
Salivary Glands	(49)	(50)	(50)	(49)	(50)
Stomach, Forestomach	(49)	(50)	(50)	(50)	(50)
Leiomyosarcoma				1 (2%)	

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

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Stomach, Glandular	(49)	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM					
Blood Vessel	(49)	(50)	(50)	(50)	(50)
Heart	(49)	(50)	(50)	(50)	(50)
Endocardium, Schwannoma Malignant	1 (2%)				
Myocardium, Schwannoma Malignant	1 (2%)				1 (2%)
ENDOCRINE SYSTEM					
Adrenal Cortex	(49)	(50)	(50)	(50)	(50)
Adrenal Medulla	(49)	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	7 (14%)	6 (12%)	11 (22%)	2 (4%)	3 (6%)
Pheochromocytoma Malignant	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Bilateral, Pheochromocytoma Benign				1 (2%)	
Islets, Pancreatic	(49)	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	7 (14%)	3 (6%)		2 (4%)
Parathyroid Gland	(48)	(48)	(42)	(47)	(47)
Pituitary Gland	(48)	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Peripheral Nerve	1 (2%)				
Pars Distalis, Adenoma	15 (31%)	10 (20%)	12 (24%)	14 (28%)	6 (12%)
Pars Intermedia, Adenoma				1 (2%)	
Thyroid Gland	(49)	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)	1 (2%)	1 (2%)		1 (2%)
C-cell, Adenoma	7 (14%)	9 (18%)	9 (18%)	11 (22%)	8 (16%)
C-cell, Carcinoma	1 (2%)			1 (2%)	
Follicular Cell, Adenoma	1 (2%)			1 (2%)	
GENERAL BODY SYSTEM					
None					

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GENITAL SYSTEM					
Coagulating Gland	(0)	(1)	(0)	(0)	(0)
Epididymis	(49)	(50)	(50)	(50)	(50)
Preputial Gland	(49)	(49)	(50)	(49)	(50)
Adenoma	1 (2%)				
Duct, Squamous Cell Carcinoma	1 (2%)				
Prostate	(49)	(50)	(50)	(50)	(50)
Ventral, Adenoma	1 (2%)				
Seminal Vesicle	(49)	(50)	(50)	(50)	(49)
Testis	(49)	(50)	(50)	(47)	(50)
Granulosa Cell Tumor Benign					1 (2%)
Interstitial Cell, Adenoma	2 (4%)	5 (10%)	1 (2%)	4 (9%)	5 (10%)
HEMATOPOIETIC SYSTEM					
Bone Marrow	(49)	(50)	(50)	(50)	(50)
Lymph Node	(5)	(0)	(3)	(2)	(2)
Bronchial, Neuroendocrine Tumor, Malignant, Metastatic, Uncertain Primary Site	1 (20%)				
Lymph Node, Mandibular	(49)	(49)	(50)	(48)	(50)
Lymph Node, Mesenteric	(49)	(49)	(50)	(50)	(50)
Hemangioma				1 (2%)	
Spleen	(49)	(50)	(50)	(50)	(50)
Hemangiosarcoma					1 (2%)
Thymus	(48)	(46)	(45)	(49)	(49)
INTEGUMENTARY SYSTEM					
Mammary Gland	(49)	(49)	(50)	(50)	(50)
Fibroadenoma	1 (2%)	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Skin	(49)	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)		1 (2%)		
Fibroma	1 (2%)				
Keratoacanthoma	8 (16%)				

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Pilomatrixoma	3 (6%)	1 (2%)			
Squamous Cell Papilloma			1 (2%)		2 (4%)
Subcutaneous Tissue, Fibrolipoma				2 (4%)	
Subcutaneous Tissue, Fibroma	2 (4%)	1 (2%)	1 (2%)	4 (8%)	
Subcutaneous Tissue, Fibrosarcoma	1 (2%)	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Subcutaneous Tissue, Lipoma		2 (4%)	2 (4%)	1 (2%)	2 (4%)
MUSCULOSKELETAL SYSTEM					
Bone	(49)	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(0)	(2)	(1)
Rhabdomyosarcoma				1 (50%)	
Sarcoma				1 (50%)	
NERVOUS SYSTEM					
Brain	(49)	(50)	(50)	(50)	(50)
Glioma Malignant	2 (4%)		1 (2%)	1 (2%)	
Meningioma Benign	1 (2%)				
Oligodendroglioma Malignant					1 (2%)
Cranial Nerve, Schwannoma Malignant				1 (2%)	
Peripheral Nerve	(2)	(0)	(2)	(1)	(2)
Paraganglioma	1 (50%)				
Schwannoma Malignant			1 (50%)		
Trigeminal, Schwannoma Malignant	1 (50%)			1 (100%)	
Spinal Cord	(0)	(0)	(1)	(1)	(0)
RESPIRATORY SYSTEM					
Lung	(49)	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)		1 (2%)	1 (2%)	
Carcinoma, Metastatic, Thyroid Gland				1 (2%)	
Leiomyosarcoma		1 (2%)			

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Pheochromocytoma Malignant, Metastatic, Adrenal Medulla	1 (2%)				
Sarcoma, Metastatic, Skeletal Muscle				1 (2%)	
Nose	(49)	(50)	(50)	(50)	(50)
Osteosarcoma					1 (2%)
Pleura	(0)	(0)	(0)	(0)	(1)
Trachea	(49)	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM					
Eye	(49)	(50)	(50)	(50)	(50)
Schwannoma Malignant			1 (2%)		
Optic Nerve, Schwannoma Malignant				1 (2%)	
Harderian Gland	(49)	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Brain				1 (2%)	
Schwannoma Malignant, Metastatic, Peripheral Nerve				1 (2%)	
Zymbal's Gland	(1)	(0)	(0)	(0)	(1)
Carcinoma	1 (100%)				1 (100%)
URINARY SYSTEM					
Kidney	(49)	(50)	(50)	(50)	(50)
Lipoma			1 (2%)		
Nephroblastoma					1 (2%)
Renal Tubule, Adenoma	1 (2%)				
Ureter	(0)	(0)	(0)	(1)	(2)
Urinary Bladder	(49)	(50)	(50)	(50)	(50)

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

* Number of animals with any tissue examined microscopically

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Lab: BAT

Harlan Sprague Dawley RATS MALE	0 ppm	300 ppm	1000 ppm	3000 ppm	10000 ppm
<hr/>					
SYSTEMIC LESIONS					
Multiple Organ	*(49)	*(50)	*(50)	*(50)	*(50)
Leukemia					1 (2%)
Leukemia Erythrocytic					1 (2%)
Leukemia Mononuclear		1 (2%)		1 (2%)	1 (2%)
Lymphoma Malignant	1 (2%)		4 (8%)		5 (10%)
Mesothelioma Malignant	1 (2%)	2 (4%)			

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* Number of animals with any tissue examined microscopically

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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	41	36	36	37	37
Total Primary Neoplasms	79	53	60	60	61
Total Animals with Benign Neoplasms	35	33	33	32	26
Total Benign Neoplasms	60	47	49	47	43
Total Animals with Malignant Neoplasms	14	5	9	12	15
Total Malignant Neoplasms	16	5	11	13	18
Total Animals with Metastatic Neoplasms	3			4	
Total Metastatic Neoplasms	3			4	
Total Animals with Malignant Neoplasms Uncertain Primary Site					
Total Animals with Neoplasms Uncertain- Benign or Malignant	3	1			
Total Uncertain Neoplasms	3	1			

*** END OF MALE ***

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

b - Primary tumors: all tumors except metastatic tumors

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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)
Cholangiocarcinoma, Metastatic, Liver					1 (2%)
Intestine Large, Cecum	(48)	(50)	(50)	(49)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(49)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(49)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(49)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(49)	(50)
Leiomyoma				2 (4%)	
Leiomyosarcoma				1 (2%)	
Liver	(50)	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus	1 (2%)				
Cholangiocarcinoma					1 (2%)
Cholangioma				1 (2%)	
Hepatocellular Adenoma		1 (2%)	2 (4%)		1 (2%)
Hepatocellular Carcinoma				1 (2%)	
Hepatocholangiocarcinoma		1 (2%)			
Leiomyosarcoma, Metastatic, Intestine Small, Jejunum				1 (2%)	
Mesentery	(0)	(0)	(0)	(1)	(1)
Cholangiocarcinoma, Metastatic, Liver					1 (100%)
Pancreas	(50)	(49)	(50)	(49)	(50)

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Adenocarcinoma, Metastatic, Uterus	1 (2%)				
Tubulostromal Carcinoma, Metastatic, Ovary			1 (2%)		
Salivary Glands	(49)	(50)	(50)	(49)	(49)
Stomach, Forestomach	(50)	(50)	(50)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver					1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)	(50)
Leiomyosarcoma		1 (2%)			
CARDIOVASCULAR SYSTEM					
Blood Vessel	(50)	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM					
Adrenal Cortex	(50)	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		2 (4%)	1 (2%)		
Pheochromocytoma Malignant			1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		1 (2%)	1 (2%)	1 (2%)
Parathyroid Gland	(45)	(45)	(37)	(47)	(43)
Pituitary Gland	(50)	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	12 (24%)	15 (30%)	12 (24%)	9 (18%)	12 (24%)
Pars Distalis, Carcinoma	1 (2%)				1 (2%)
Thyroid Gland	(50)	(50)	(49)	(50)	(50)
C-cell, Adenoma	12 (24%)	8 (16%)	7 (14%)	9 (18%)	5 (10%)
C-cell, Carcinoma	1 (2%)				2 (4%)
GENERAL BODY SYSTEM					
None					

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GENITAL SYSTEM					
Clitoral Gland	(49)	(50)	(50)	(49)	(50)
Ovary	(50)	(50)	(50)	(49)	(50)
Schwannoma Malignant	1 (2%)				
Tubulostromal Adenoma					1 (2%)
Tubulostromal Carcinoma			1 (2%)		
Uterus	(50)	(50)	(50)	(49)	(50)
Adenocarcinoma	1 (2%)				
Polyp Stromal	3 (6%)	6 (12%)	5 (10%)	5 (10%)	9 (18%)
Sarcoma Stromal	1 (2%)			1 (2%)	
Schwannoma Malignant				2 (4%)	
Squamous Cell Carcinoma, Metastatic, Vagina				1 (2%)	
Squamous Cell Papilloma				1 (2%)	
Tubulostromal Carcinoma, Metastatic, Ovary			1 (2%)		
Cervix, Schwannoma Malignant		1 (2%)			
Endometrium, Polyp, Glandular	2 (4%)				1 (2%)
Vagina	(0)	(0)	(1)	(2)	(0)
Schwannoma Malignant			1 (100%)	1 (50%)	
Squamous Cell Carcinoma				1 (50%)	
HEMATOPOIETIC SYSTEM					
Bone Marrow	(50)	(50)	(50)	(50)	(50)
Lymph Node	(0)	(0)	(0)	(5)	(1)
Lumbar, Squamous Cell Carcinoma, Metastatic, Vagina				1 (20%)	
Lymph Node, Mandibular	(49)	(50)	(50)	(48)	(49)
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)	(50)
Schwannoma Malignant, Metastatic, Uterus				1 (2%)	
Spleen	(50)	(50)	(50)	(50)	(50)
Adenocarcinoma, Metastatic, Uterus	1 (2%)				
Thymus	(49)	(48)	(50)	(48)	(48)

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INTEGUMENTARY SYSTEM					
Mammary Gland	(50)	(50)	(50)	(49)	(50)
Adenocarcinoma	4 (8%)	2 (4%)	5 (10%)	2 (4%)	1 (2%)
Adenoma		1 (2%)	2 (4%)	1 (2%)	
Fibroadenoma	23 (46%)	25 (50%)	21 (42%)	20 (41%)	16 (32%)
Fibroadenoma, Multiple	10 (20%)	9 (18%)	5 (10%)	8 (16%)	4 (8%)
Myoepithelioma		1 (2%)			1 (2%)
Skin	(50)	(50)	(50)	(49)	(50)
Basal Cell Adenoma					1 (2%)
Neural Crest Tumor		1 (2%)			
Subcutaneous Tissue, Fibrosarcoma			2 (4%)	1 (2%)	1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)				
Subcutaneous Tissue, Lipoma			1 (2%)		
Subcutaneous Tissue, Neural Crest Tumor			1 (2%)		
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)				
MUSCULOSKELETAL SYSTEM					
Bone	(50)	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(1)	(0)	(0)
Sarcoma			1 (100%)		
NERVOUS SYSTEM					
Brain	(50)	(49)	(50)	(50)	(50)
Glioma Malignant	1 (2%)			1 (2%)	
Granular Cell Tumor Benign					1 (2%)
RESPIRATORY SYSTEM					
Lung	(50)	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			1 (2%)		
Carcinoma, Metastatic, Thyroid Gland					1 (2%)

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Neural Crest Tumor, Metastatic, Skin		1 (2%)			
Neuroendocrine Tumor, Malignant, Metastatic, Uncertain Primary Site	1 (2%)				
Nose	(50)	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM					
Eye	(50)	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(1)	(0)	(0)	(0)
Adenoma		1 (100%)			
URINARY SYSTEM					
Kidney	(50)	(50)	(50)	(50)	(50)
Lipoma		1 (2%)			
Nephroblastoma			1 (2%)		
Urinary Bladder	(50)	(49)	(50)	(49)	(49)
SYSTEMIC LESIONS					
Multiple Organ	*(50)	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				2 (4%)	
Leukemia Granulocytic	1 (2%)				
Lymphoma Malignant	1 (2%)	2 (4%)	3 (6%)		2 (4%)

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* Number of animals with any tissue examined microscopically

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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	44	46	46	43	39
Total Primary Neoplasms	77	79	75	71	61
Total Animals with Benign Neoplasms	40	44	39	41	36
Total Benign Neoplasms	63	71	59	58	53
Total Animals with Malignant Neoplasms	13	6	14	10	7
Total Malignant Neoplasms	14	7	15	13	8
Total Animals with Metastatic Neoplasms	2	1	1	3	2
Total Metastatic Neoplasms	4	1	2	4	4
Total Animals with Malignant Neoplasms Uncertain Primary Site					
Total Animals with Neoplasms Uncertain- Benign or Malignant		1	1		
Total Uncertain Neoplasms		1	1		

*** END OF REPORT ***

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

b - Primary tumors: all tumors except metastatic tumors