

TDMS No. 88148 - 06

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

Date Report Requested: 07/18/2008

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 08:29:30

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 01/29/03 / 01/30/03

Species/Strain: RATS/SD

Lab: BAT

F2_R8

C Number: C88148C
Lock Date: 09/22/2005
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed			1	
Dosing Accident	1			1
Moribund Sacrifice	10	12	14	14
Natural Death	11	29	31	33
Survivors				
Terminal Sacrifice	28	9	4	2
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Cholangiocarcinoma		3 (6%)	4 (8%)	5 (10%)
Cholangiocarcinoma, Multiple		1 (2%)		1 (2%)
Cholangioma			1 (2%)	
Hepatocellular Adenoma		1 (2%)		
Hepatocholangiocarcinoma, Multiple				1 (2%)
Mesentery	(0)	(0)	(0)	(1)
Transitional Epithelial Carcinoma, Metastatic, Kidney				1 (100%)
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Squamous Cell Carcinoma	1 (2%)	4 (8%)	4 (8%)	5 (10%)
Gingival, Squamous Cell Carcinoma, Multiple		1 (2%)		
Pancreas	(50)	(49)	(50)	(50)
Transitional Epithelial Carcinoma, Metastatic, Kidney				1 (2%)
Acinus, Adenoma	5 (10%)	1 (2%)		

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

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Acinus, Adenoma, Multiple Salivary Glands	4 (8%) (50)	(50)	(49)	(50)
Schwannoma Malignant	1 (2%)	2 (4%)		1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma		1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Tissue Nos			1 (2%)	
Schwannoma Benign		3 (6%)		
Schwannoma Malignant, Metastatic, Tissue Nos			1 (2%)	
Epicardium, Sarcoma, Metastatic, Tissue Nos		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)		2 (4%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	5 (10%)	4 (8%)	6 (12%)	6 (12%)
Pheochromocytoma Benign, Multiple		1 (2%)		
Pheochromocytoma Malignant		1 (2%)		
Bilateral, Pheochromocytoma Benign		1 (2%)		1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)			
Parathyroid Gland	(43)	(48)	(44)	(44)
Adenoma	1 (2%)			
Pituitary Gland	(50)	(50)	(50)	(49)
Schwannoma Malignant, Metastatic, Eye	1 (2%)			
Pars Distalis, Adenoma	13 (26%)	6 (12%)	7 (14%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)	1 (2%)		
C-cell, Adenoma	12 (24%)	2 (4%)	1 (2%)	4 (8%)
C-cell, Carcinoma	1 (2%)	1 (2%)		

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Follicular Cell, Adenoma		2 (4%)	3 (6%)	3 (6%)
Follicular Cell, Adenoma, Multiple		1 (2%)	1 (2%)	1 (2%)
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(2)	(3)
Mediastinum, Fibrosarcoma			1 (50%)	
Mediastinum, Sarcoma		1 (100%)		
Mediastinum, Schwannoma Malignant			1 (50%)	3 (100%)
GENITAL SYSTEM				
Coagulating Gland	(50)	(50)	(50)	(49)
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(49)
Squamous Cell Papilloma		1 (2%)	1 (2%)	1 (2%)
Prostate	(50)	(50)	(50)	(50)
Adenoma	3 (6%)			
Adenoma, Multiple	2 (4%)			
Carcinoma				1 (2%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Transitional Epithelial Carcinoma, Multiple				1 (2%)
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	1 (2%)	1 (2%)	1 (2%)	
Interstitial Cell, Adenoma, Multiple	1 (2%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(49)	(50)
Lymph Node	(38)	(28)	(29)	(41)
Mediastinal, Fibrosarcoma, Metastatic, Tissue Nos			1 (3%)	
Mediastinal, Thymoma Malignant, Metastatic, Thymus				1 (2%)
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Lymph Node, Mesenteric	(50)	(48)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(48)	(48)	(46)	(48)

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Hemangioma		1 (2%)		
Thymoma Malignant				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)	2 (4%)		1 (2%)
Keratoacanthoma	2 (4%)			
Squamous Cell Papilloma		1 (2%)		
Trichoepithelioma			1 (2%)	
Pinna, Neural Crest Tumor	1 (2%)			
Subcutaneous Tissue, Fibroma	5 (10%)			
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)			
Subcutaneous Tissue, Schwannoma Malignant		1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(2)	(0)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Benign	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)	1 (2%)	
Alveolar/Bronchiolar Carcinoma	1 (2%)			
Carcinoma, Metastatic, Thyroid Gland	1 (2%)			
Cystic Keratinizing Epithelioma		6 (12%)	5 (10%)	13 (26%)
Cystic Keratinizing Epithelioma, Multiple		8 (16%)	26 (52%)	24 (48%)
Hemangiosarcoma, Metastatic, Skin	1 (2%)			
Hepatocholangiocarcinoma, Metastatic,				1 (2%)

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Liver				
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Transitional Epithelial Carcinoma, Metastatic, Kidney				1 (2%)
Nose	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(1)	(0)	(0)
Eye	(48)	(50)	(50)	(50)
Schwannoma Malignant	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Schwannoma Malignant			1 (2%)	
Schwannoma Malignant, Metastatic, Eye	1 (2%)			
Lacrimal Gland	(0)	(1)	(0)	(0)
Zymbal's Gland	(1)	(0)	(1)	(0)
Carcinoma	1 (100%)		1 (100%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Transitional Epithelium, Carcinoma				1 (2%)
Ureter	(41)	(31)	(42)	(49)
Urethra	(50)	(50)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	1 (2%)			
Lymphoma Malignant	1 (2%)	1 (2%)	1 (2%)	4 (8%)

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* Number of animals with any tissue examined microscopically

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Tumor Summary for Males				
Total Animals with Primary Neoplasms (b)	44	39	39	46
Total Primary Neoplasms	71	62	67	80
Total Animals with Benign Neoplasms	40	31	35	41
Total Benign Neoplasms	61	45	54	56
Total Animals with Malignant Neoplasms	9	15	13	19
Total Malignant Neoplasms	9	17	13	24
Total Animals with Metastatic Neoplasms	3	2	2	3
Total Metastatic Neoplasms	4	2	3	5
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant	1			
Total Uncertain Neoplasms	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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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed			1	
Dosing Accident	1		1	
Moribund Sacrifice	15	12	10	11
Natural Death	9	8	19	22
Survivors				
Moribund Sacrifice			1	
Terminal Sacrifice	25	30	18	17
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(50)	(48)	(50)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(49)
Carcinoma	1 (2%)			
Intestine Small, Ileum	(50)	(49)	(49)	(49)
Intestine Small, Jejunum	(50)	(49)	(50)	(49)
Leiomyosarcoma		1 (2%)		
Liver	(50)	(50)	(49)	(49)
Carcinoma, Metastatic, Pancreas	1 (2%)		1 (2%)	
Cholangiocarcinoma	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Hepatocellular Adenoma	2 (4%)		1 (2%)	2 (4%)
Hepatocellular Carcinoma		1 (2%)		
Mesentery	(3)	(2)	(1)	(3)
Carcinoma, Metastatic, Pancreas	1 (33%)			
Schwannoma Malignant				1 (33%)
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Squamous Cell Carcinoma			4 (8%)	5 (10%)
Gingival, Squamous Cell Carcinoma, Multiple				1 (2%)
Pancreas	(50)	(49)	(49)	(49)
Carcinoma, Metastatic, Intestine Small, Duodenum	1 (2%)			
Duct, Carcinoma	1 (2%)		1 (2%)	

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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Salivary Glands	(50)	(49)	(50)	(49)
Stomach, Forestomach	(50)	(49)	(50)	(49)
Leiomyosarcoma			1 (2%)	
Squamous Cell Carcinoma		1 (2%)		1 (2%)
Squamous Cell Papilloma				2 (4%)
Squamous Cell Papilloma, Multiple				1 (2%)
Stomach, Glandular	(50)	(49)	(49)	(49)
Carcinoma, Metastatic, Pancreas	1 (2%)			
Tooth	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(49)	(49)
Sarcoma			1 (2%)	
Schwannoma Benign		1 (2%)		
Schwannoma Malignant				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Adenoma	1 (2%)	1 (2%)	3 (6%)	4 (8%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Pheochromocytoma Benign, Multiple			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(49)
Adenoma		1 (2%)	1 (2%)	
Parathyroid Gland	(46)	(46)	(46)	(45)
Adenoma				1 (2%)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	13 (26%)	11 (22%)	4 (8%)	6 (12%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(50)	(49)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)			
C-cell, Adenoma	9 (18%)	9 (18%)	11 (22%)	1 (2%)
C-cell, Carcinoma	1 (2%)	1 (2%)		
Follicular Cell, Adenoma				1 (2%)

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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
GENERAL BODY SYSTEM				
Peritoneum	(0)	(1)	(1)	(0)
Carcinoma, Metastatic, Pancreas			1 (100%)	
Sarcoma		1 (100%)		
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Ovary	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas	1 (2%)		1 (2%)	
Granulosa Cell Tumor Malignant	1 (2%)			
Schwannoma Malignant			1 (2%)	
Thecoma Benign		1 (2%)	2 (4%)	
Oviduct	(2)	(0)	(3)	(2)
Uterus	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Intestine Small, Duodenum	1 (2%)			
Carcinoma, Metastatic, Pancreas			1 (2%)	
Polyp Stromal	6 (12%)	10 (20%)	10 (20%)	10 (20%)
Polyp Stromal, Multiple		1 (2%)		
Sarcoma Stromal				1 (2%)
Squamous Cell Carcinoma	1 (2%)	1 (2%)		
Squamous Cell Papilloma				1 (2%)
Cervix, Fibroma			1 (2%)	
Endometrium, Carcinoma	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Endometrium, Polyp Stromal	2 (4%)			
Vagina	(2)	(2)	(0)	(4)
Sarcoma Stromal, Metastatic, Uterus				1 (25%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(1)	(0)	(4)	(2)
Lymph Node, Mandibular	(50)	(49)	(49)	(49)
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Carcinoma, Metastatic, Pancreas			1 (2%)	
Spleen	(50)	(50)	(49)	(49)
Carcinoma, Metastatic, Pancreas	1 (2%)			

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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Thymus	(50)	(50)	(47)	(50)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)		
Carcinoma	4 (8%)	1 (2%)		
Fibroadenoma	23 (46%)	21 (42%)	20 (40%)	12 (24%)
Fibroadenoma, Multiple	8 (16%)	9 (18%)	4 (8%)	8 (16%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma				1 (2%)
Subcutaneous Tissue, Fibrosarcoma				1 (2%)
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(2)	(1)	(0)	(0)
Rhabdomyosarcoma	1 (50%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Benign		1 (2%)		
Peripheral Nerve	(2)	(1)	(0)	(1)
Ganglioneuroma		1 (100%)		
Schwannoma Malignant	1 (50%)			
Squamous Cell Carcinoma, Metastatic, Oral Mucosa				1 (100%)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(49)	(49)
Carcinoma, Metastatic, Mammary Gland	1 (2%)			
Cystic Keratinizing Epithelioma		4 (8%)	7 (14%)	4 (8%)
Cystic Keratinizing Epithelioma, Multiple		2 (4%)	19 (39%)	35 (71%)
Sarcoma, Metastatic, Heart			1 (2%)	
Schwannoma Malignant, Metastatic, Heart				1 (2%)
Nose	(50)	(50)	(50)	(50)

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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Trachea Schwannoma Malignant, Metastatic, Heart	(50)	(50)	(50)	(50) 1 (2%)
SPECIAL SENSES SYSTEM				
Ear	(0)	(0)	(1)	(0)
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland Carcinoma	(0)	(1) 1 (100%)	(0)	(0)
URINARY SYSTEM				
Kidney Carcinoma, Metastatic, Intestine Small, Duodenum	(50) 1 (2%)	(50)	(50)	(49)
Lipoma	1 (2%)			
Urethra	(50)	(50)	(50)	(49)
Urinary Bladder Carcinoma, Metastatic, Uterus	(50)	(50)	(50) 1 (2%)	(50) 1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		
Leukemia Mononuclear	1 (2%)			
Lymphoma Malignant		1 (2%)	2 (4%)	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	44	42	44
Total Primary Neoplasms	86	88	99	108
Total Animals with Benign Neoplasms	40	42	39	42
Total Benign Neoplasms	71	76	86	90
Total Animals with Malignant Neoplasms	13	10	12	12
Total Malignant Neoplasms	15	12	13	18
Total Animals with Metastatic Neoplasms	3		3	3
Total Metastatic Neoplasms	9		7	5
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant				
Total Uncertain Neoplasms				

*** 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