

**TDMS No.** 88148 - 06

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

**Date Report Requested:** 04/15/2009

**Test Type:** CHRONIC

3,3',4,4'-Tetrachloroazobenzene

**Time Report Requested:** 09:57:26

**Route:** GAVAGE

**CAS Number:** 14047-09-7

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

**Species/Strain:** RATS/SD

**Lab:** BAT

F3\_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:** 2.1.0

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Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
<b>Disposition Summary</b>				
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)
<b>CARDIOVASCULAR SYSTEM</b>				
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%)		
<b>ENDOCRINE SYSTEM</b>				
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%)
<b>GENERAL BODY SYSTEM</b>				
Tissue NOS	(0)	(1)	(2)	(3)
Mediastinum, Fibrosarcoma			1 (50%)	
Mediastinum, Sarcoma		1 (100%)		
Mediastinum, Schwannoma Malignant			1 (50%)	3 (100%)
<b>GENITAL SYSTEM</b>				
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%)			
<b>HEMATOPOIETIC SYSTEM</b>				
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%)
<b>INTEGUMENTARY SYSTEM</b>				
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%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(2)	(0)
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Benign	1 (2%)			
<b>RESPIRATORY SYSTEM</b>				
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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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Liver				
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Transitional Epithelial Carcinoma, Metastatic, Kidney				1 (2%)
Nose	(50)	(50)	(50)	(50)
<b>SPECIAL SENSES SYSTEM</b>				
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%)	
<b>URINARY SYSTEM</b>				
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)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	1 (2%)			
Lymphoma Malignant	1 (2%)	1 (2%)	1 (2%)	4 (8%)

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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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
<b>Tumor Summary for Males</b>				
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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Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
<b>Disposition Summary</b>				
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%)	1 (2%)
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)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(49)	(49)
Sarcoma			1 (2%)	
Schwannoma Benign		1 (2%)		
Schwannoma Malignant				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
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
<b>GENERAL BODY SYSTEM</b>				
Peritoneum	(0)	(1)	(1)	(0)
Carcinoma, Metastatic, Pancreas			1 (100%)	
Sarcoma		1 (100%)		
<b>GENITAL SYSTEM</b>				
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%)
<b>HEMATOPOIETIC SYSTEM</b>				
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)
<b>INTEGUMENTARY SYSTEM</b>				
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%)
<b>MUSCULOSKELETAL SYSTEM</b>				
Skeletal Muscle	(2)	(1)	(0)	(0)
Rhabdomyosarcoma	1 (50%)			
<b>NERVOUS SYSTEM</b>				
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%)
<b>RESPIRATORY SYSTEM</b>				
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%)
<b>SPECIAL SENSES SYSTEM</b>				
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)
<b>URINARY SYSTEM</b>				
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%)
<b>SYSTEMIC LESIONS</b>				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		
Leukemia Mononuclear	1 (2%)			
Lymphoma Malignant		1 (2%)	2 (4%)	2 (4%)

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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SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
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**Tumor Summary for Females**

<b>Total Animals with Primary Neoplasms (b)</b>	44	44	42	44
<b>Total Primary Neoplasms</b>	86	88	99	107
<b>Total Animals with Benign Neoplasms</b>	40	42	39	42
<b>Total Benign Neoplasms</b>	71	76	86	89
<b>Total Animals with Malignant Neoplasms</b>	13	10	12	12
<b>Total Malignant Neoplasms</b>	15	12	13	18
<b>Total Animals with Metastatic Neoplasms</b>	3		3	3
<b>Total Metastatic Neoplasms</b>	9		7	5
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>				
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>				
<b>Total Uncertain Neoplasms</b>				

\*\*\* 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