

TDMs No. 88148 - 06

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

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

Test Type: CHRONIC

Time Report Requested: 09:57:26

Route: GAVAGE

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

Species/Strain: RATS/SD

Lab: BAT

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)
Muscularis, Inflammation		1 [1.0]		
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Inflammation			1 [2.0]	
Necrosis				1 [3.0]
Intestine Large, Colon	(50)	(50)	(50)	(50)
Inflammation				1 [3.0]
Parasite Metazoan	6	6	3	5
Thrombosis				1 [2.0]
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Fibrosis				1 [4.0]
Necrosis			1 [2.0]	1 [4.0]
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Dysplasia			1 [3.0]	
Fibrosis			1 [3.0]	
Inflammation			1 [3.0]	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Necrosis			1 [4.0]	
Liver	(50)	(50)	(50)	(50)
Angiectasis	2 [2.5]	1 [1.0]	1 [2.0]	
Basophilic Focus	3	1	5	2
Cholangiofibrosis	1 [2.0]	3 [2.7]	2 [2.5]	

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Lab: BAT

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Clear Cell Focus	32	12	8	4
Congestion		1 [3.0]		
Degeneration, Cystic	2 [1.0]		1 [1.0]	1 [1.0]
Eosinophilic Focus	3	9	4	12
Fatty Change, Focal	1 [1.0]	2 [1.0]	7 [1.1]	3 [1.7]
Fatty Change, Diffuse	3 [1.3]	9 [1.7]	18 [1.9]	34 [1.6]
Fibrosis		1 [2.0]		4 [1.8]
Hematopoietic Cell Proliferation	5 [1.4]	40 [1.2]	37 [1.3]	30 [1.2]
Hepatodiaphragmatic Nodule		2	1	
Hyperplasia, Nodular		1	1	3
Inflammation, Granulomatous			1 [1.0]	
Inflammation, Chronic Active	40 [1.0]	37 [1.2]	30 [1.4]	28 [1.4]
Mixed Cell Focus	7	3	3	1
Necrosis	1 [1.0]	7 [2.6]	18 [1.9]	21 [1.8]
Pigmentation	1 [1.0]	4 [1.5]	5 [1.8]	6 [1.2]
Toxic Hepatopathy			5 [1.6]	8 [1.1]
Bile Duct, Cyst			1 [3.0]	4 [1.5]
Bile Duct, Dilatation		1 [1.0]	3 [3.7]	
Bile Duct, Fibrosis	10 [1.2]	3 [1.0]	1 [2.0]	3 [1.7]
Bile Duct, Hyperplasia	34 [1.4]	38 [1.6]	36 [1.7]	29 [2.0]
Bile Duct, Metaplasia				1 [1.0]
Centrilobular, Degeneration		10 [1.4]	23 [1.4]	24 [1.8]
Centrilobular, Fatty Change				1 [3.0]
Hepatocyte, Hypertrophy		6 [2.3]	11 [2.7]	22 [2.5]
Hepatocyte, Multinucleated			1 [1.0]	3 [1.3]
Oval Cell, Hyperplasia		4 [1.0]	8 [1.6]	5 [1.8]
Mesentery	(0)	(0)	(0)	(1)
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Hyperplasia, Cystic Keratinizing		4 [2.3]	18 [1.9]	11 [2.7]
Gingival, Hyperplasia, Squamous	2 [1.0]	21 [1.7]	24 [1.8]	31 [1.8]
Pancreas	(50)	(49)	(50)	(50)
Atrophy	4 [1.3]	13 [1.1]	10 [1.1]	10 [2.1]
Fibrosis	1 [3.0]			
Inflammation	1 [3.0]	7 [1.9]	7 [2.7]	3 [3.3]
Acinus, Hyperplasia	8 [2.9]	2 [2.0]	2 [1.0]	
Acinus, Necrosis		1 [1.0]		
Acinus, Vacuolization Cytoplasmic		16 [1.3]	30 [1.6]	13 [1.4]
Salivary Glands	(50)	(50)	(49)	(50)
Atrophy		1 [2.0]		3 [2.0]
Cyst			1 [4.0]	

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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
Fibrosis				1 [2.0]
Hyperplasia	1 [3.0]			
Inflammation	1 [1.0]			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Cyst				1 [3.0]
Inflammation	5 [1.4]	2 [2.5]	2 [2.0]	3 [1.0]
Mineralization	2 [2.5]		1 [1.0]	
Necrosis		3 [1.3]	1 [2.0]	1 [2.0]
Epithelium, Hyperplasia	8 [1.4]	36 [1.8]	44 [2.2]	45 [2.5]
Stomach, Glandular	(50)	(50)	(50)	(50)
Inflammation	2 [1.0]		1 [2.0]	
Mineralization	3 [2.3]	2 [1.5]	2 [2.0]	1 [2.0]
Necrosis			1 [2.0]	
Tooth	(50)	(50)	(50)	(50)
Peridontal Tissue, Inflammation	11 [1.4]	12 [1.3]	19 [1.4]	16 [1.4]
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	21 [1.7]	29 [2.7]	30 [2.6]	29 [2.6]
Mineralization	5 [2.2]	1 [1.0]	4 [1.8]	3 [1.7]
Aorta, Intima, Hyperplasia		1 [2.0]		
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	47 [1.5]	48 [1.6]	45 [1.5]	40 [1.7]
Inflammation	1 [2.0]		2 [2.5]	1 [2.0]
Mineralization	5 [1.8]		1 [1.0]	1 [2.0]
Necrosis				2 [2.0]
Thrombosis		4 [2.3]	2 [2.0]	4 [1.8]
Endocardium, Hyperplasia		1 [1.0]		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Angiectasis	1 [1.0]		1 [2.0]	
Degeneration	4 [1.0]	14 [1.4]	14 [1.4]	9 [1.8]
Hypertrophy	33 [1.7]	24 [1.5]	11 [1.6]	17 [1.4]
Infiltration Cellular, Mononuclear Cell		1 [2.0]		
Necrosis		2 [1.0]	4 [1.3]	13 [1.8]
Vacuolization Cytoplasmic	20 [1.2]	29 [1.2]	31 [1.5]	25 [1.7]

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Zona Fasciculata, Hyperplasia	14 [1.6]	22 [2.0]	19 [1.9]	21 [2.2]
Adrenal Medulla	(50)	(50)	(50)	(50)
Hyperplasia	10 [1.7]	8 [2.3]	5 [2.2]	6 [2.2]
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	1 [2.0]			1 [2.0]
Parathyroid Gland	(43)	(48)	(44)	(44)
Hyperplasia	8 [2.4]	9 [1.6]	6 [1.8]	2 [2.0]
Pituitary Gland	(50)	(50)	(50)	(49)
Angiectasis		1 [2.0]		
Hemorrhage				1 [4.0]
Hyperplasia	1 [1.0]			
Necrosis				2 [2.0]
Pars Distalis, Hyperplasia	18 [1.7]	10 [1.5]	13 [1.2]	10 [1.7]
Pars Intermedia, Necrosis		1 [2.0]		
Rathke's Cleft, Hyperplasia	1 [1.0]			
Thyroid Gland	(50)	(50)	(50)	(50)
Angiectasis		1 [3.0]		
Atrophy			1 [3.0]	
Fibrosis				1 [2.0]
Inflammation		3 [3.0]	9 [2.8]	14 [2.6]
C-cell, Hyperplasia	7 [2.7]	1 [2.0]	2 [2.5]	1 [3.0]
Follicle, Cyst	1 [1.0]			
Follicular Cell, Hyperplasia		2 [4.0]	10 [3.5]	12 [3.6]
Follicular Cell, Hypertrophy	2 [2.0]	2 [4.0]	6 [2.7]	6 [3.2]
GENERAL BODY SYSTEM				
Tissue NOS	(0)	(1)	(2)	(3)
GENITAL SYSTEM				
Coagulating Gland	(50)	(50)	(50)	(49)
Inflammation	1 [3.0]	3 [2.3]	2 [2.5]	4 [3.5]
Metaplasia, Squamous				1 [4.0]
Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 [3.0]	3 [3.7]	2 [3.5]
Inflammation	3 [1.7]			
Preputial Gland	(50)	(50)	(50)	(49)
Ectasia	1 [2.0]			

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Hyperplasia, Squamous	2 [2.0]	3 [2.0]	1 [2.0]	4 [1.5]
Inflammation	5 [2.0]			1 [1.0]
Prostate	(50)	(50)	(50)	(50)
Inflammation	13 [1.5]	12 [1.8]	7 [2.3]	16 [1.8]
Epithelium, Hyperplasia	12 [1.8]	4 [1.3]	3 [2.0]	2 [1.5]
Seminal Vesicle	(50)	(50)	(50)	(50)
Hyperplasia				2 [2.5]
Inflammation		2 [3.0]	1 [2.0]	4 [3.0]
Metaplasia, Squamous				3 [2.7]
Mineralization	1 [1.0]			
Testes	(50)	(50)	(50)	(50)
Inflammation	1 [2.0]	1 [2.0]		1 [3.0]
Necrosis		2 [2.5]	1 [4.0]	3 [2.7]
Thrombosis		1 [2.0]		
Germinal Epithelium, Degeneration	15 [2.3]	16 [2.7]	18 [2.2]	21 [2.7]
Germinal Epithelium, Mineralization	3 [1.3]	3 [1.3]	3 [1.3]	4 [1.3]
Interstitial Cell, Hyperplasia		1 [2.0]		1 [1.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(49)	(50)
Atrophy		1 [2.0]	2 [2.5]	2 [2.5]
Hyperplasia	12 [2.2]	7 [2.7]	21 [2.0]	19 [2.2]
Necrosis				1 [1.0]
Lymph Node	(38)	(28)	(29)	(41)
Pigmentation		1 [1.0]		
Deep Cervical, Atrophy				1 [4.0]
Deep Cervical, Ectasia				1 [2.0]
Deep Cervical, Hematopoietic Cell Proliferation	1 [3.0]			
Mediastinal, Atrophy	2 [2.5]			1 [4.0]
Mediastinal, Ectasia		1 [2.0]		1 [2.0]
Mediastinal, Hemorrhage			1 [4.0]	1 [1.0]
Mediastinal, Hyperplasia, Lymphoid		1 [3.0]		3 [2.0]
Mediastinal, Infiltration Cellular, Histiocyte		1 [2.0]		
Pancreatic, Hyperplasia, Lymphoid		1 [2.0]		
Lymph Node, Mandibular	(49)	(50)	(49)	(50)
Atrophy	5 [2.0]	1 [2.0]		7 [2.3]

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Lab: BAT

SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Congestion		1 [2.0]		
Ectasia		1 [2.0]		
Hyperplasia, Lymphoid	2 [2.0]	6 [2.2]	1 [2.0]	2 [2.0]
Infiltration Cellular, Histiocyte			1 [2.0]	
Necrosis			2 [2.0]	
Pigmentation	1 [1.0]			2 [1.5]
Lymph Node, Mesenteric	(50)	(48)	(50)	(50)
Atrophy		1 [2.0]	1 [2.0]	5 [2.6]
Hyperplasia, Lymphoid		2 [2.0]	2 [2.0]	
Inflammation, Granulomatous				1 [2.0]
Pigmentation	1 [1.0]	24 [1.2]	25 [1.1]	20 [1.2]
Spleen	(50)	(50)	(50)	(50)
Atrophy	1 [2.0]			
Congestion			1 [2.0]	
Hematopoietic Cell Proliferation	38 [1.5]	48 [1.5]	44 [1.5]	41 [1.4]
Pigmentation	38 [1.4]	39 [1.2]	40 [1.5]	35 [1.3]
Thrombosis	1 [4.0]			
Lymphoid Follicle, Atrophy	5 [2.6]	4 [2.0]	5 [2.2]	12 [2.5]
Thymus	(48)	(48)	(46)	(48)
Atrophy	45 [3.1]	47 [3.3]	44 [3.5]	47 [3.4]
Inflammation				1 [2.0]
Thymocyte, Hyperplasia	1 [3.0]			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Mineralization	1 [2.0]			
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	2	3	2	4
Hyperplasia	2 [2.0]		1 [1.0]	
Inflammation	1 [3.0]	1 [3.0]	2 [3.0]	2 [3.0]
Ulcer		1 [4.0]	1 [2.0]	1 [4.0]
Hair Follicle, Hyperplasia		1 [2.0]		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hyperostosis				1 [3.0]

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SPRAGUE-DAWLEY RATS MALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Tendon, Inflammation			1 [2.0]	1 [3.0]
Skeletal Muscle	(0)	(0)	(2)	(0)
Hemorrhage			1 [3.0]	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Edema		1 [1.0]		
Gliosis		2 [2.0]		
Hemorrhage	1 [2.0]			2 [1.5]
Necrosis		4 [2.3]	1 [2.0]	3 [2.7]
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Congestion	1 [3.0]	2 [2.0]		
Fibrosis		1 [2.0]		
Foreign Body	1			
Hemorrhage	1 [2.0]			
Inflammation, Granulomatous	7 [1.1]	1 [1.0]	2 [1.0]	5 [1.2]
Inflammation, Chronic Active	6 [2.2]	6 [2.0]	6 [1.8]	5 [1.2]
Mineralization	1 [3.0]			
Necrosis	1 [2.0]	1 [2.0]		
Pigmentation	3 [1.0]	16 [1.3]	12 [1.3]	16 [1.1]
Alveolar Epithelium, Hyperplasia	2 [2.5]	3 [2.7]		2 [2.5]
Alveolar Epithelium, Metaplasia, Bronchiolar	1 [1.0]	32 [2.0]	32 [1.9]	34 [2.1]
Alveolar Epithelium, Metaplasia, Squamous		14 [2.0]	22 [1.9]	22 [3.0]
Alveolus, Infiltration Cellular, Histiocyte	23 [1.3]	34 [1.8]	35 [1.8]	35 [2.0]
Smooth Muscle, Hyperplasia, Focal	1 [2.0]			
Nose	(50)	(50)	(50)	(50)
Foreign Body	2			
Inflammation	10 [1.5]	5 [1.2]	9 [1.0]	9 [1.1]
Nasolacrimal Duct, Hyperplasia			1 [2.0]	

SPECIAL SENSES SYSTEM

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Ear	(0)	(1)	(0)	(0)
External Ear, Hyperplasia, Squamous		1 [3.0]		
Eye	(48)	(50)	(50)	(50)
Anterior Chamber, Inflammation	1 [1.0]	2 [2.5]	1 [1.0]	1 [3.0]
Cornea, Degeneration		1 [2.0]		
Cornea, Hyperplasia, Squamous	1 [2.0]			
Cornea, Inflammation	3 [2.3]	12 [2.0]	5 [1.2]	2 [2.0]
Cornea, Mineralization		1 [2.0]		
Lens, Cataract			1 [1.0]	
Optic Nerve, Infiltration Cellular, Mononuclear Cell			1 [1.0]	
Retina, Atrophy				1 [3.0]
Retina, Degeneration	1 [4.0]	1 [3.0]	6 [1.5]	2 [3.0]
Harderian Gland	(50)	(50)	(50)	(50)
Atrophy	1 [4.0]			1 [2.0]
Inflammation		1 [3.0]		
Lacrimal Gland	(0)	(1)	(0)	(0)
Cytoplasmic Alteration		1 [4.0]		
Zymbal's Gland	(1)	(0)	(1)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Mineralization	22 [1.2]	20 [1.1]	24 [1.1]	24 [1.1]
Nephropathy	50 [2.6]	50 [2.3]	47 [2.2]	48 [2.0]
Cortex, Cyst	2 [3.0]	3 [2.3]	1 [2.0]	2 [2.5]
Pelvis, Dilatation				1 [2.0]
Pelvis, Inflammation	1 [1.0]	2 [2.0]		2 [2.0]
Pelvis, Transitional Epithelium, Hyperplasia	1 [1.0]	1 [1.0]	1 [1.0]	1 [4.0]
Renal Tubule, Hyperplasia, Atypical Transitional Epithelium, Hyperplasia	1 [1.0]		1 [1.0]	
Ureter	(41)	(31)	(42)	(49)
Transitional Epithelium, Hyperplasia				3 [2.3]
Urethra	(50)	(50)	(50)	(50)
Transitional Epithelium, Hyperplasia				2 [2.0]
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation	1 [3.0]	1 [2.0]	2 [2.0]	

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SPRAGUE-DAWLEY RATS MALE

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10 MG/KG

30 MG/KG

100 MG/KG

*** END OF MALE ***

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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)
Necrosis				1 [3.0]
Intestine Large, Colon	(50)	(50)	(50)	(50)
Parasite Metazoan	6	2		3
Intestine Small, Duodenum	(50)	(50)	(50)	(49)
Intestine Small, Ileum	(50)	(49)	(49)	(49)
Intestine Small, Jejunum	(50)	(49)	(50)	(49)
Liver	(50)	(50)	(49)	(49)
Angiectasis		4 [1.0]	3 [1.3]	5 [1.4]
Basophilic Focus	14	10	9	7
Cholangiofibrosis		1 [1.0]		11 [1.6]
Clear Cell Focus	13	22	9	7
Degeneration, Cystic		2 [1.0]	3 [1.3]	
Eosinophilic Focus	3	27	31	38
Fatty Change, Focal	2 [1.0]	2 [1.0]	2 [1.0]	9 [1.3]
Fatty Change, Diffuse		3 [1.0]	10 [1.3]	10 [1.6]
Fibrosis	1 [2.0]		2 [2.5]	6 [1.7]
Hematopoietic Cell Proliferation	28 [1.1]	42 [1.1]	32 [1.1]	37 [1.2]
Hepatodiaphragmatic Nodule	1		1	1
Hyperplasia, Nodular	1	3	11	22
Inflammation, Chronic Active	29 [1.1]	29 [1.1]	32 [1.2]	30 [1.4]
Mixed Cell Focus	6	16	14	16
Necrosis	3 [2.7]	6 [1.5]	10 [1.4]	10 [2.2]

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Necrosis, Focal				2 [1.0]
Pigmentation	1 [3.0]	17 [1.2]	32 [1.6]	40 [2.1]
Thrombosis	1 [4.0]		1 [4.0]	
Toxic Hepatopathy		4 [1.0]	14 [1.5]	25 [2.2]
Bile Duct, Cyst	3 [1.3]	4 [1.8]	5 [1.4]	12 [1.6]
Bile Duct, Fibrosis	1 [1.0]	1 [1.0]	5 [1.0]	1 [1.0]
Bile Duct, Hyperplasia	12 [1.1]	26 [1.2]	29 [1.6]	38 [1.8]
Centrilobular, Degeneration	1 [2.0]	2 [1.0]	18 [1.8]	17 [1.5]
Hepatocyte, Hypertrophy	4 [1.5]	33 [1.8]	38 [2.3]	42 [2.6]
Hepatocyte, Multinucleated		2 [1.0]	1 [1.0]	28 [1.2]
Oval Cell, Hyperplasia		7 [1.0]	24 [1.3]	36 [1.8]
Serosa, Fibrosis		1 [1.0]		
Mesentery	(3)	(2)	(1)	(3)
Thrombosis			1 [2.0]	
Fat, Necrosis	1 [3.0]	1 [3.0]		2 [3.0]
Oral Mucosa	(50)	(50)	(50)	(50)
Gingival, Hyperplasia, Cystic Keratinizing		4 [2.0]	9 [2.1]	13 [2.5]
Gingival, Hyperplasia, Squamous		8 [1.8]	24 [1.4]	24 [1.4]
Pancreas	(50)	(49)	(49)	(49)
Atrophy		11 [1.2]	12 [1.6]	13 [2.0]
Inflammation	1 [1.0]	1 [1.0]	4 [2.3]	6 [2.5]
Acinus, Hyperplasia			1 [2.0]	1 [1.0]
Acinus, Vacuolization Cytoplasmic		27 [1.7]	33 [1.9]	40 [2.1]
Duct, Atypia Cellular			1 [2.0]	
Salivary Glands	(50)	(49)	(50)	(49)
Atrophy	1 [2.0]	1 [2.0]		2 [2.5]
Fibrosis		1 [2.0]		
Duct, Cyst				1 [1.0]
Stomach, Forestomach	(50)	(49)	(50)	(49)
Cyst				2 [3.5]
Inflammation	1 [1.0]	3 [2.0]	5 [1.6]	7 [2.3]
Mineralization	2 [1.0]	2 [1.5]	1 [1.0]	
Necrosis			3 [1.7]	2 [2.0]
Epithelium, Hyperplasia		32 [1.7]	46 [2.4]	46 [2.5]
Stomach, Glandular	(50)	(49)	(49)	(49)
Inflammation	1 [1.0]			
Mineralization		1 [1.0]	1 [2.0]	
Tooth	(50)	(50)	(50)	(50)
Peridontal Tissue, Inflammation	5 [1.2]	10 [1.2]	14 [1.1]	9 [1.4]

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

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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

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Inflammation	1 [1.0]	10 [1.9]	14 [2.1]	16 [2.4]
Mineralization	2 [1.0]	1 [1.0]	2 [2.5]	1 [1.0]
Thrombosis				1 [3.0]
Heart	(50)	(50)	(49)	(49)
Cardiomyopathy	12 [1.0]	16 [1.1]	13 [1.0]	24 [1.1]
Dilatation				1 [3.0]
Inflammation			1 [3.0]	1 [2.0]
Mineralization			1 [3.0]	
Necrosis			1 [3.0]	1 [2.0]
Thrombosis			1 [2.0]	3 [2.7]
Endocardium, Hyperplasia	2 [1.5]			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Atrophy		1 [3.0]	1 [2.0]	
Degeneration	13 [1.5]	12 [1.7]	17 [1.5]	16 [1.5]
Hypertrophy	41 [1.5]	31 [1.4]	30 [1.6]	30 [1.5]
Inflammation				1 [2.0]
Necrosis	1 [2.0]		7 [1.9]	5 [1.8]
Thrombosis		1 [1.0]	1 [1.0]	1 [1.0]
Vacuolization Cytoplasmic	7 [1.3]	16 [1.5]	13 [1.5]	15 [1.6]
Zona Fasciculata, Hyperplasia	14 [1.6]	20 [1.9]	25 [1.9]	21 [1.8]
Adrenal Medulla	(50)	(50)	(50)	(49)
Hyperplasia	11 [1.8]	5 [2.2]	3 [1.3]	6 [1.3]
Islets, Pancreatic	(50)	(50)	(50)	(49)
Hyperplasia				1 [1.0]
Parathyroid Gland	(46)	(46)	(46)	(45)
Hyperplasia				2 [1.0]
Pituitary Gland	(50)	(50)	(50)	(50)
Necrosis	1 [1.0]		2 [1.5]	
Pigmentation	1 [1.0]			
Pars Distalis, Hyperplasia	20 [1.6]	13 [1.8]	12 [1.7]	19 [1.6]
Pars Intermedia, Hyperplasia			1 [1.0]	
Thyroid Gland	(50)	(49)	(50)	(50)
Inflammation			2 [3.0]	4 [2.3]

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
C-cell, Hyperplasia	12 [1.7]	5 [2.2]	3 [1.7]	4 [2.3]
Follicle, Cyst		1 [2.0]		1 [2.0]
Follicular Cell, Hyperplasia		1 [2.0]	3 [3.0]	3 [3.3]
Follicular Cell, Hypertrophy		1 [2.0]	2 [1.5]	4 [2.0]
GENERAL BODY SYSTEM				
Peritoneum	(0)	(1)	(1)	(0)
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Cyst	5 [2.2]	1 [2.0]	6 [2.0]	
Hyperplasia, Squamous		1 [2.0]	3 [2.0]	
Inflammation	3 [2.0]			
Ovary	(50)	(50)	(50)	(50)
Cyst	12 [1.8]	8 [2.0]	13 [1.8]	12 [2.0]
Inflammation		1 [4.0]	2 [4.0]	5 [3.6]
Necrosis				1 [1.0]
Oviduct	(2)	(0)	(3)	(2)
Cyst			2 [2.0]	
Fibrosis	1 [4.0]			
Inflammation	2 [3.5]		1 [3.0]	2 [3.5]
Metaplasia, Squamous	1 [3.0]			
Uterus	(50)	(50)	(50)	(50)
Adenomyosis				1 [2.0]
Angiectasis		1 [2.0]	1 [2.0]	2 [2.0]
Cyst				2 [2.5]
Hemorrhage			1 [3.0]	1 [3.0]
Hydrometra				1 [3.0]
Inflammation	4 [2.3]	5 [2.4]	3 [3.7]	3 [3.0]
Endometrium, Hyperplasia, Adenomatous	1 [4.0]			
Endometrium, Hyperplasia, Cystic	15 [2.3]	4 [1.8]	5 [1.8]	6 [1.8]
Endometrium, Metaplasia, Squamous	20 [2.8]	28 [2.6]	22 [2.5]	22 [2.4]
Vagina	(2)	(2)	(0)	(4)
Fibrosis				1 [3.0]
Hyperplasia, Squamous				1 [4.0]
Inflammation				1 [4.0]

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b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Epithelium, Atypia Cellular	1 [2.0]			
Epithelium, Hyperplasia	2 [2.0]	2 [1.5]		1 [3.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Atrophy				1 [4.0]
Hyperplasia	36 [3.1]	41 [2.6]	40 [2.8]	45 [2.8]
Myelofibrosis			1 [2.0]	1 [2.0]
Lymph Node	(1)	(0)	(4)	(2)
Pancreatic, Hemorrhage			1 [2.0]	
Popliteal, Inflammation, Chronic Active				1 [4.0]
Popliteal, Necrosis				1 [3.0]
Thoracic, Hyperplasia, Lymphoid			1 [3.0]	
Lymph Node, Mandibular	(50)	(49)	(49)	(49)
Atrophy				4 [2.8]
Hyperplasia, Lymphoid			2 [3.0]	
Infiltration Cellular, Plasma Cell	1 [3.0]			
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Atrophy			4 [3.3]	6 [3.0]
Atrophy, Lymphoid				2 [1.0]
Pigmentation	14 [1.0]	32 [1.3]	32 [1.2]	30 [1.3]
Spleen	(50)	(50)	(49)	(49)
Accessory Spleen	1			
Hematopoietic Cell Proliferation	41 [2.3]	47 [2.2]	45 [1.9]	45 [1.9]
Necrosis, Fibrinoid		1 [2.0]		
Pigmentation	31 [1.2]	44 [1.5]	42 [1.6]	47 [1.6]
Lymphoid Follicle, Atrophy	3 [1.3]	4 [2.3]	8 [2.6]	10 [2.3]
Thymus	(50)	(50)	(47)	(50)
Atrophy	47 [2.8]	49 [3.6]	46 [3.9]	50 [3.9]
Hyperplasia, Lymphoid	1 [3.0]			
Inflammation, Granulomatous				1 [3.0]
Vein, Thrombosis				1 [2.0]
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Dilatation		1 [2.0]		
Galactocele	3 [3.0]			

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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

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Hyperplasia	4 [1.8]	11 [1.6]	11 [1.4]	4 [1.8]
Inflammation				1 [3.0]
Pigmentation		1 [4.0]		
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion				1
Hyperplasia, Squamous				1 [2.0]
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(2)	(1)	(0)	(0)
Inflammation		1 [4.0]		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Hemorrhage			2 [1.5]	
Necrosis				1 [3.0]
Peripheral Nerve	(2)	(1)	(0)	(1)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(49)	(49)
Congestion	1 [3.0]			
Inflammation, Suppurative	1 [3.0]			
Inflammation, Chronic Active	4 [1.3]	5 [1.4]	1 [1.0]	4 [1.3]
Metaplasia, Cartilagenous	1 [1.0]			
Necrosis	1 [2.0]	1 [2.0]		
Pigmentation	1 [1.0]	11 [1.0]	21 [1.4]	26 [1.1]
Thrombosis			1 [1.0]	1 [1.0]
Alveolar Epithelium, Hyperplasia	5 [1.6]	1 [1.0]		
Alveolar Epithelium, Metaplasia, Bronchiolar		21 [1.4]	26 [1.5]	35 [1.8]
Alveolar Epithelium, Metaplasia, Squamous	2 [1.5]	4 [2.5]	18 [2.8]	30 [2.6]
Alveolus, Infiltration Cellular, Histiocyte	36 [1.6]	23 [1.5]	29 [1.6]	33 [1.9]
Artery, Hypertrophy				1 [2.0]
Serosa, Inflammation, Granulomatous			1 [4.0]	
Nose	(50)	(50)	(50)	(50)

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Test Type: CHRONIC

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Route: GAVAGE

CAS Number: 14047-09-7

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

Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Inflammation Trachea	(50)	7 [1.1] (50)	6 [1.2] (50)	8 [1.5] (50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(0)	(1)	(0)
External Ear, Hyperplasia, Squamous			1 [3.0]	
Eye	(50)	(50)	(50)	(50)
Synechia				1 [1.0]
Anterior Chamber, Inflammation			1 [2.0]	
Cornea, Inflammation	2 [1.0]			2 [4.0]
Lens, Cataract				1 [1.0]
Retina, Degeneration	1 [2.0]		4 [1.5]	1 [2.0]
Harderian Gland	(50)	(50)	(50)	(50)
Inflammation				1 [2.0]
Zymbal's Gland	(0)	(1)	(0)	(0)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(49)
Accumulation, Hyaline Droplet		2 [1.0]		
Casts	1 [1.0]			2 [1.0]
Infarct		1 [4.0]	4 [2.3]	2 [3.5]
Inflammation, Diffuse		1 [4.0]	3 [3.3]	2 [2.5]
Mineralization	36 [1.1]	32 [1.0]	28 [1.0]	29 [1.1]
Nephropathy	30 [1.2]	39 [1.5]	39 [1.4]	42 [1.5]
Thrombosis				1 [2.0]
Cortex, Cyst		1 [2.0]		1 [2.0]
Papilla, Necrosis			1 [4.0]	2 [2.0]
Pelvis, Dilatation			2 [2.5]	1 [3.0]
Pelvis, Inflammation	1 [2.0]	2 [1.5]	1 [1.0]	2 [2.0]
Pelvis, Transitional Epithelium, Hyperplasia	1 [2.0]	1 [2.0]	2 [2.0]	3 [2.7]
Renal Tubule, Hyperplasia, Atypical	1 [1.0]		1 [1.0]	
Renal Tubule, Necrosis			3 [2.0]	3 [2.0]
Urethra	(50)	(50)	(50)	(49)
Inflammation		1 [2.0]		
Transitional Epithelium, Hyperplasia		1 [1.0]	1 [1.0]	1 [4.0]
Transitional Epithelium, Metaplasia,				1 [1.0]

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**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**
3,3',4,4'-Tetrachloroazobenzene
CAS Number: 14047-09-7

Test Type: CHRONIC

Time Report Requested: 09:57:26

Route: GAVAGE

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

Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 MG/KG	10 MG/KG	30 MG/KG	100 MG/KG
Squamous				
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation		1 [2.0]		1 [1.0]
Metaplasia, Squamous		1 [3.0]		
Transitional Epithelium, Hyperplasia	1 [2.0]			

*** END OF REPORT ***

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