

**TDMS No.** 88148 - 07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

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

3,3',4,4'-Tetrachloroazobenzene

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

**Date Report Reqsted:** 02/27/2008

**Time Report Reqsted:** 09:10:26

**First Dose M/F:** 02/04/03 / 02/03/03

**Lab:** BAT

F\_1\_ M3

**C Number:** C88148C

**Lock Date:** 08/31/2005

**Cage Range:** ALL

**Date Range:** ALL

**Reasons For Removal:** 25022 ACCK 25021 TSAC 25020 NATD

25019 MSAC 25018 DACC

**Removal Date Range:** ALL

**Treatment Groups:** Include ALL

**TDMSE Version:** 1.9.1

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B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidentally Killed			1	
Dosing Accident	1		1	
Moribund Sacrifice	10	11	16	19
Natural Death	4	8	26	31
Survivors				
Terminal Sacrifice	35	31	5	
Animals Examined Microscopically	50	50	49	50

**ALIMENTARY SYSTEM**

Esophagus	(50)	(50)	(49)	(50)
Perforation	1 (2%)			
Epithelium, Necrosis	1 (2%)			
Periesophageal Tissue, Inflammation, Chronic Active	1 (2%)			
Gallbladder	(49)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid	2 (4%)			
Inflammation, Chronic Active	1 (2%)			
Intestine Large, Cecum	(50)	(50)	(49)	(50)
Cyst			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(49)	(50)
Intestine Small, Duodenum	(50)	(50)	(49)	(50)
Intussusception		1 (2%)		
Intestine Small, Ileum	(50)	(50)	(49)	(50)
Intestine Small, Jejunum	(50)	(50)	(49)	(50)
Liver	(50)	(50)	(49)	(50)
Amyloid Deposition		3 (6%)	2 (4%)	
Atypia Cellular		1 (2%)		
Basophilic Focus		4 (8%)	2 (4%)	2 (4%)
Clear Cell Focus	12 (24%)	6 (12%)	1 (2%)	
Congestion			1 (2%)	1 (2%)
Eosinophilic Focus	5 (10%)	1 (2%)	3 (6%)	
Hematopoietic Cell Proliferation	2 (4%)	9 (18%)	9 (18%)	3 (6%)
Hemorrhage	1 (2%)		1 (2%)	
Infarct	1 (2%)	1 (2%)		
Infiltration Cellular, Lymphoid	7 (14%)	16 (32%)	11 (22%)	2 (4%)
Inflammation, Chronic Active	35 (70%)	32 (64%)	17 (35%)	14 (28%)
Mineralization	1 (2%)	1 (2%)		
Mixed Cell Focus	4 (8%)	6 (12%)		2 (4%)

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

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3,3',4,4'-Tetrachloroazobenzene

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Pigmentation	2 (4%)	1 (2%)		
Tension Lipidosis	2 (4%)	5 (10%)	12 (24%)	15 (30%)
Thrombosis	1 (2%)			
Bile Duct, Hyperplasia	1 (2%)			
Hepatocyte, Necrosis	5 (10%)	4 (8%)	2 (4%)	
Hepatocyte, Vacuolization Cytoplasmic	31 (62%)	31 (62%)	23 (47%)	11 (22%)
Mesentery	(5)	(5)	(4)	(2)
Fat, Fibrosis	4 (80%)	2 (40%)		
Fat, Inflammation, Chronic Active	3 (60%)	5 (100%)	3 (75%)	1 (50%)
Fat, Mineralization	1 (20%)	2 (40%)		
Fat, Necrosis	4 (80%)	3 (60%)	1 (25%)	
Oral Mucosa	(0)	(1)	(0)	(0)
Gingival, Inflammation, Chronic Active		1 (100%)		
Pancreas	(50)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid	6 (12%)	5 (10%)	1 (2%)	
Inflammation, Chronic Active		2 (4%)	1 (2%)	1 (2%)
Duct, Cyst	1 (2%)			
Salivary Glands	(50)	(50)	(49)	(50)
Degeneration	1 (2%)			
Infiltration Cellular, Lymphoid	43 (86%)	34 (68%)	22 (45%)	4 (8%)
Mineralization			1 (2%)	
Stomach, Forestomach	(50)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid			1 (2%)	
Inflammation, Chronic Active	6 (12%)	7 (14%)	6 (12%)	3 (6%)
Epithelium, Cyst	1 (2%)			
Epithelium, Hyperplasia	8 (16%)	21 (42%)	33 (67%)	44 (88%)
Epithelium, Ulcer	5 (10%)	3 (6%)	3 (6%)	2 (4%)
Stomach, Glandular	(50)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid	3 (6%)	20 (40%)	19 (39%)	15 (30%)
Infiltration Cellular, Mast Cell		1 (2%)		
Inflammation, Chronic Active		1 (2%)	1 (2%)	1 (2%)
Mineralization		4 (8%)	6 (12%)	13 (26%)
Epithelium, Hyperplasia	1 (2%)			
Epithelium, Hyperplasia, Focal		10 (20%)	20 (41%)	34 (68%)
Epithelium, Ulcer			1 (2%)	
Epithelium, Glands, Cyst	5 (10%)	18 (36%)	21 (43%)	26 (52%)
Glands, Cyst			1 (2%)	1 (2%)
Tongue	(0)	(1)	(0)	(0)
Cyst, Multiple		1 (100%)		
Artery, Inflammation, Chronic Active		1 (100%)		
Tooth	(8)	(3)	(0)	(0)
Dysplasia	3 (38%)			
Malformation	4 (50%)	3 (100%)		

## CARDIOVASCULAR SYSTEM

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 09:10:26

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 02/04/03 / 02/03/03

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Blood Vessel	(50)	(50)	(49)	(50)
Hyperplasia	1 (2%)			
Aorta, Inflammation, Chronic Active		2 (4%)		
Aorta, Mineralization			6 (12%)	8 (16%)
Heart	(50)	(50)	(49)	(50)
Cardiomyopathy	5 (10%)	5 (10%)	17 (35%)	9 (18%)
Hyperplasia, Atypical		2 (4%)		
Infiltration Cellular, Lymphoid	1 (2%)			
Inflammation, Chronic Active	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Mineralization		2 (4%)		1 (2%)
Necrosis				3 (6%)
Artery, Hyperplasia	1 (2%)			
Artery, Inflammation, Chronic Active	2 (4%)	2 (4%)		
Myocardium, Necrosis		1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(49)	(50)
Accessory Adrenal Cortical Nodule		2 (4%)	4 (8%)	
Amyloid Deposition			1 (2%)	
Hematopoietic Cell Proliferation			1 (2%)	
Hyperplasia	1 (2%)			
Hypertrophy	9 (18%)	5 (10%)	1 (2%)	
Bilateral, Accessory Adrenal Cortical Nodule				1 (2%)
Subcapsular, Hyperplasia	45 (90%)	38 (76%)	37 (76%)	27 (54%)
Islets, Pancreatic	(50)	(50)	(49)	(50)
Hyperplasia	5 (10%)	3 (6%)		
Parathyroid Gland	(45)	(47)	(46)	(44)
Cyst	1 (2%)			
Cyst, Multiple		1 (2%)		
Pituitary Gland	(49)	(50)	(48)	(50)
Pars Distalis, Cyst	2 (4%)	4 (8%)	1 (2%)	3 (6%)
Pars Distalis, Cyst, Multiple	1 (2%)			1 (2%)
Thyroid Gland	(50)	(50)	(49)	(50)
Inflammation, Chronic Active	2 (4%)			
Follicle, Cyst		1 (2%)		
Follicle, Degeneration	1 (2%)			

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Coagulating Gland	(50)	(50)	(49)	(50)
Atrophy	1 (2%)			
Dilatation	9 (18%)	16 (32%)	36 (73%)	47 (94%)
Fibrosis		6 (12%)	23 (47%)	30 (60%)
Infiltration Cellular, Lymphoid	3 (6%)	6 (12%)	2 (4%)	
Inflammation, Chronic Active		6 (12%)	22 (45%)	33 (66%)
Epithelium, Hyperplasia	1 (2%)	1 (2%)	5 (10%)	1 (2%)
Ductus Deferens	(50)	(50)	(49)	(50)
Inflammation, Chronic Active			3 (6%)	
Epididymis	(50)	(50)	(49)	(50)
Atrophy	1 (2%)			
Cyst		1 (2%)	1 (2%)	
Granuloma Sperm	1 (2%)	3 (6%)	6 (12%)	8 (16%)
Infiltration Cellular, Lymphoid	40 (80%)	30 (60%)	21 (43%)	15 (30%)
Inflammation, Chronic Active		3 (6%)	2 (4%)	
Preputial Gland	(50)	(50)	(49)	(50)
Atrophy	20 (40%)	23 (46%)	24 (49%)	9 (18%)
Infiltration Cellular, Lymphoid	18 (36%)	3 (6%)		
Inflammation, Chronic Active		7 (14%)	3 (6%)	2 (4%)
Duct, Ectasia	19 (38%)	15 (30%)	23 (47%)	10 (20%)
Prostate	(50)	(50)	(49)	(50)
Fibrosis		1 (2%)	3 (6%)	1 (2%)
Infiltration Cellular, Lymphoid	42 (84%)	43 (86%)	26 (53%)	9 (18%)
Inflammation, Chronic Active	3 (6%)	10 (20%)	27 (55%)	44 (88%)
Mineralization	1 (2%)			
Artery, Hyperplasia	1 (2%)			
Artery, Inflammation, Chronic Active	1 (2%)			
Epithelium, Hyperplasia	4 (8%)		1 (2%)	
Seminal Vesicle	(50)	(50)	(49)	(50)
Atrophy	1 (2%)			
Dilatation	12 (24%)	14 (28%)	38 (78%)	41 (82%)
Fibrosis		3 (6%)	18 (37%)	29 (58%)
Inflammation, Chronic Active		4 (8%)	14 (29%)	22 (44%)
Epithelium, Hyperplasia		1 (2%)	5 (10%)	1 (2%)
Testes	(50)	(50)	(49)	(50)
Mineralization	1 (2%)	1 (2%)	3 (6%)	2 (4%)
Germinal Epithelium, Degeneration	8 (16%)	1 (2%)	3 (6%)	3 (6%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(49)	(50)
Hyperplasia	13 (26%)	10 (20%)	17 (35%)	20 (40%)
Myelofibrosis			1 (2%)	
Erythroid Cell, Hyperplasia	1 (2%)			
Lymph Node	(2)	(1)	(2)	(0)

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Mediastinal, Hyperplasia, Lymphoid			1 (50%)	
Lymph Node, Mandibular	(49)	(50)	(48)	(49)
Hematopoietic Cell Proliferation			1 (2%)	
Hyperplasia, Lymphoid	3 (6%)	7 (14%)	7 (15%)	
Hyperplasia, Plasma Cell		2 (4%)	1 (2%)	
Necrosis, Lymphoid			1 (2%)	
Lymph Node, Mesenteric	(50)	(49)	(48)	(50)
Hyperplasia, Lymphoid	1 (2%)		1 (2%)	
Spleen	(50)	(50)	(49)	(49)
Amyloid Deposition		4 (8%)	2 (4%)	
Atrophy	2 (4%)	9 (18%)	30 (61%)	39 (80%)
Hematopoietic Cell Proliferation	18 (36%)	16 (32%)	12 (24%)	7 (14%)
Artery, Hyperplasia	1 (2%)			
Artery, Inflammation, Chronic Active	1 (2%)			
Lymphoid Follicle, Necrosis, Lymphoid			1 (2%)	
Thymus	(41)	(42)	(40)	(49)
Atrophy	11 (27%)	15 (36%)	30 (75%)	45 (92%)
Cyst	5 (12%)	2 (5%)	5 (13%)	5 (10%)
Cyst, Multiple	19 (46%)	28 (67%)	27 (68%)	35 (71%)
Ectopic Parathyroid Gland	8 (20%)	8 (19%)	3 (8%)	9 (18%)
Inflammation, Chronic Active			1 (3%)	
Thymocyte, Necrosis			2 (5%)	3 (6%)
<b>INTEGUMENTARY SYSTEM</b>				
Skin	(50)	(50)	(49)	(50)
Cyst Epithelial Inclusion		1 (2%)		
Hemorrhage			1 (2%)	
Inflammation, Acute				1 (2%)
Inflammation, Chronic Active	3 (6%)	13 (26%)	12 (24%)	5 (10%)
Dermis, Fibrosis	3 (6%)	12 (24%)	12 (24%)	4 (8%)
Dermis, Metaplasia, Osseous		1 (2%)		
Epidermis, Hyperkeratosis		1 (2%)		
Epidermis, Hyperplasia	3 (6%)	13 (26%)	12 (24%)	6 (12%)
Epidermis, Ulcer	3 (6%)	13 (26%)	11 (22%)	6 (12%)
Hair Follicle, Dilatation	7 (14%)	10 (20%)	13 (27%)	28 (56%)
Sebaceous Gland, Atrophy	13 (26%)	10 (20%)	20 (41%)	29 (58%)
Subcutaneous Tissue, Inflammation, Chronic Active				1 (2%)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(49)	(50)
Osteopetrosis		2 (4%)	1 (2%)	

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Skeletal Muscle	(50)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid	2 (4%)			
Inflammation, Chronic Active		1 (2%)		
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(49)	(50)
Degeneration		1 (2%)		
Inflammation, Chronic Active	1 (2%)			
Neuron, Necrosis			1 (2%)	
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(49)	(50)
Congestion			1 (2%)	
Fibrosis		1 (2%)	1 (2%)	
Infiltration Cellular, Lymphoid		4 (8%)		
Inflammation, Chronic Active		2 (4%)	1 (2%)	1 (2%)
Alveolar Epithelium, Hyperplasia	5 (10%)	6 (12%)	2 (4%)	2 (4%)
Alveolus, Infiltration Cellular, Histiocyte	4 (8%)	6 (12%)	1 (2%)	
Mediastinum, Inflammation, Chronic Active		1 (2%)		
Nose	(50)	(50)	(49)	(50)
Hemorrhage			1 (2%)	
Inflammation, Chronic Active			1 (2%)	
Nasolacrimal Duct, Inflammation, Chronic Active	1 (2%)			
Nasolacrimal Duct, Squamous Epithelium, Hyperplasia	2 (4%)			
Pleura	(1)	(1)	(1)	(0)
Trachea	(50)	(50)	(49)	(50)
Epithelium, Mineralization				1 (2%)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(50)	(50)	(49)	(50)
Atrophy			1 (2%)	2 (4%)
Anterior Chamber, Cornea, Inflammation, Suppurative	1 (2%)			
Cornea, Inflammation, Chronic Active	1 (2%)			
Cornea, Pigmentation			1 (2%)	
Optic Nerve, Inflammation, Chronic Active		1 (2%)		
Harderian Gland	(50)	(50)	(49)	(50)
Degeneration				1 (2%)

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Hyperplasia	3 (6%)	2 (4%)	1 (2%)	
Infiltration Cellular, Lymphoid	33 (66%)	26 (52%)	7 (14%)	1 (2%)
Inflammation, Chronic Active		1 (2%)		
Necrosis			1 (2%)	
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(49)	(50)
Hydronephrosis	1 (2%)	5 (10%)	17 (35%)	29 (58%)
Infarct	4 (8%)		1 (2%)	
Infiltration Cellular, Lymphoid	39 (78%)	38 (76%)	12 (24%)	3 (6%)
Inflammation, Acute				3 (6%)
Inflammation, Chronic Active			5 (10%)	2 (4%)
Metaplasia, Osseous	2 (4%)	3 (6%)	1 (2%)	1 (2%)
Mineralization	40 (80%)	43 (86%)	40 (82%)	42 (84%)
Nephropathy	47 (94%)	45 (90%)	28 (57%)	24 (48%)
Thrombosis				4 (8%)
Artery, Inflammation, Chronic Active	2 (4%)	1 (2%)		
Cortex, Cyst	11 (22%)	6 (12%)	2 (4%)	
Cortex, Cyst, Multiple			1 (2%)	
Glomerulus, Amyloid Deposition		6 (12%)	4 (8%)	1 (2%)
Papilla, Necrosis		3 (6%)	3 (6%)	
Pelvis, Hyperplasia	1 (2%)			1 (2%)
Renal Tubule, Dilatation	1 (2%)	8 (16%)	31 (63%)	43 (86%)
Renal Tubule, Hyperplasia	1 (2%)			
Ureter	(43)	(45)	(47)	(50)
Dilatation		6 (13%)	22 (47%)	42 (84%)
Inflammation, Chronic Active		3 (7%)	24 (51%)	39 (78%)
Urethra	(48)	(50)	(49)	(50)
Dilatation		1 (2%)	2 (4%)	2 (4%)
Inflammation, Chronic Active	1 (2%)		1 (2%)	
Artery, Hyperplasia	1 (2%)			
Artery, Inflammation, Chronic Active	1 (2%)			
Glands, Transitional Epithelium, Hyperplasia		17 (34%)	2 (4%)	
Transitional Epithelium, Inflammation, Chronic Active		1 (2%)		
Urinary Bladder	(50)	(50)	(49)	(50)
Infiltration Cellular, Lymphoid	25 (50%)	25 (50%)	4 (8%)	
Inflammation, Chronic Active		1 (2%)	1 (2%)	2 (4%)
Transitional Epithelium, Hyperplasia		1 (2%)		4 (8%)



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First Dose M/F: 02/04/03 / 02/03/03

Lab: BAT

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B6C3F1 MICE MALE

0 MG/KG

3 MG/KG

10 MG/KG

30 MG/KG

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\*\*\* END OF MALE \*\*\*

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
<b>Disposition Summary</b>				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident	1		1	1
Moribund Sacrifice	6	9	9	21
Natural Death	8	11	8	8
Survivors				
Natural Death				1
Terminal Sacrifice	35	30	32	19
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(49)	(50)	(50)	(50)
Perforation	1 (2%)		1 (2%)	1 (2%)
Gallbladder	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	3 (6%)	3 (6%)	2 (4%)	1 (2%)
Inflammation, Chronic Active			1 (2%)	
Intestine Large, Cecum	(49)	(50)	(49)	(50)
Inflammation, Chronic Active		1 (2%)		
Ulcer		1 (2%)		
Intestine Large, Colon	(49)	(50)	(49)	(50)
Intestine Large, Rectum	(49)	(50)	(50)	(50)
Inflammation, Chronic Active	1 (2%)			
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Intestine Small, Jejunum	(49)	(50)	(50)	(50)
Peyer's Patch, Hyperplasia, Lymphoid			1 (2%)	3 (6%)
Liver	(49)	(50)	(50)	(50)
Amyloid Deposition			2 (4%)	4 (8%)
Basophilic Focus	1 (2%)	6 (12%)	3 (6%)	1 (2%)
Clear Cell Focus	2 (4%)	1 (2%)	1 (2%)	
Eosinophilic Focus	2 (4%)		1 (2%)	1 (2%)
Hematopoietic Cell Proliferation	3 (6%)	9 (18%)	9 (18%)	21 (42%)
Infarct				3 (6%)
Infiltration Cellular, Histiocyte				1 (2%)
Infiltration Cellular, Lymphoid	38 (78%)	40 (80%)	38 (76%)	28 (56%)
Inflammation, Chronic Active	39 (80%)	37 (74%)	37 (74%)	32 (64%)
Mineralization		1 (2%)		1 (2%)
Mixed Cell Focus	3 (6%)	3 (6%)	4 (8%)	1 (2%)
Tension Lipidosis	4 (8%)	6 (12%)	4 (8%)	4 (8%)
Bile Duct, Hyperplasia		1 (2%)		2 (4%)
Bile Duct, Inflammation, Chronic Active				1 (2%)

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Hepatocyte, Necrosis	1 (2%)	1 (2%)	3 (6%)	3 (6%)
Hepatocyte, Vacuolization Cytoplasmic	33 (67%)	33 (66%)	35 (70%)	20 (40%)
Mesentery	(5)	(12)	(9)	(15)
Congestion			1 (11%)	
Fat, Cyst	1 (20%)			
Fat, Fibrosis	3 (60%)	6 (50%)	5 (56%)	6 (40%)
Fat, Inflammation, Chronic Active	2 (40%)	6 (50%)	4 (44%)	7 (47%)
Fat, Mineralization		1 (8%)	3 (33%)	
Fat, Necrosis	3 (60%)	5 (42%)	5 (56%)	8 (53%)
Pancreas	(49)	(50)	(50)	(50)
Basophilic Focus	1 (2%)			
Congestion				1 (2%)
Infiltration Cellular, Lymphoid	12 (24%)	5 (10%)	6 (12%)	3 (6%)
Inflammation, Chronic Active			2 (4%)	1 (2%)
Mineralization				1 (2%)
Acinus, Atrophy		1 (2%)		
Duct, Cyst		1 (2%)		
Duct, Cyst, Multiple				1 (2%)
Salivary Glands	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	36 (73%)	23 (46%)	13 (26%)	1 (2%)
Mineralization		1 (2%)		
Stomach, Forestomach	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	2 (4%)		2 (4%)	10 (20%)
Inflammation, Chronic Active	1 (2%)	4 (8%)	1 (2%)	1 (2%)
Mineralization				1 (2%)
Epithelium, Cyst		1 (2%)	2 (4%)	
Epithelium, Hyperplasia	8 (16%)	27 (54%)	38 (76%)	43 (86%)
Epithelium, Ulcer	1 (2%)	3 (6%)	1 (2%)	
Stomach, Glandular	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	1 (2%)	14 (28%)	30 (60%)	28 (56%)
Infiltration Cellular, Mast Cell	1 (2%)			
Inflammation, Chronic Active	2 (4%)		1 (2%)	1 (2%)
Mineralization	1 (2%)	4 (8%)	3 (6%)	3 (6%)
Epithelium, Erosion		1 (2%)		
Epithelium, Hyperplasia, Focal	1 (2%)	19 (38%)	26 (52%)	28 (56%)
Epithelium, Necrosis			1 (2%)	
Epithelium, Ulcer		1 (2%)		1 (2%)
Epithelium, Glands, Cyst	8 (16%)	19 (38%)	13 (26%)	22 (44%)
Tongue	(0)	(1)	(0)	(1)
Tooth	(2)	(0)	(0)	(0)
Malformation	2 (100%)			

CARDIOVASCULAR SYSTEM

Blood Vessel	(49)	(50)	(50)	(50)
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Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 09:10:26

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 02/04/03 / 02/03/03

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Aorta, Mineralization	1 (2%)	2 (4%)		1 (2%)
Heart	(49)	(50)	(50)	(50)
Cardiomyopathy	3 (6%)	5 (10%)	4 (8%)	9 (18%)
Hyperplasia, Atypical				1 (2%)
Inflammation, Chronic Active		1 (2%)		1 (2%)
Mineralization	3 (6%)	3 (6%)	3 (6%)	2 (4%)
Valve, Inflammation, Chronic Active		1 (2%)		
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(49)	(50)	(50)	(50)
Accessory Adrenal Cortical Nodule	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Cyst	1 (2%)			
Degeneration, Fatty				1 (2%)
Hematopoietic Cell Proliferation		2 (4%)	1 (2%)	
Hyperplasia	1 (2%)			
Hypertrophy	2 (4%)			
Inflammation, Chronic Active				1 (2%)
Subcapsular, Hyperplasia	48 (98%)	50 (100%)	47 (94%)	48 (96%)
Adrenal Medulla	(49)	(50)	(50)	(50)
Hyperplasia	2 (4%)		2 (4%)	
Islets, Pancreatic	(49)	(50)	(50)	(50)
Hyperplasia	1 (2%)			
Parathyroid Gland	(43)	(47)	(48)	(41)
Cyst		1 (2%)		
Cyst, Multiple		1 (2%)		1 (2%)
Pituitary Gland	(49)	(49)	(50)	(50)
Pars Distalis, Angiectasis	2 (4%)	1 (2%)	3 (6%)	2 (4%)
Pars Distalis, Cyst				1 (2%)
Pars Distalis, Hyperplasia	6 (12%)	5 (10%)	8 (16%)	5 (10%)
Thyroid Gland	(49)	(50)	(50)	(50)
Ectopic Thymus	1 (2%)		2 (4%)	
Infiltration Cellular, Lymphoid	1 (2%)			
C-cell, Hyperplasia			1 (2%)	
Follicle, Cyst	1 (2%)	1 (2%)		1 (2%)
Follicle, Degeneration	17 (35%)	28 (56%)	24 (48%)	20 (40%)

**GENERAL BODY SYSTEM**

None

**GENITAL SYSTEM**

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 09:10:26

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 02/04/03 / 02/03/03

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Clitoral Gland	(49)	(50)	(49)	(50)
Atrophy	25 (51%)	44 (88%)	37 (76%)	40 (80%)
Fibrosis				1 (2%)
Infiltration Cellular, Lymphoid		5 (10%)	6 (12%)	3 (6%)
Inflammation, Chronic Active	3 (6%)	4 (8%)	17 (35%)	25 (50%)
Duct, Cyst	5 (10%)	46 (92%)	43 (88%)	43 (86%)
Ovary	(49)	(50)	(50)	(50)
Angiectasis	3 (6%)			
Atrophy	29 (59%)	44 (88%)	47 (94%)	45 (90%)
Cyst	11 (22%)	8 (16%)	5 (10%)	4 (8%)
Cyst, Multiple	1 (2%)			
Infiltration Cellular, Lymphoid	2 (4%)			
Inflammation, Chronic Active		1 (2%)		
Mineralization	1 (2%)			
Pigmentation	2 (4%)			
Bilateral, Cyst		1 (2%)		
Oviduct	(0)	(0)	(1)	(0)
Inflammation, Chronic Active			1 (100%)	
Uterus	(49)	(50)	(50)	(50)
Cyst		1 (2%)	1 (2%)	
Infiltration Cellular, Lymphoid	1 (2%)			
Inflammation, Chronic Active			1 (2%)	
Endometrium, Hyperplasia, Cystic	45 (92%)	45 (90%)	45 (90%)	41 (82%)
Vagina	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	1 (2%)			1 (2%)
Infiltration Cellular, Polymorphonuclear	11 (22%)	21 (42%)	15 (30%)	18 (36%)
Inflammation, Chronic Active	2 (4%)		3 (6%)	
Epithelium, Atrophy	3 (6%)	2 (4%)	3 (6%)	3 (6%)
Epithelium, Hyperplasia		1 (2%)		
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	2 (4%)	8 (16%)	9 (18%)	16 (32%)
Myelofibrosis	16 (32%)	30 (60%)	33 (66%)	15 (30%)
Lymph Node	(7)	(8)	(9)	(16)
Bronchial, Hyperplasia, Lymphoid	1 (14%)			
Inguinal, Hyperplasia, Lymphoid	1 (14%)			
Inguinal, Pigmentation				1 (6%)
Mediastinal, Hematopoietic Cell Proliferation		1 (13%)		
Mediastinal, Hyperplasia, Lymphoid		1 (13%)	2 (22%)	1 (6%)
Mediastinal, Inflammation, Chronic Active			1 (11%)	
Mediastinal, Necrosis, Lymphoid	1 (14%)			
Pancreatic, Hematopoietic Cell Proliferation				1 (6%)
Pancreatic, Hyperplasia, Lymphoid				1 (6%)

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 09:10:26

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 02/04/03 / 02/03/03

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Pancreatic, Pigmentation				1 (6%)
Renal, Hyperplasia, Lymphoid				1 (6%)
Lymph Node, Mandibular	(49)	(49)	(50)	(49)
Hyperplasia, Lymphoid	10 (20%)	8 (16%)	9 (18%)	15 (31%)
Necrosis, Lymphoid	1 (2%)			1 (2%)
Pigmentation		1 (2%)	1 (2%)	2 (4%)
Lymph Node, Mesenteric	(48)	(49)	(48)	(49)
Hyperplasia, Lymphoid	3 (6%)		4 (8%)	2 (4%)
Mineralization		1 (2%)		
Artery, Mineralization		1 (2%)		
Spleen	(49)	(50)	(50)	(50)
Amyloid Deposition			1 (2%)	4 (8%)
Atrophy	1 (2%)	3 (6%)	6 (12%)	3 (6%)
Fibrosis		1 (2%)		
Hematopoietic Cell Proliferation	10 (20%)	25 (50%)	21 (42%)	33 (66%)
Hyperplasia, Lymphoid			1 (2%)	
Infarct				1 (2%)
Lymphoid Follicle, Hyperplasia	8 (16%)		1 (2%)	1 (2%)
Thymus	(48)	(48)	(45)	(48)
Atrophy	7 (15%)	15 (31%)	12 (27%)	25 (52%)
Cyst	9 (19%)	5 (10%)	4 (9%)	3 (6%)
Cyst, Multiple	21 (44%)	31 (65%)	33 (73%)	37 (77%)
Ectopic Parathyroid Gland	10 (21%)	11 (23%)	20 (44%)	5 (10%)
Ectopic Thyroid	1 (2%)			
Hyperplasia, Lymphoid	2 (4%)			
Infiltration Cellular, Histiocyte		1 (2%)		
Inflammation, Chronic Active		5 (10%)	12 (27%)	5 (10%)
Thymocyte, Necrosis	1 (2%)	1 (2%)		
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(49)	(50)	(50)	(50)
Skin	(49)	(50)	(50)	(50)
Inflammation, Chronic Active		2 (4%)	6 (12%)	11 (22%)
Dermis, Fibrosis		1 (2%)	4 (8%)	11 (22%)
Epidermis, Hyperplasia	1 (2%)	2 (4%)	4 (8%)	11 (22%)
Epidermis, Ulcer		1 (2%)	4 (8%)	11 (22%)
Hair Follicle, Dilatation	2 (4%)		11 (22%)	23 (46%)
Sebaceous Gland, Atrophy	6 (12%)	10 (20%)	11 (22%)	15 (30%)
Subcutaneous Tissue, Inflammation, Chronic Active			2 (4%)	
Subcutaneous Tissue, Metaplasia, Osseous			1 (2%)	
<b>MUSCULOSKELETAL SYSTEM</b>				

Test Type: CHRONIC

3,3',4,4'-Tetrachloroazobenzene

Time Report Requested: 09:10:26

Route: GAVAGE

CAS Number: 14047-09-7

First Dose M/F: 02/04/03 / 02/03/03

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Bone	(50)	(50)	(50)	(50)
Osteopetrosis				1 (2%)
Skeletal Muscle	(4)	(5)	(1)	(8)
Infiltration Cellular, Lymphoid	1 (25%)			
Inflammation, Chronic Active		1 (20%)		
Mineralization				1 (13%)
<b>NERVOUS SYSTEM</b>				
Brain	(49)	(50)	(50)	(50)
Compression	1 (2%)	1 (2%)		
Hydrocephalus	1 (2%)			
Infiltration Cellular, Lymphoid	1 (2%)			
Meninges, Hemorrhage		1 (2%)		
Neuron, Necrosis	2 (4%)			
Peripheral Nerve	(0)	(2)	(1)	(0)
Sciatic, Degeneration		1 (50%)		
Spinal Cord	(0)	(1)	(1)	(0)
Degeneration		1 (100%)	1 (100%)	
<b>RESPIRATORY SYSTEM</b>				
Lung	(49)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Infiltration Cellular, Lymphoid	4 (8%)	2 (4%)		2 (4%)
Infiltration Cellular, Polymorphonuclear		1 (2%)		
Inflammation, Chronic Active		3 (6%)	5 (10%)	7 (14%)
Alveolar Epithelium, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	4 (8%)
Alveolar Epithelium, Metaplasia, Squamous				1 (2%)
Alveolus, Infiltration Cellular, Histiocyte		3 (6%)	1 (2%)	6 (12%)
Artery, Mineralization		1 (2%)		
Artery, Mediastinum, Mineralization	1 (2%)	1 (2%)		
Bronchiole, Metaplasia, Squamous				1 (2%)
Mediastinum, Inflammation	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Inflammation, Chronic Active	4 (8%)			
Glands, Olfactory Epithelium, Dilatation				2 (4%)
Glands, Olfactory Epithelium, Hyperplasia	1 (2%)			
Olfactory Epithelium, Metaplasia	1 (2%)			
<b>SPECIAL SENSES SYSTEM</b>				
Ear	(1)	(0)	(1)	(2)

B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
Inflammation, Chronic Active	1 (100%)			
Eye	(49)	(50)	(50)	(49)
Atrophy	1 (2%)			
Cornea, Inflammation, Chronic Active				1 (2%)
Optic Nerve, Infiltration Cellular, Lymphoid			1 (2%)	1 (2%)
Optic Nerve, Pigmentation				1 (2%)
Harderian Gland	(49)	(50)	(49)	(49)
Atrophy	1 (2%)			
Hyperplasia	2 (4%)	3 (6%)	2 (4%)	2 (4%)
Infiltration Cellular, Lymphoid	32 (65%)	13 (26%)	7 (14%)	4 (8%)
Inflammation, Chronic Active	1 (2%)		2 (4%)	3 (6%)
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Hydronephrosis			5 (10%)	3 (6%)
Infarct	3 (6%)	6 (12%)	11 (22%)	2 (4%)
Infiltration Cellular, Lymphoid	39 (80%)	35 (70%)	37 (74%)	26 (52%)
Inflammation, Chronic Active				2 (4%)
Metaplasia, Osseous		2 (4%)		
Mineralization	6 (12%)	14 (28%)	13 (26%)	14 (28%)
Nephropathy	29 (59%)	32 (64%)	38 (76%)	41 (82%)
Cortex, Cyst	1 (2%)			
Cortex, Cyst, Multiple	1 (2%)			
Glomerulus, Amyloid Deposition			1 (2%)	5 (10%)
Papilla, Necrosis		1 (2%)	8 (16%)	2 (4%)
Pelvis, Metaplasia, Osseous				1 (2%)
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Renal Tubule, Dilatation	1 (2%)	5 (10%)	6 (12%)	7 (14%)
Renal Tubule, Pigmentation	1 (2%)			
Ureter	(0)	(1)	(0)	(2)
Transitional Epithelium, Hyperplasia				1 (50%)
Urethra	(49)	(50)	(49)	(49)
Dilatation			1 (2%)	
Infiltration Cellular, Lymphoid				1 (2%)
Inflammation, Suppurative			1 (2%)	
Glands, Transitional Epithelium, Hyperplasia		4 (8%)		3 (6%)
Urinary Bladder	(49)	(50)	(50)	(50)
Infiltration Cellular, Lymphoid	41 (84%)	30 (60%)	27 (54%)	25 (50%)
Inflammation, Chronic Active				2 (4%)
Transitional Epithelium, Hyperplasia				4 (8%)



**TDMS No.** 88148 - 07  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

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

3,3',4,4'-Tetrachloroazobenzene

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

**Date Report Requested:** 02/27/2008

**Time Report Requested:** 09:10:26

**First Dose M/F:** 02/04/03 / 02/03/03

**Lab:** BAT

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B6C3F1 MICE FEMALE	0 MG/KG	3 MG/KG	10 MG/KG	30 MG/KG
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\*\*\* END OF REPORT \*\*\*