C Number:	C20107
Lock Date:	07/14/2004
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Both
PWG Approval Date	NONE

Experiment Number: 20107-01
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
Test Compound: N,N-Dimethyl-p-toluidine
CAS Number: 99-97-8

Date Report Requested: 10/22/2014
Time Report Requested: 11:57:34
First Dose M/F: NA / NA
Lab: BAT

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Disposition Summary						
Animals Initially In Study	**10**	**10**	**10**	**10**	**10**	**10**
Early Deaths						
Moribund Sacrifice					**1**	**1**
Natural Death						**9**
Survivors						
Terminal Sacrifice	**10**	**10**	**10**	**10**	**9**	
Animals Examined Microscopically	**10**	**10**	**10**	**10**	**10**	**10**
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(10)
Hyperplasia, Lymphoid	1 (10%)					
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Basophilic Focus					2 (20%)	
Bile Duct, Hyperplasia				3 (30%)	1 (10%)	
Centrilobular, Fatty Change					1 (10%)	2 (20%)
Centrilobular, Hepatocyte, Necrosis					1 (10%)	10 (100%)
Fatty Change, Focal	1 (10%)					
Hematopoietic Cell Proliferation	4 (40%)	8 (80%)	10 (100%)	8 (80%)	7 (70%)	
Hepatocyte, Hypertrophy		2 (20%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
Hepatocyte, Necrosis	3 (30%)	3 (30%)	5 (50%)	3 (30%)	5 (50%)	
Hepatodiaphragmatic Nodule			1 (10%)	1 (10%)	1 (10%)	
Inflammation, Chronic Active	7 (70%)	10 (100%)	9 (90%)	6 (60%)	7 (70%)	2 (20%)
Pigmentation		4 (40%)	7 (70%)	9 (90%)	9 (90%)	

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

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Lymphocyte	9 (90%)				6 (60%)	
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Fibrosis					1 (10%)	
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						1 (10%)
Hyperplasia, Squamous				2 (20%)	2 (20%)	
Inflammation			1 (10%)		5 (50%)	9 (90%)
Mineralization					1 (10%)	1 (10%)
Ulcer			1 (10%)		1 (10%)	7 (70%)
Stomach, Glandular	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation					1 (10%)	
Ulcer						1 (10%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(10)	(10)
Heart	(10)	(0)	(0)	(0)	(10)	(10)
Cardiomyopathy	10 (100%)				6 (60%)	1 (10%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Mineralization					1 (10%)	
Vacuolization Cytoplasmic	10 (100%)				1 (10%)	
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(8)	(7)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(9)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)
GENERAL BODY SYSTEM						
None						

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

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
GENITAL SYSTEM						
Epididymis	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	2 (20%)					
Preputial Gland	(10)	(0)	(0)	(0)	(10)	(10)
Duct, Ectasia	1 (10%)					
Prostate	(10)	(0)	(0)	(0)	(10)	(10)
Epithelium, Hyperplasia	2 (20%)				2 (20%)	
Inflammation, Chronic Active					1 (10%)	
Seminal Vesicle	(10)	(0)	(0)	(0)	(10)	(8)
Testes	(10)	(0)	(0)	(0)	(10)	(10)
Atrophy					1 (10%)	
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Lymph Node	(1)	(0)	(0)	(0)	(1)	(0)
Mediastinal, Hyperplasia, Lymphoid	1 (100%)				1 (100%)	
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy					3 (30%)	6 (60%)
Necrosis, Lymphoid						2 (20%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Capsule, Fibrosis	1 (10%)	5 (50%)	10 (100%)	10 (100%)	9 (90%)	
Congestion		10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Hematopoietic Cell Proliferation	9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	9 (90%)
Lymph Follic, Atrophy				8 (80%)	10 (100%)	10 (100%)
Mesothelium, Hypertrophy	3 (30%)	5 (50%)	8 (80%)	10 (100%)	9 (90%)	
Pigmentation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Red Pulp, Atrophy					1 (10%)	10 (100%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage	1 (10%)					7 (70%)

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

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Thymocyte, Necrosis					1 (10%)	10 (100%)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(5)	(10)
Skin	(10)	(0)	(0)	(0)	(10)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(10)	(10)
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte	1 (10%)				1 (10%)	
Alveolus, Metaplasia, Squamous, Focal			1 (10%)			
Hemorrhage		1 (10%)				
Inflammation, Chronic Active	10 (100%)	8 (80%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
Thrombosis						2 (20%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Glands, Hyperplasia			10 (100%)	10 (100%)	9 (90%)	
Olfactory Epi, Degeneration		5 (50%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Olfactory Epi, Metaplasia				9 (90%)	9 (90%)	
Respirat Epith, Hyperplasia	1 (10%)	2 (20%)	7 (70%)	10 (100%)	9 (90%)	7 (70%)
Respirat Epith, Metaplasia, Squamous		8 (80%)	10 (100%)	10 (100%)	9 (90%)	1 (10%)
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation, Chronic Active	2 (20%)		2 (20%)	3 (30%)	3 (30%)	
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Antr Chamber, Inflammation, Suppurative					1 (10%)	
Cataract					1 (10%)	
Ciliary Body, Inflammation, Suppurative					1 (10%)	

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

F 344/N Rat MALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Cornea, Ulcer					1 (10%)	
Retina, Degeneration					1 (10%)	
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
Epithelium, Hyperplasia					1 (10%)	
Hemorrhage					1 (10%)	
Infiltration Cellular, Lymphocyte					1 (10%)	
Inflammation, Chronic Active					1 (10%)	
Pigmentation	2 (20%)				1 (10%)	9 (90%)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						2 (20%)
Mineralization	1 (10%)	4 (40%)	10 (100%)	10 (100%)	8 (80%)	
Nephropathy	9 (90%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)	3 (30%)
Papilla, Necrosis			7 (70%)	7 (70%)	9 (90%)	2 (20%)
Pigmentation		10 (100%)	10 (100%)	10 (100%)	9 (90%)	
Renal Tubule, Dilatation			2 (20%)	1 (10%)	3 (30%)	3 (30%)
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(9)
Hemorrhage						2 (22%)

END OF MALE DATA

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

F 344/N Rat FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Disposition Summary						
Animals Initially In Study	**10**	**10**	**10**	**10**	**10**	**10**
Early Deaths						
Moribund Sacrifice						**10**
Survivors						
Terminal Sacrifice	**10**	**10**	**10**	**10**	**10**	
Animals Examined Microscopically	**10**	**10**	**10**	**10**	**10**	**10**
ALIMENTARY SYSTEM						
Esophagus	(10)	(0)	(0)	(0)	(10)	(10)
Muscularis, Inflammation	1 (10%)					
Intestine Large, Cecum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Colon	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Large, Rectum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Duodenum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Ileum	(10)	(0)	(0)	(0)	(10)	(10)
Intestine Small, Jejunum	(10)	(0)	(0)	(0)	(10)	(10)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Angiectasis				1 (10%)		
Bile Duct, Hyperplasia					1 (10%)	
Centrilobular, Fatty Change						9 (90%)
Centrilobular, Hepatocyte, Necrosis					1 (10%)	7 (70%)
Clear Cell Focus					2 (20%)	
Fatty Change, Focal					1 (10%)	
Hematopoietic Cell Proliferation	5 (50%)	6 (60%)	8 (80%)	6 (60%)	9 (90%)	1 (10%)
Hepatocyte, Hypertrophy		1 (10%)	7 (70%)	9 (90%)	10 (100%)	10 (100%)
Hepatocyte, Necrosis	1 (10%)	6 (60%)	5 (50%)	7 (70%)	6 (60%)	2 (20%)
Hepatodiaphragmatic Nodule				1 (10%)	1 (10%)	
Inflammation, Chronic Active	8 (80%)	10 (100%)	10 (100%)	4 (40%)	5 (50%)	
Pigmentation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	

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

F 344/N Rat FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Pancreas	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Lymphocyte	7 (70%)				4 (40%)	1 (10%)
Salivary Glands	(10)	(0)	(0)	(0)	(10)	(10)
Stomach, Forestomach	(10)	(10)	(10)	(10)	(10)	(10)
Erosion				1 (10%)		
Inflammation				3 (30%)	2 (20%)	10 (100%)
Mineralization					1 (10%)	4 (40%)
Ulcer					1 (10%)	8 (80%)
Stomach, Glandular	(10)	(10)	(10)	(10)	(10)	(10)
Inflammation						1 (10%)
Inflammation, Granulomatous					1 (10%)	
Ulcer						2 (20%)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(0)	(0)	(0)	(10)	(10)
Heart	(10)	(10)	(10)	(10)	(10)	(10)
Cardiomyopathy	7 (70%)	4 (40%)	7 (70%)	7 (70%)	6 (60%)	2 (20%)
Inflammation	1 (10%)					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(0)	(0)	(0)	(10)	(10)
Hemorrhage						1 (10%)
Adrenal Medulla	(10)	(0)	(0)	(0)	(10)	(10)
Islets, Pancreatic	(10)	(0)	(0)	(0)	(10)	(10)
Parathyroid Gland	(9)	(0)	(0)	(0)	(9)	(8)
Pituitary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Thyroid Gland	(10)	(0)	(0)	(0)	(10)	(10)
Infiltration Cellular, Lymphocyte					1 (10%)	
GENERAL BODY SYSTEM						
None						

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

Experiment Number: 20107-01
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)
Test Compound: N,N-Dimethyl-p-toluidine
CAS Number: 99-97-8

Date Report Requested: 10/22/2014
Time Report Requested: 11:57:35
First Dose M/F: NA / NA
Lab: BAT

F 344/N Rat FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
GENITAL SYSTEM						
Clitoral Gland	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	2 (20%)				1 (10%)	
Ovary	(10)	(0)	(0)	(0)	(10)	(10)
Uterus	(10)	(0)	(0)	(0)	(10)	(10)
Endometrium, Hyperplasia, Cystic	1 (10%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia		10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Lymph Node, Mesenteric	(10)	(10)	(10)	(10)	(10)	(10)
Atrophy				1 (10%)	6 (60%)	5 (50%)
Necrosis, Lymphoid						1 (10%)
Spleen	(10)	(10)	(10)	(10)	(10)	(10)
Capsule, Fibrosis		3 (30%)	7 (70%)	10 (100%)	10 (100%)	
Congestion		2 (20%)	10 (100%)	10 (100%)	10 (100%)	
Hematopoietic Cell Proliferation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	9 (90%)
Lymph Follic, Atrophy					10 (100%)	10 (100%)
Mesothelium, Hypertrophy		1 (10%)	2 (20%)	9 (90%)	9 (90%)	1 (10%)
Pigmentation	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Red Pulp, Atrophy						10 (100%)
Thymus	(10)	(10)	(10)	(10)	(10)	(10)
Hemorrhage						2 (20%)
Thymocyte, Necrosis						10 (100%)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(0)	(0)	(0)	(10)	(10)
Skin	(10)	(0)	(0)	(0)	(10)	(10)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(0)	(0)	(0)	(10)	(10)

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

F 344/N Rat FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
NERVOUS SYSTEM						
Brain	(10)	(0)	(0)	(0)	(10)	(10)
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(10)	(10)	(10)	(10)
Alveolus, Infiltration Cellular, Histiocyte						2 (20%)
Hemorrhage						1 (10%)
Inflammation, Chronic Active	8 (80%)	5 (50%)	8 (80%)	8 (80%)	8 (80%)	2 (20%)
Nose	(10)	(10)	(10)	(10)	(10)	(10)
Glands, Hyperplasia		3 (30%)	9 (90%)	10 (100%)	10 (100%)	
Olfactory Epi, Degeneration		7 (70%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Olfactory Epi, Metaplasia				7 (70%)	10 (100%)	
Respirat Epith, Hyperplasia		1 (10%)	7 (70%)	10 (100%)	10 (100%)	1 (10%)
Respirat Epith, Metaplasia, Squamous			6 (60%)	10 (100%)	10 (100%)	7 (70%)
Trachea	(10)	(10)	(10)	(10)	(10)	(10)
SPECIAL SENSES SYSTEM						
Eye	(10)	(0)	(0)	(0)	(10)	(10)
Ciliary Body, Inflammation	1 (10%)					
Cornea, Inflammation	1 (10%)					
Retina, Atrophy	1 (10%)					
Retina, Degeneration	1 (10%)					
Harderian Gland	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	3 (30%)				2 (20%)	
Mineralization	1 (10%)					
Pigmentation	10 (100%)				8 (80%)	9 (90%)
Lacrimal Gland	(1)	(0)	(0)	(0)	(0)	(0)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Mineralization	9 (90%)	6 (60%)	6 (60%)	8 (80%)	8 (80%)	

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

F 344/N Rat FEMALE	0 MG/KG	62.5 MG/KG	125 MG/KG	250 MG/KG	500 MG/KG	1000 MG/KG
Nephropathy	2 (20%)	2 (20%)	9 (90%)	10 (100%)	10 (100%)	1 (10%)
Papilla, Necrosis				6 (60%)	2 (20%)	1 (10%)
Pigmentation		10 (100%)	10 (100%)	10 (100%)	10 (100%)	
Renal Tubule, Dilatation					1 (10%)	10 (100%)
Urinary Bladder	(10)	(0)	(0)	(0)	(10)	(10)
Inflammation	1 (10%)				1 (10%)	

** END OF REPORT **

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