

TDMS No. 20107 - 03

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

Date Report Requested: 01/24/2011

Test Type: CHRONIC

N,N-Dimethyl-p-toluidine

Time Report Requested: 10:59:00

Route: GAVAGE

CAS Number: 99-97-8

First Dose M/F: 10/20/04 / 10/21/04

Species/Strain: RATS/F 344/N

Lab: BAT

F1_R2

C Number: C20107
Lock Date: 02/20/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: NONE

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident		1	1	3
Moribund Sacrifice	11	7	11	7
Natural Death	2	5	7	19
Survivors				
Terminal Sacrifice	37	37	31	21
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)
Carcinoma		1 (2%)		
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)
Hepatocellular Adenoma			1 (2%)	1 (2%)
Hepatocellular Carcinoma			1 (2%)	6 (12%)
Mesentery	(7)	(5)	(2)	(1)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Sarcoma	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(1)	(0)	(1)
Squamous Cell Carcinoma				1 (100%)
Squamous Cell Papilloma		1 (100%)		
Tooth	(1)	(2)	(2)	(0)

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

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FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uncertain Primary Site	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			1 (2%)
Osteosarcoma, Metastatic, Bone		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	6 (12%)	2 (4%)	8 (16%)	4 (8%)
Pheochromocytoma Complex	1 (2%)	1 (2%)		
Pheochromocytoma Malignant	1 (2%)		3 (6%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	6 (12%)	4 (8%)	1 (2%)
Carcinoma	1 (2%)			
Parathyroid Gland	(49)	(49)	(45)	(48)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	23 (46%)	27 (54%)	18 (36%)	15 (30%)
Pars Distalis, Carcinoma	1 (2%)	1 (2%)		
Pars Intermedia, Carcinoma				1 (2%)
Thyroid Gland	(50)	(49)	(50)	(49)
Sarcoma, Metastatic, Salivary Glands	1 (2%)			
Bilateral, C-cell, Adenoma	1 (2%)		1 (2%)	1 (2%)
C-cell, Adenoma	10 (20%)	7 (14%)	7 (14%)	2 (4%)
C-cell, Carcinoma		1 (2%)		
Follicular Cell, Adenoma	1 (2%)		1 (2%)	3 (6%)
Follicular Cell, Carcinoma		2 (4%)	1 (2%)	2 (4%)

GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(2)	(0)
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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Carcinoma, Metastatic, Zymbal'S Gland			1 (50%)	

GENITAL SYSTEM

Coagulating Gland	(1)	(2)	(1)	(0)
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Prostate	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Bilateral, Interstitial Cell, Adenoma	29 (58%)	23 (46%)	33 (66%)	25 (50%)
Interstitial Cell, Adenoma	11 (22%)	13 (26%)	10 (20%)	12 (24%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(4)	(3)	(3)	(7)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Thymus	(50)	(48)	(48)	(47)

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(49)	(50)
Carcinoma		1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)		1 (2%)	1 (2%)
Basal Cell Carcinoma		1 (2%)	3 (6%)	
Fibroma	5 (10%)	3 (6%)	5 (10%)	3 (6%)
Fibroma, Multiple	1 (2%)	1 (2%)		

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Keratoacanthoma	3 (6%)	3 (6%)	1 (2%)	2 (4%)
Keratoacanthoma, Multiple			1 (2%)	
Lipoma		1 (2%)	1 (2%)	
Liposarcoma			1 (2%)	
Sarcoma		1 (2%)	1 (2%)	
Squamous Cell Papilloma				1 (2%)
Trichoepithelioma				1 (2%)
Sebaceous Gland, Adenoma	1 (2%)		2 (4%)	1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Chondroma			1 (2%)	
Osteosarcoma	1 (2%)	1 (2%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant			1 (2%)	
Carcinoma, Metastatic, Pituitary Gland	1 (2%)	1 (2%)		1 (2%)
Granular Cell Tumor Malignant			1 (2%)	
Spinal Cord	(0)	(1)	(0)	(0)
Osteosarcoma, Metastatic, Bone		1 (100%)		

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		1 (2%)	1 (2%)	1 (2%)
Carcinoma, Metastatic, Tissue Nos			1 (2%)	
Hepatocellular Carcinoma, Metastatic, Liver				2 (4%)
Osteosarcoma, Metastatic, Bone		1 (2%)		
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla	1 (2%)		1 (2%)	1 (2%)
Nose	(50)	(49)	(50)	(49)

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Glands, Olfactory Epithelium, Adenoma				1 (2%)
Transitional Epithelium, Adenoma		3 (6%)	2 (4%)	11 (22%)
Transitional Epithelium, Carcinoma				2 (4%)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(49)	(50)	(50)	(50)
Adenoma				1 (2%)
Carcinoma			2 (4%)	1 (2%)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Oncocytoma Benign		1 (2%)		
Renal Tubule, Adenoma	1 (2%)			
Ureter	(0)	(0)	(0)	(1)
Urinary Bladder	(50)	(50)	(50)	(50)
Transitional Epithelium, Papilloma				1 (2%)

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	14 (28%)	1 (2%)	2 (4%)	
Mesothelioma Malignant	1 (2%)	2 (4%)	3 (6%)	1 (2%)

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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Lab: BAT

FISCHER 344 RATS MALE

0 MG/KG

6 MG/KG

20 MG/KG

60 MG/KG

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	49	48	46	44
Total Primary Neoplasms	118	107	119	104
Total Animals with Benign Neoplasms	48	46	46	43
Total Benign Neoplasms	97	93	100	89
Total Animals with Malignant Neoplasms	19	13	16	15
Total Malignant Neoplasms	21	14	19	15
Total Animals with Metastatic Neoplasms	4	2	2	4
Total Metastatic Neoplasms	4	4	3	4
Total Animals with Malignant Neoplasms Uncertain Primary Site	1			
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** 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/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Dosing Accident				1
Moribund Sacrifice	14	3	8	8
Natural Death	3	4	9	18
Survivors				
Terminal Sacrifice	33	42	33	23
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)
Leiomyosarcoma	1 (2%)			
Liver	(50)	(50)	(50)	(49)
Hepatocellular Adenoma		1 (2%)	1 (2%)	3 (6%)
Hepatocellular Carcinoma				3 (6%)
Hepatocellular Carcinoma, Multiple				1 (2%)
Mesentery	(8)	(9)	(9)	(3)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(48)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Neural Crest Tumor, Metastatic, Ear				1 (2%)
Tongue	(1)	(0)	(0)	(2)
Squamous Cell Carcinoma				1 (50%)
Squamous Cell Papilloma	1 (100%)			1 (50%)
Tooth	(0)	(1)	(0)	(0)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(49)
Adenoma	3 (6%)	3 (6%)	1 (2%)	2 (4%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign	2 (4%)	2 (4%)	1 (2%)	1 (2%)
Pheochromocytoma Malignant			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma			1 (2%)	
Parathyroid Gland	(50)	(50)	(50)	(46)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	31 (62%)	29 (58%)	30 (60%)	20 (40%)
Thyroid Gland	(49)	(47)	(47)	(45)
C-cell, Adenoma	9 (18%)	3 (6%)	5 (11%)	2 (4%)
C-cell, Carcinoma			1 (2%)	
Follicular Cell, Adenoma	1 (2%)	1 (2%)	2 (4%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(50)	(49)	(50)	(50)
Adenoma	5 (10%)	3 (6%)	7 (14%)	2 (4%)
Adenoma, Multiple			1 (2%)	

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Carcinoma		2 (4%)	2 (4%)	
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Benign		1 (2%)		
Granulosa Cell Tumor Malignant		2 (4%)		1 (2%)
Bilateral, Fibrosarcoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Adenocarcinoma		1 (2%)		
Adenoma			1 (2%)	
Polyp Stromal	3 (6%)	9 (18%)	3 (6%)	8 (16%)
Polyp Stromal, Multiple			1 (2%)	
Sarcoma Stromal			1 (2%)	
Vagina	(1)	(1)	(0)	(0)
Polyp		1 (100%)		
Schwannoma Malignant	1 (100%)			

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(2)	(1)	(2)	(1)
Deep Cervical, Sarcoma, Metastatic, Skin			1 (50%)	
Mediastinal, Neural Crest Tumor, Metastatic, Ear				1 (100%)
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Spleen	(50)	(50)	(50)	(50)
Thymus	(47)	(50)	(50)	(48)
Thymoma Benign			1 (2%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)	2 (4%)	
Carcinoma, Multiple	1 (2%)			
Fibroadenoma	17 (34%)	11 (22%)	19 (38%)	11 (22%)
Fibroadenoma, Multiple	12 (24%)	15 (30%)	7 (14%)	
Skin	(50)	(50)	(50)	(50)

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FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Basal Cell Adenoma		1 (2%)		
Basal Cell Carcinoma	1 (2%)		1 (2%)	1 (2%)
Fibroma	1 (2%)	4 (8%)	1 (2%)	
Fibrosarcoma	2 (4%)			
Fibrosarcoma, Multiple	1 (2%)			
Keratoacanthoma	1 (2%)	1 (2%)		1 (2%)
Lipoma			1 (2%)	
Liposarcoma	1 (2%)		1 (2%)	
Sarcoma			1 (2%)	1 (2%)
Schwannoma Malignant		1 (2%)	1 (2%)	
Squamous Cell Papilloma				1 (2%)
Trichoepithelioma		1 (2%)		

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Chordoma				1 (2%)
Osteosarcoma				2 (4%)

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Oligodendroglioma Malignant				1 (2%)
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)			1 (2%)
Fibrosarcoma, Metastatic, Skin	1 (2%)			
Neural Crest Tumor, Metastatic, Ear				1 (2%)
Osteosarcoma, Metastatic, Bone				1 (2%)
Sarcoma, Metastatic, Skin			1 (2%)	

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
Nose	(50)	(49)	(50)	(49)
Transitional Epithelium, Adenoma		1 (2%)		2 (4%)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(1)
Neural Crest Tumor	1 (100%)			1 (100%)
Eye	(50)	(50)	(50)	(50)
Melanoma Benign	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Lacrimal Gland	(0)	(0)	(0)	(1)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Lipoma			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Transitional Epithelium, Papilloma	1 (2%)			

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	15 (30%)	2 (4%)	1 (2%)	1 (2%)

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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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	6 MG/KG	20 MG/KG	60 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	49	46	43	36
Total Primary Neoplasms	114	96	98	69
 Total Animals with Benign Neoplasms	 46	 44	 42	 33
Total Benign Neoplasms	89	87	84	55
 Total Animals with Malignant Neoplasms	 23	 9	 12	 11
Total Malignant Neoplasms	24	9	14	13
 Total Animals with Metastatic Neoplasms	 1		 1	 2
Total Metastatic Neoplasms	1		2	4
 Total Animals with Malignant Neoplasms Uncertain Primary Site				
 Total Animals with Neoplasms Uncertain- Benign or Malignant	 1			 1
Total Uncertain Neoplasms	1			1

*** 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