

TDMs No. 99032 - 03

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

Date Report Requested: 12/17/2009

Test Type: CHRONIC

Pyrogallol

Time Report Requested: 08:48:44

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

F1_R2

C Number: C99032
Lock Date: 09/07/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.2.0

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CAS Number: 87-66-1

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	17	14	15	17
Natural Death	10	8	7	5
Survivors				
Natural Death		2		
Terminal Sacrifice	23	26	28	28
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
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)
Hepatocellular Adenoma	1 (2%)		1 (2%)	1 (2%)
Hepatocellular Adenoma, Multiple			1 (2%)	
Hepatocellular Carcinoma		1 (2%)		
Mesentery	(9)	(2)	(3)	(5)
Fibrous Histiocytoma	1 (11%)			
Oral Mucosa	(2)	(1)	(4)	(3)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Schwannoma Malignant	1 (2%)		1 (2%)	
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma		1 (2%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		1 (2%)

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

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Carcinosarcoma	1 (2%)			
Leiomyosarcoma		1 (2%)		
Tongue	(1)	(0)	(0)	(2)
Squamous Cell Carcinoma	1 (100%)			
Squamous Cell Papilloma				1 (50%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Urethra				1 (2%)
Schwannoma Malignant	2 (4%)	1 (2%)	1 (2%)	
Thymoma Malignant, Metastatic, Thymus			1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	3 (6%)	5 (10%)	7 (14%)	3 (6%)
Pheochromocytoma Malignant	1 (2%)			1 (2%)
Bilateral, Pheochromocytoma Benign	1 (2%)	1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	5 (10%)	4 (8%)	5 (10%)
Parathyroid Gland	(50)	(49)	(47)	(49)
Pituitary Gland	(50)	(49)	(50)	(50)
Pars Distalis, Adenoma	33 (66%)	33 (67%)	34 (68%)	27 (54%)
Pars Intermedia, Adenoma	1 (2%)	1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Bilateral, C-cell, Adenoma	1 (2%)	1 (2%)	1 (2%)	
C-cell, Adenoma	8 (16%)	8 (16%)	6 (12%)	6 (12%)
C-cell, Carcinoma		1 (2%)		1 (2%)
Follicular Cell, Adenoma			1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	1 (2%)

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FISCHER 344 RATS MALE

0 MG/KG

5 MG/KG

20 MG/KG

75 MG/KG

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Penis	(0)	(0)	(1)	(0)
Preputial Gland	(50)	(50)	(50)	(50)
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	26 (52%)	19 (38%)	28 (56%)	20 (40%)
Interstitial Cell, Adenoma	11 (22%)	12 (24%)	14 (28%)	17 (34%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(10)	(8)	(4)	(7)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(47)	(48)	(48)	(47)
Carcinoma, Metastatic, Thyroid Gland				1 (2%)
Thymoma Malignant			1 (2%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(49)	(50)	(50)
Adenocarcinoma	1 (2%)			
Fibroadenoma		2 (4%)	1 (2%)	1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma				1 (2%)

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Keratoacanthoma	2 (4%)	1 (2%)	2 (4%)	2 (4%)
Squamous Cell Papilloma	1 (2%)			3 (6%)
Control, Subcutaneous Tissue, Fibrous Histiocytoma		1 (2%)		
Subcutaneous Tissue, Fibroma	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	
Subcutaneous Tissue, Fibrous Histiocytoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Hemangiosarcoma		1 (2%)		
Subcutaneous Tissue, Lipoma		1 (2%)		1 (2%)
Subcutaneous Tissue, Schwannoma Malignant		1 (2%)	3 (6%)	

MUSCULOSKELETAL SYSTEM

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

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant			1 (2%)	

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)		
Alveolar/Bronchiolar Carcinoma	3 (6%)	2 (4%)	2 (4%)	
Carcinoma, Metastatic, Urethra				1 (2%)
Carcinoma, Metastatic, Zymbal'S Gland	1 (2%)			
Osteosarcoma, Metastatic, Bone		1 (2%)		
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla				1 (2%)
Thymoma Malignant, Metastatic, Thymus			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

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SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(1)	(0)	(0)	(0)
Carcinoma	1 (100%)			

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Urethra	(0)	(0)	(0)	(1)
Urinary Bladder	(50)	(50)	(50)	(50)
Transitional Epithelium, Papilloma	1 (2%)			

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		
Leukemia Mononuclear	11 (22%)	12 (24%)	11 (22%)	10 (20%)
Mesothelioma Malignant	2 (4%)	5 (10%)	1 (2%)	4 (8%)

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* Number of animals with any tissue examined microscopically

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FISCHER 344 RATS MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	49	50	50	48
Total Primary Neoplasms	122	124	127	107
Total Animals with Benign Neoplasms	47	49	50	45
Total Benign Neoplasms	96	95	103	89
Total Animals with Malignant Neoplasms	22	24	22	15
Total Malignant Neoplasms	26	29	24	18
Total Animals with Metastatic Neoplasms	1	2	1	2
Total Metastatic Neoplasms	1	4	2	4
Total Animals with Malignant Neoplasms Uncertain Primary Site				
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	5 MG/KG	20 MG/KG	75 MG/KG
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Accidentally Killed		1		
Moribund Sacrifice	12	7	18	9
Natural Death	9	9	6	10
Survivors				
Natural Death			1	
Terminal Sacrifice	29	33	25	31
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	2 (4%)			
Hepatocellular Adenoma, Multiple		1 (2%)		
Hepatocellular Carcinoma		1 (2%)		
Hepatocellular Carcinoma, Multiple				1 (2%)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Mesentery	(8)	(11)	(13)	(10)
Schwannoma Malignant	2 (25%)			
Oral Mucosa	(2)	(2)	(0)	(0)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)

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CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)	1 (2%)	2 (4%)	2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)			1 (2%)
Parathyroid Gland	(49)	(49)	(50)	(49)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	25 (50%)	29 (58%)	28 (56%)	27 (54%)
Pars Distalis, Carcinoma			1 (2%)	
Pars Intermedia, Adenoma			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	7 (14%)	6 (12%)	6 (12%)	7 (14%)
Follicle, Adenoma		1 (2%)		
Follicular Cell, Adenoma	1 (2%)			1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	3 (6%)		3 (6%)	

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Carcinoma	1 (2%)	3 (6%)		1 (2%)
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Benign	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Leiomyoma			1 (2%)	
Leiomyosarcoma		1 (2%)		
Polyp Stromal	7 (14%)	6 (12%)	5 (10%)	3 (6%)
Cervix, Polyp Stromal		1 (2%)		
Cervix, Sarcoma	1 (2%)			
Cervix, Sarcoma Stromal			1 (2%)	
Vagina	(0)	(1)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(3)	(2)	(4)	(2)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(50)	(50)	(49)	(50)
Thymoma Benign	1 (2%)			

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	2 (4%)		1 (2%)	
Carcinoma	1 (2%)	1 (2%)		2 (4%)
Fibroadenoma	22 (44%)	12 (24%)	18 (36%)	11 (22%)
Fibroadenoma, Multiple	2 (4%)	3 (6%)	3 (6%)	2 (4%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)			
Keratoacanthoma				1 (2%)
Site Of Application, Subcutaneous Tissue, Schwannoma Benign				1 (2%)
Subcutaneous Tissue, Fibroma	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	

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Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)			1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Cranium, Osteoma	1 (2%)			
Skeletal Muscle	(0)	(0)	(2)	(0)
Sarcoma			1 (50%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
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RESPIRATORY SYSTEM

Larynx	(0)	(1)	(0)	(0)
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		1 (2%)		
Alveolar/Bronchiolar Carcinoma		1 (2%)		1 (2%)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Squamous Cell Carcinoma				1 (2%)
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Adenoma				1 (2%)
Lipoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(49)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		1 (2%)
Leukemia Mononuclear	8 (16%)	9 (18%)	17 (34%)	11 (22%)
Lymphoma Malignant				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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FISCHER 344 RATS FEMALE

0 MG/KG

5 MG/KG

20 MG/KG

75 MG/KG

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	45	42	47	44
Total Primary Neoplasms	96	79	92	77
Total Animals with Benign Neoplasms	43	40	42	34
Total Benign Neoplasms	81	62	71	57
Total Animals with Malignant Neoplasms	12	17	20	18
Total Malignant Neoplasms	15	17	21	20
Total Animals with Metastatic Neoplasms		1	1	
Total Metastatic Neoplasms		7	4	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** 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