

TDMS No. 99020 - 05

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

Date Report Requested: 05/21/2008

Test Type: CHRONIC

Pulegone

Time Report Requested: 09:15:32

Route: GAVAGE

CAS Number: 89-82-7

First Dose M/F: 04/09/03 / 04/10/03

Species/Strain: RATS/F 344

Lab: BAT

F1_R2

C Number: C99020
Lock Date: 01/06/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

Test Type: CHRONIC

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Route: GAVAGE

CAS Number: 89-82-7

First Dose M/F: 04/09/03 / 04/10/03

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		
Moribund Sacrifice	8	10	12	35
Natural Death	3	7	10	13
Survivors				
Terminal Sacrifice	39	32	28	2
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(49)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Intestine Small, Ileum	(50)	(50)	(49)	(50)
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Lipoma		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	1 (2%)		1 (2%)	1 (2%)
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Mesentery	(9)	(11)	(11)	(4)
Carcinoma, Metastatic, Kidney		1 (9%)		
Osteosarcoma, Metastatic, Spleen			1 (9%)	
Oral Mucosa	(0)	(1)	(3)	(0)
Pharyngeal, Squamous Cell Carcinoma		1 (100%)		
Pancreas	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	3 (6%)		
Carcinoma, Metastatic, Kidney		1 (2%)		
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Salivary Glands	(50)	(49)	(50)	(50)
Schwannoma Malignant, Metastatic, Skin		1 (2%)		

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

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(1)	(2)	(0)
Squamous Cell Papilloma		1 (100%)	2 (100%)	
Tooth	(0)	(2)	(0)	(0)
Odontoma		1 (50%)		
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	2 (4%)		1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	8 (16%)	12 (24%)	12 (24%)	2 (4%)
Pheochromocytoma Benign, Multiple		1 (2%)		
Pheochromocytoma Malignant		2 (4%)	1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)			
Parathyroid Gland	(49)	(44)	(45)	(48)
Adenoma	1 (2%)			
Pituitary Gland	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma, Metastatic, Nose	1 (2%)			
Pars Distalis, Adenoma	11 (22%)	14 (28%)	17 (34%)	1 (2%)
Thyroid Gland	(50)	(50)	(44)	(47)
C-cell, Adenoma	8 (16%)	7 (14%)	4 (9%)	1 (2%)
Follicular Cell, Adenoma		4 (8%)	2 (5%)	1 (2%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				

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

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Epididymis	(50)	(50)	(50)	(49)
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	5 (10%)	2 (4%)	1 (2%)
Carcinoma	1 (2%)			
Prostate	(50)	(50)	(50)	(49)
Seminal Vesicle	(50)	(50)	(50)	(49)
Osteosarcoma, Metastatic, Spleen			1 (2%)	
Testes	(50)	(50)	(50)	(49)
Bilateral, Interstitial Cell, Adenoma	41 (82%)	37 (74%)	38 (76%)	26 (53%)
Interstitial Cell, Adenoma	5 (10%)	8 (16%)	5 (10%)	18 (37%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(2)	(8)	(3)	(6)
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (13%)		
Pancreatic, Osteosarcoma, Metastatic, Spleen			1 (33%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Osteosarcoma			1 (2%)	
Thymus	(50)	(48)	(48)	(47)
Schwannoma Malignant, Metastatic, Skin		1 (2%)		
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Fibroadenoma	1 (2%)	3 (6%)	1 (2%)	1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma			1 (2%)	1 (2%)
Basal Cell Carcinoma		2 (4%)		
Fibrous Histiocytoma				1 (2%)
Keratoacanthoma	3 (6%)		1 (2%)	
Schwannoma Malignant	1 (2%)			
Squamous Cell Carcinoma		1 (2%)		
Pinna, Squamous Cell Papilloma				1 (2%)
Subcutaneous Tissue, Fibroma	3 (6%)	2 (4%)	3 (6%)	

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Subcutaneous Tissue, Fibrous Histiocytoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant	2 (4%)	2 (4%)	1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Maxilla, Osteosarcoma		1 (2%)		
Skeletal Muscle	(0)	(0)	(1)	(0)
Perimysium, Osteosarcoma, Metastatic, Spleen			1 (100%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant	1 (2%)	1 (2%)		
Meningioma Malignant			1 (2%)	
Squamous Cell Carcinoma, Metastatic, Nose	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		1 (2%)	3 (6%)	
Alveolar/Bronchiolar Carcinoma	1 (2%)	1 (2%)	1 (2%)	
Carcinoma, Metastatic, Kidney		1 (2%)		
Meningioma Malignant, Metastatic, Brain			1 (2%)	
Squamous Cell Carcinoma			1 (2%)	
Alveolus, Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Nose	(50)	(50)	(46)	(50)
Squamous Cell Carcinoma	1 (2%)			
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)

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FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
Squamous Cell Carcinoma, Metastatic, Nose	1 (2%)			
Harderian Gland	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma, Metastatic, Nose	1 (2%)			
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Renal Tubule, Adenoma	1 (2%)		2 (4%)	2 (4%)
Urinary Bladder	(50)	(50)	(50)	(49)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	4 (8%)	6 (12%)	6 (12%)	
Mesothelioma Benign		2 (4%)	1 (2%)	
Mesothelioma Malignant	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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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	18.75 MG/KG	37.5 MG/KG	75 CHG 0 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	47	49	49	45
Total Primary Neoplasms	105	120	110	59
Total Animals with Benign Neoplasms	47	48	48	44
Total Benign Neoplasms	92	100	95	56
Total Animals with Malignant Neoplasms	10	16	14	3
Total Malignant Neoplasms	13	18	14	3
Total Animals with Metastatic Neoplasms	3	4	2	1
Total Metastatic Neoplasms	15	7	10	7
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

Test Type: CHRONIC

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Route: GAVAGE

CAS Number: 89-82-7

First Dose M/F: 04/09/03 / 04/10/03

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		1
Moribund Sacrifice	13	8	7	29
Natural Death	6	4	5	20
Survivors				
Terminal Sacrifice	31	37	38	
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(49)	(45)
Intestine Large, Colon	(50)	(50)	(49)	(45)
Intestine Large, Rectum	(50)	(50)	(50)	(49)
Intestine Small, Ileum	(50)	(50)	(49)	(45)
Intestine Small, Jejunum	(50)	(50)	(49)	(45)
Liver	(50)	(50)	(50)	(47)
Cholangioma			1 (2%)	
Hepatocellular Adenoma	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Mesentery	(6)	(12)	(5)	(1)
Oral Mucosa	(1)	(0)	(0)	(2)
Pancreas	(50)	(50)	(49)	(46)
Adenoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(49)
Stomach, Forestomach	(50)	(50)	(49)	(46)
Squamous Cell Papilloma	1 (2%)			
Stomach, Glandular	(50)	(50)	(49)	(46)
Tongue	(0)	(1)	(1)	(0)
Squamous Cell Papilloma		1 (100%)	1 (100%)	
Tooth	(1)	(0)	(2)	(1)
Odontoma	1 (100%)			
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
Heart	(50)	(50)	(50)	(50)
Schwannoma Benign	1 (2%)			1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign	3 (6%)	1 (2%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(49)	(46)
Adenoma	1 (2%)	1 (2%)		
Parathyroid Gland	(46)	(47)	(49)	(49)
Adenoma	2 (4%)			
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	27 (54%)	12 (24%)	9 (18%)	3 (6%)
Thyroid Gland	(50)	(50)	(50)	(49)
Bilateral, C-cell, Adenoma	1 (2%)			
C-cell, Adenoma	7 (14%)	6 (12%)	3 (6%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(49)
Adenoma	3 (6%)	3 (6%)	2 (4%)	1 (2%)
Sarcoma		1 (2%)		
Bilateral, Adenoma			1 (2%)	
Ovary	(50)	(50)	(49)	(46)
Cystadenoma		1 (2%)		
Uterus	(50)	(50)	(50)	(47)
Polyp Stromal	5 (10%)	2 (4%)	5 (10%)	2 (4%)
Vagina	(0)	(0)	(1)	(0)
Sarcoma			1 (100%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
Lymph Node	(2)	(3)	(5)	(11)
Lymph Node, Mesenteric	(50)	(50)	(50)	(45)
Spleen	(50)	(50)	(50)	(46)
Hemangiosarcoma	2 (4%)			
Thymus	(50)	(49)	(47)	(47)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(49)
Adenoma	2 (4%)			
Carcinoma		1 (2%)		
Fibroadenoma	21 (42%)	27 (54%)	8 (16%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma			2 (4%)	
Keratoacanthoma				1 (2%)
Lipoma		3 (6%)		
Squamous Cell Papilloma	1 (2%)			1 (2%)
Subcutaneous Tissue, Fibroma	3 (6%)	1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Mandible, Osteosarcoma			1 (2%)	
Skeletal Muscle	(1)	(0)	(0)	(1)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	2 (4%)	1 (2%)		
Cystic Keratinizing Epithelioma		1 (2%)		
Nose	(50)	(50)	(50)	(41)
Adenoma			1 (2%)	
Trachea	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(1)	(0)	(1)	(0)
Adenoma			1 (100%)	
Carcinoma	1 (100%)			
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(49)
Renal Tubule, Adenoma			1 (2%)	1 (2%)
Urinary Bladder	(50)	(49)	(50)	(47)
Transitional Epithelium, Carcinoma				2 (4%)
Transitional Epithelium, Papilloma			1 (2%)	3 (6%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			1 (2%)	
Leukemia Mononuclear	4 (8%)	4 (8%)	11 (22%)	9 (18%)
Mesothelioma 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	37.5 MG/KG	75.0 MG/KG	150 CHG 0 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	44	41	38	20
Total Primary Neoplasms	90	67	53	28
Total Animals with Benign Neoplasms	42	39	27	12
Total Benign Neoplasms	82	61	39	17
Total Animals with Malignant Neoplasms	8	6	14	11
Total Malignant Neoplasms	8	6	14	11
Total Animals with Metastatic Neoplasms	1			
Total Metastatic Neoplasms	6			
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