

TDMS No. 99023 - 03

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

Date Report Reqsted: 09/24/2007

Test Type: CHRONIC

beta-Myrcene

Time Report Reqsted: 12:14:59

Route: GAVAGE

CAS Number: 123-35-3

First Dose M/F: 03/25/02 / 03/26/02

Species/Strain: RATS/F 344

Lab: BAT

F1_R2

C Number: C99023

Lock Date: 12/22/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

TDMSE Version: 1.8.0

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Route: GAVAGE

CAS Number: 123-35-3

First Dose M/F: 03/25/02 / 03/26/02

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		1
Moribund Sacrifice	18	8	13	24
Natural Death	3	5	9	25
Survivors				
Terminal Sacrifice	29	36	28	
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)	(48)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Kidney		1 (2%)		
Hepatocellular Adenoma			1 (2%)	
Mesentery	(13)	(8)	(5)	(3)
Carcinoma, Metastatic, Kidney		1 (13%)		
Sarcoma		1 (13%)		
Oral Mucosa	(2)	(0)	(0)	(0)
Squamous Cell Papilloma	1 (50%)			
Pancreas	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		2 (4%)	
Salivary Glands	(50)	(50)	(50)	(48)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Osteosarcoma, Metastatic, Bone			1 (2%)	

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)		
Carcinoma, Metastatic, Kidney		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Ganglioneuroma	1 (2%)			
Pheochromocytoma Benign	10 (20%)	5 (10%)	4 (8%)	
Pheochromocytoma Benign, Multiple		1 (2%)		
Pheochromocytoma Malignant	2 (4%)			
Bilateral, Pheochromocytoma Benign	1 (2%)		1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)			
Carcinoma	1 (2%)			
Parathyroid Gland	(45)	(47)	(48)	(45)
Adenoma	1 (2%)			1 (2%)
Pituitary Gland	(50)	(49)	(50)	(50)
Pars Distalis, Adenoma	6 (12%)	9 (18%)	5 (10%)	1 (2%)
Pars Distalis, Adenoma, Multiple		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(49)
Bilateral, C-cell, Adenoma	3 (6%)	1 (2%)		
C-cell, Adenoma	8 (16%)	5 (10%)	4 (8%)	1 (2%)
C-cell, Adenoma, Multiple	1 (2%)			
Follicle, Adenoma	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Follicle, Carcinoma	2 (4%)	2 (4%)	1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(48)
Carcinoma, Metastatic, Kidney		1 (2%)		
Preputial Gland	(50)	(50)	(50)	(47)
Adenoma	4 (8%)	1 (2%)		
Adenoma, Multiple	1 (2%)			
Carcinoma		1 (2%)		

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Prostate	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Mesenchymal Tumor Malignant, Metastatic, Kidney		1 (2%)		
Testes	(50)	(50)	(50)	(48)
Bilateral, Interstitial Cell, Adenoma	39 (78%)	43 (86%)	40 (80%)	18 (38%)
Interstitial Cell, Adenoma	8 (16%)	2 (4%)	6 (12%)	7 (15%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(3)	(5)	(6)	(0)
Lymph Node, Mandibular	(0)	(0)	(1)	(0)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Mesenchymal Tumor Malignant, Metastatic, Kidney		1 (2%)		
Spleen	(50)	(50)	(50)	(50)
Thymus	(47)	(50)	(48)	(47)
Thymoma Benign				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(49)	(50)
Fibroadenoma		2 (4%)	4 (8%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma		1 (2%)	1 (2%)	
Basal Cell Carcinoma	1 (2%)			
Keratoacanthoma	2 (4%)	6 (12%)	2 (4%)	1 (2%)
Trichoepithelioma		1 (2%)		
Sebaceous Gland, Adenoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Fibroma	3 (6%)	4 (8%)	3 (6%)	
Subcutaneous Tissue, Fibrosarcoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Fibrous Histiocytoma			1 (2%)	
Subcutaneous Tissue, Lipoma		2 (4%)		
Subcutaneous Tissue, Sarcoma	1 (2%)			

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CAS Number: 123-35-3

First Dose M/F: 03/25/02 / 03/26/02

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Chordoma	1 (2%)			
Osteoma			1 (2%)	
Osteosarcoma	1 (2%)		1 (2%)	
Skeletal Muscle	(1)	(1)	(1)	(0)
Fibrous Histiocytoma			1 (100%)	
Hemangiosarcoma		1 (100%)		
Rhabdomyosarcoma	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Ependymoma Benign	1 (2%)			
Oligodendroglioma Benign	1 (2%)			
Cranial Nerve, Schwannoma Malignant		1 (2%)		
Peripheral Nerve	(2)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	6 (12%)	1 (2%)	
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)		
Carcinoma, Metastatic, Kidney		1 (2%)		
Carcinoma, Metastatic, Preputial Gland		1 (2%)		
Chordoma, Metastatic, Bone	1 (2%)			
Fibrous Histiocytoma, Metastatic, Skeletal Muscle			1 (2%)	
Mesenchymal Tumor Malignant, Metastatic, Kidney		1 (2%)		
Osteosarcoma, Metastatic, Bone	1 (2%)		1 (2%)	
Sarcoma, Metastatic, Skin	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Harderian Gland	(50)	(50)	(50)	(49)
Adenoma			1 (2%)	
Carcinoma		1 (2%)		
Zymbal's Gland	(0)	(1)	(0)	(0)
Carcinoma		1 (100%)		
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	
Lipoma	1 (2%)			
Mesenchymal Tumor Malignant		1 (2%)		
Nephroblastoma			1 (2%)	
Renal Tubule, Adenoma		2 (4%)	7 (14%)	2 (4%)
Renal Tubule, Adenoma, Multiple		2 (4%)	1 (2%)	
Renal Tubule, Carcinoma		3 (6%)	1 (2%)	
Transitional Epithelium, Carcinoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(49)
Papilloma	1 (2%)			
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Mononuclear	9 (18%)	10 (20%)	15 (30%)	
Lymphoma Malignant	1 (2%)	1 (2%)		
Mesothelioma Benign			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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First Dose M/F: 03/25/02 / 03/26/02

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	50	49	48	27
Total Primary Neoplasms	126	124	113	34
Total Animals with Benign Neoplasms	49	47	47	27
Total Benign Neoplasms	102	99	89	34
Total Animals with Malignant Neoplasms	23	22	23	
Total Malignant Neoplasms	24	25	23	
Total Animals with Metastatic Neoplasms	4	3	2	
Total Metastatic Neoplasms	4	9	3	
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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Route: GAVAGE

CAS Number: 123-35-3

First Dose M/F: 03/25/02 / 03/26/02

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Accidently Killed		1		
Dosing Accident		1		1
Moribund Sacrifice	11	9	12	7
Natural Death	8	6	10	9
Survivors				
Terminal Sacrifice	31	33	28	33
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(49)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(49)	(50)
Leiomyosarcoma				1 (2%)
Intestine Small, Ileum	(50)	(50)	(49)	(50)
Liver	(50)	(50)	(49)	(50)
Hepatocellular Adenoma				1 (2%)
Hepatocellular Carcinoma		1 (2%)		
Mesentery	(7)	(13)	(7)	(9)
Oral Mucosa	(1)	(0)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)			
Pancreas	(50)	(50)	(49)	(50)
Salivary Glands	(50)	(49)	(49)	(50)
Myoepithelioma			1 (2%)	
Stomach, Forestomach	(50)	(50)	(49)	(50)
Stomach, Glandular	(50)	(50)	(49)	(50)
Tongue	(1)	(0)	(1)	(0)
Squamous Cell Papilloma	1 (100%)			
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(49)	(50)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Pheochromocytoma Benign	1 (2%)			
Islets, Pancreatic	(50)	(50)	(49)	(50)
Adenoma	1 (2%)	1 (2%)		
Parathyroid Gland	(47)	(48)	(47)	(45)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	24 (48%)	21 (42%)	13 (26%)	14 (28%)
Pars Distalis, Adenoma, Multiple	1 (2%)	1 (2%)		1 (2%)
Pars Intermedia, Adenoma			1 (2%)	
Thyroid Gland	(50)	(49)	(49)	(50)
Bilateral, C-cell, Adenoma	1 (2%)			
C-cell, Adenoma	4 (8%)	13 (27%)	4 (8%)	4 (8%)
Follicle, Adenoma		2 (4%)		1 (2%)
Follicle, Carcinoma			1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	2 (4%)	2 (4%)	1 (2%)
Carcinoma			1 (2%)	
Bilateral, Adenoma	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Benign	1 (2%)			
Granulosa Cell Tumor Malignant		1 (2%)		1 (2%)
Thecoma Benign		1 (2%)		
Uterus	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma	1 (2%)			
Deciduoma Malignant		1 (2%)		
Polyp Stromal	8 (16%)	3 (6%)	10 (20%)	6 (12%)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Polyp Stromal, Multiple Sarcoma Stromal Bilateral, Polyp Stromal		1 (2%)	2 (4%) 1 (2%)	1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(5)	(3)	(2)	(6)
Mediastinal, Schwannoma Malignant, Metastatic, Skin			1 (50%)	
Mediastinal, Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (20%)			
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(49)	(48)	(49)	(50)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma		2 (4%)		
Fibroadenoma	13 (26%)	15 (30%)	8 (16%)	7 (14%)
Fibroadenoma, Multiple	4 (8%)	5 (10%)	4 (8%)	
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)			
Basal Cell Carcinoma			1 (2%)	
Keratoacanthoma		1 (2%)		
Subcutaneous Tissue, Fibroma	2 (4%)		1 (2%)	
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Lipoma		1 (2%)	3 (6%)	
Subcutaneous Tissue, Mast Cell Tumor			1 (2%)	
Malignant				
Subcutaneous Tissue, Schwannoma			1 (2%)	
Malignant				
MUSCULOSKELETAL SYSTEM				
Skeletal Muscle	(0)	(0)	(1)	(0)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Spinal Cord	(1)	(0)	(0)	(0)
Astrocytoma Benign	1 (100%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(49)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	3 (6%)	2 (4%)	1 (2%)
Alveolar/Bronchiolar Carcinoma		1 (2%)		1 (2%)
Carcinoma, Metastatic, Clitoral Gland			1 (2%)	
Fibrosarcoma, Metastatic, Skin	1 (2%)			
Schwannoma Malignant, Metastatic, Skin			1 (2%)	
Squamous Cell Carcinoma	1 (2%)			
Nose	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Ear	(0)	(3)	(0)	(0)
Pinna, Neural Crest Tumor		1 (33%)		
Eye	(50)	(50)	(49)	(50)
Harderian Gland	(50)	(50)	(49)	(50)
Zymbal's Gland	(0)	(0)	(0)	(2)
Carcinoma				2 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Nephroblastoma	1 (2%)			
Renal Tubule, Adenoma		1 (2%)		2 (4%)
Urinary Bladder	(50)	(50)	(50)	(50)
Transitional Epithelium, Carcinoma			1 (2%)	
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	5 (10%)	8 (16%)	4 (8%)	11 (22%)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Lymphoma Malignant				1 (2%)
Mesothelioma Malignant	1 (2%)			

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* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 G/KG	0.25 G/KG	0.5 G/KG	1.0 G/KG
Tumor Summary for Females				
Total Animals with Primary Neoplasms (b)	45	44	39	37
Total Primary Neoplasms	86	86	63	56
Total Animals with Benign Neoplasms	40	39	35	27
Total Benign Neoplasms	75	70	53	38
Total Animals with Malignant Neoplasms	11	14	10	17
Total Malignant Neoplasms	11	15	10	18
Total Animals with Metastatic Neoplasms	2		2	
Total Metastatic Neoplasms	2		3	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant		1		
Total Uncertain Neoplasms		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