

TDMS No. 99028 - 05

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

Date Report Reqsted: 11/12/2007

Test Type: CHRONIC

bis(2-Chloroethoxy)methane

Time Report Reqsted: 14:57:37

Route: SKIN APPLICATION

CAS Number: 111-91-1

First Dose M/F: 09/16/02 / 09/17/02

Species/Strain: RATS/F 344

Lab: BAT

F1_R2

C Number: C99028

Lock Date: 07/12/2005

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

TDMSE Version: 1.9.1

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	21	17	31	20
Natural Death	8	4	5	6
Survivors				
Moribund Sacrifice		1		
Terminal Sacrifice	21	28	14	24
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Adenoma		1 (2%)		
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Granular Cell Tumor Malignant	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle			1 (2%)	
Mesentery	(10)	(10)	(9)	(9)
Oral Mucosa	(2)	(0)	(0)	(0)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Schwannoma Malignant				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Schwannoma Benign	2 (4%)	1 (2%)	1 (2%)	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	75 MG/KG	150 MG/KG	300 MG/KG
Schwannoma Malignant, Metastatic, Skin			1 (2%)	
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Ganglioneuroma			1 (2%)	1 (2%)
Pheochromocytoma Benign	2 (4%)	4 (8%)	5 (10%)	6 (12%)
Pheochromocytoma Complex		1 (2%)		
Bilateral, Pheochromocytoma Benign	1 (2%)	1 (2%)	1 (2%)	
Bilateral, Pheochromocytoma Benign, Multiple			1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	3 (6%)	7 (14%)	2 (4%)	3 (6%)
Carcinoma			1 (2%)	1 (2%)
Parathyroid Gland	(49)	(44)	(45)	(47)
Pituitary Gland	(49)	(50)	(50)	(50)
Pars Distalis, Adenoma	32 (65%)	23 (46%)	22 (44%)	29 (58%)
Pars Distalis, Adenoma, Multiple	3 (6%)	1 (2%)	4 (8%)	
Pars Intermedia, Adenoma		1 (2%)		1 (2%)
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma			1 (2%)	
Bilateral, C-cell, Adenoma, Multiple	1 (2%)			
C-cell, Adenoma	8 (16%)	9 (18%)	7 (14%)	7 (14%)
C-cell, Adenoma, Multiple	1 (2%)			1 (2%)
C-cell, Carcinoma	1 (2%)			
Follicle, Adenoma				1 (2%)
Follicle, Carcinoma			1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Penis	(0)	(0)	(1)	(0)
Preputial Gland	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Adenoma	2 (4%)	3 (6%)	2 (4%)	1 (2%)
Carcinoma			1 (2%)	
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	18 (36%)	21 (42%)	17 (34%)	19 (38%)
Interstitial Cell, Adenoma	12 (24%)	8 (16%)	14 (28%)	14 (28%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(4)	(0)	(6)	(5)
Deep Cervical, Rhabdomyosarcoma, Metastatic, Skeletal Muscle			1 (17%)	
Mediastinal, Rhabdomyosarcoma, Metastatic, Skeletal Muscle			1 (17%)	
Mediastinal, Sarcoma			1 (17%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle			1 (2%)	
Spleen	(50)	(50)	(49)	(50)
Hemangioma		1 (2%)		
Hemangiosarcoma				1 (2%)
Sarcoma	1 (2%)			
Thymus	(49)	(50)	(50)	(48)
Schwannoma Malignant, Metastatic, Skin			1 (2%)	
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma			1 (2%)	
Fibroadenoma	3 (6%)	1 (2%)		1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma		2 (4%)		
Basal Cell Carcinoma		1 (2%)		
Squamous Cell Papilloma			1 (2%)	
Trichoepithelioma	1 (2%)		1 (2%)	1 (2%)
Dermis, Fibroma				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	75 MG/KG	150 MG/KG	300 MG/KG
Epidermis, Squamous Cell Carcinoma Site Of Application - Epidermis, Basal Cell Adenoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Fibroma	1 (2%)		2 (4%)	
Subcutaneous Tissue, Fibrosarcoma	2 (4%)			
Subcutaneous Tissue, Hemangioma			1 (2%)	
Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)		1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Fibrosarcoma		1 (2%)		
Osteosarcoma			1 (2%)	
Skeletal Muscle	(1)	(0)	(1)	(0)
Hemangiosarcoma	1 (100%)			
Rhabdomyosarcoma			1 (100%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant				1 (2%)
Glioma Malignant				1 (2%)
Cranial Nerve, Schwannoma Malignant	1 (2%)			
Spinal Cord	(1)	(1)	(0)	(0)
Astrocytoma Malignant	1 (100%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	1 (2%)	3 (6%)	
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)			
Alveolar/Bronchiolar Carcinoma	1 (2%)	1 (2%)	1 (2%)	
Carcinoma, Metastatic, Mammary Gland			1 (2%)	
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Hemangiosarcoma, Metastatic, Skeletal Muscle	1 (2%)			
Hemangiosarcoma, Metastatic, Spleen				1 (2%)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Nose	(50)	(49)	(50)	(49)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Zymbal's Gland	(1)	(0)	(0)	(1)
Adenoma	1 (100%)			
Carcinoma				1 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Hemangiosarcoma			1 (2%)	
Lipoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)			
Leukemia Granulocytic				1 (2%)
Leukemia Mononuclear	17 (34%)	14 (28%)	19 (38%)	12 (24%)
Mesothelioma Malignant	2 (4%)	3 (6%)	2 (4%)	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	75 MG/KG	150 MG/KG	300 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	49	47	49	49
Total Primary Neoplasms	127	108	120	109
Total Animals with Benign Neoplasms	49	45	47	46
Total Benign Neoplasms	96	87	89	89
Total Animals with Malignant Neoplasms	26	18	26	19
Total Malignant Neoplasms	31	21	31	20
Total Animals with Metastatic Neoplasms	2	1	5	1
Total Metastatic Neoplasms	2	1	10	1
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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CAS Number: 111-91-1

First Dose M/F: 09/16/02 / 09/17/02

Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	19	18	15	19
Natural Death	12	2	7	13
Survivors				
Terminal Sacrifice	19	30	28	18
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Periesophageal Tissue, Lipoma	1 (2%)			
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Lipoma			1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Carcinoma				1 (2%)
Mesentery	(13)	(13)	(17)	(6)
Leiomyosarcoma, Metastatic, Uterus		1 (8%)		
Oral Mucosa	(1)	(0)	(0)	(0)
Squamous Cell Papilloma	1 (100%)			
Pancreas	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(0)	(1)
Squamous Cell Papilloma				1 (100%)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Schwannoma Benign		1 (2%)		

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			2 (4%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)	1 (2%)		2 (4%)
Pheochromocytoma Complex		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma	1 (2%)			
Parathyroid Gland	(43)	(46)	(48)	(50)
Adenoma			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	20 (40%)	23 (46%)	22 (44%)	17 (34%)
Pars Distalis, Adenoma, Multiple	2 (4%)	5 (10%)	2 (4%)	1 (2%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)			
C-cell, Adenoma	5 (10%)	9 (18%)	11 (22%)	2 (4%)
C-cell, Adenoma, Multiple		2 (4%)		
C-cell, Carcinoma			1 (2%)	
Follicle, Adenoma	1 (2%)	1 (2%)		
Follicle, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	4 (8%)	5 (10%)	3 (6%)
Carcinoma			2 (4%)	1 (2%)
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Malignant	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Leiomyosarcoma		1 (2%)		
Polyp Stromal	5 (10%)	5 (10%)	8 (16%)	4 (8%)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Sarcoma Stromal Bilateral, Polyp Stromal	1 (2%)	1 (2%)	1 (2%)	2 (4%) 1 (2%)
Vagina Polyp	(0)	(0)	(0)	(1) 1 (100%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(49)
Lymph Node Deep Cervical, Carcinoma, Metastatic, Thyroid Gland	(3)	(1)	(5) 1 (20%)	(1)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(49)	(50)	(50)	(49)
INTEGUMENTARY SYSTEM				
Mammary Gland Adenoma	(50)	(50) 1 (2%)	(50)	(50) 1 (2%)
Carcinoma	1 (2%)	2 (4%)	1 (2%)	
Fibroadenoma	12 (24%)	18 (36%)	12 (24%)	14 (28%)
Fibroadenoma, Multiple	4 (8%)	4 (8%)	6 (12%)	2 (4%)
Skin Subcutaneous Tissue, Fibroma	(50)	(50)	(50)	(49)
Subcutaneous Tissue, Fibrosarcoma	2 (4%)	1 (2%) 1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone Osteosarcoma	(50)	(50)	(50) 1 (2%)	(50)
NERVOUS SYSTEM				
Brain Oligodendroglioma Malignant	(50) 1 (2%)	(50)	(50)	(50)
RESPIRATORY SYSTEM				

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma			3 (6%)	2 (4%)
Nose	(49)	(49)	(50)	(49)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Lacrimal Gland	(0)	(1)	(0)	(0)
Zymbal's Gland	(0)	(0)	(0)	(1)
Carcinoma				1 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Lipoma			1 (2%)	
Sarcoma	1 (2%)			
Urinary Bladder	(50)	(50)	(49)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)		1 (2%)	
Leukemia Mononuclear	12 (24%)	9 (18%)	12 (24%)	13 (26%)

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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 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	44	43	45	34
Total Primary Neoplasms	79	92	93	69
Total Animals with Benign Neoplasms	37	41	41	31
Total Benign Neoplasms	59	77	74	51
Total Animals with Malignant Neoplasms	19	15	18	16
Total Malignant Neoplasms	20	15	19	18
Total Animals with Metastatic Neoplasms		1	1	
Total Metastatic Neoplasms		1	1	
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