

**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
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
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)
<b>CARDIOVASCULAR SYSTEM</b>				
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%)	
<b>ENDOCRINE SYSTEM</b>				
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%)	
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
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%)
<b>HEMATOPOIETIC SYSTEM</b>				
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%)	
<b>INTEGUMENTARY SYSTEM</b>				
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%)

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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	1 (2%)			
Site Of Application - Epidermis, Basal Cell Adenoma		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	1 (2%)		1 (2%)	
Malignant				
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Fibrosarcoma		1 (2%)		
Osteosarcoma			1 (2%)	
Skeletal Muscle	(1)	(0)	(1)	(0)
Hemangiosarcoma	1 (100%)			
Rhabdomyosarcoma			1 (100%)	
<b>NERVOUS SYSTEM</b>				
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%)			
<b>RESPIRATORY SYSTEM</b>				
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)
<b>SPECIAL SENSES SYSTEM</b>				
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%)
<b>URINARY SYSTEM</b>				
Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Hemangiosarcoma			1 (2%)	
Lipoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
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

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
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**Tumor Summary for Males**

<b>Total Animals with Primary Neoplasms (b)</b>	49	47	49	49
<b>Total Primary Neoplasms</b>	127	108	120	109
<b>Total Animals with Benign Neoplasms</b>	49	45	47	46
<b>Total Benign Neoplasms</b>	96	87	89	89
<b>Total Animals with Malignant Neoplasms</b>	26	18	26	19
<b>Total Malignant Neoplasms</b>	31	21	31	20
<b>Total Animals with Metastatic Neoplasms</b>	2	1	5	1
<b>Total Metastatic Neoplasms</b>	2	1	10	1
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>				
<b>Total Animals with Neoplasms Uncertain-Benign or Malignant</b>				
<b>Total Uncertain Neoplasms</b>				

\*\*\* 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
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
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%)
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Schwannoma Benign		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 FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
<b>ENDOCRINE SYSTEM</b>				
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%)			
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
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%)
<b>HEMATOPOIETIC SYSTEM</b>				
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)
<b>INTEGUMENTARY SYSTEM</b>				
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%)		
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone Osteosarcoma	(50)	(50)	(50) 1 (2%)	(50)
<b>NERVOUS SYSTEM</b>				
Brain Oligodendroglioma Malignant	(50) 1 (2%)	(50)	(50)	(50)
<b>RESPIRATORY SYSTEM</b>				

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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%)

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

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

\*\*\* 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