

TDMS No. 97003 - 07

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

Date Report Reqsted: 08/21/2007

Test Type: CHRONIC

1,2-Dibromo-2,4-dicyanobutane

Time Report Reqsted: 12:46:31

Route: SKIN APPLICATION

CAS Number: 35691-65-7

First Dose M/F: 07/10/02 / 07/11/02

Species/Strain: RATS/F 344

Lab: BAT

F_1.Rev.1_R2

C Number: C97003D
Lock Date: 03/23/2005
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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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	19	15	17	12
Natural Death	6	8	6	1
Survivors				
Terminal Sacrifice	25	27	27	37
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)
Adenoma		2 (4%)		
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Leiomyoma		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma		1 (2%)		
Hepatocellular Carcinoma	1 (2%)			
Mesentery	(10)	(6)	(10)	(9)
Schwannoma Malignant			1 (10%)	
Pancreas	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Acinus, Adenoma		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)			
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(0)	(0)	(1)	(1)
CARDIOVASCULAR SYSTEM				

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	2 MG/KG	6 MG/KG	18 MG/KG
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	3 (6%)		1 (2%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Ganglioneuroma			1 (2%)	
Pheochromocytoma Benign	5 (10%)	2 (4%)	5 (10%)	4 (8%)
Pheochromocytoma Malignant		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	3 (6%)	5 (10%)	4 (8%)
Parathyroid Gland	(49)	(47)	(49)	(46)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	32 (64%)	34 (68%)	26 (52%)	24 (48%)
Pars Intermedia, Adenoma				2 (4%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	10 (20%)	4 (8%)	6 (12%)	10 (20%)
C-cell, Carcinoma	2 (4%)			
Follicular Cell, Adenoma			1 (2%)	
Follicular Cell, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	3 (6%)	5 (10%)	1 (2%)
Bilateral, Adenoma		1 (2%)		
Prostate	(50)		(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	30 (60%)	25 (50%)	33 (66%)	26 (52%)
Interstitial Cell, Adenoma	7 (14%)	10 (20%)	12 (24%)	16 (32%)

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(6)	(4)	(5)	(6)
Fibrous Histiocytoma, Metastatic, Skin	1 (17%)			
Mediastinal, Schwannoma Malignant, Metastatic, Skin		1 (25%)		
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Fibrosarcoma	1 (2%)			
Thymus	(49)	(46)	(48)	(44)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(49)	(49)	(50)
Adenoma		3 (6%)		1 (2%)
Fibroadenoma	1 (2%)	2 (4%)		1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma		1 (2%)	1 (2%)	
Basal Cell Carcinoma				1 (2%)
Keratoacanthoma	2 (4%)		1 (2%)	
Lipoma	1 (2%)			
Squamous Cell Papilloma				1 (2%)
Subcutaneous Tissue, Fibroma	7 (14%)	3 (6%)	6 (12%)	3 (6%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Sarcoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Benign	1 (2%)			1 (2%)
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)	1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Rib, Osteosarcoma		1 (2%)		
Skeletal Muscle	(0)	(0)	(0)	(1)

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant	1 (2%)		1 (2%)	
Meningioma Benign		1 (2%)		
Oligodendroglioma Malignant				1 (2%)
Spinal Cord	(2)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	3 (6%)	1 (2%)	3 (6%)
Alveolar/Bronchiolar Carcinoma	1 (2%)			
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Schwannoma Malignant, Metastatic, Skin	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)
Adenoma		1 (2%)		
Zymbal's Gland	(0)	(1)	(1)	(0)
Adenoma			1 (100%)	
Carcinoma		1 (100%)		
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Lipoma			1 (2%)	
Mesenchymal Tumor Benign	1 (2%)			
Mesenchymal Tumor Malignant		1 (2%)		
Renal Tubule, Adenoma	1 (2%)			

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Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Urinary Bladder Papilloma	(50)	(50)	(50)	(50) 1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	1 (2%)		1 (2%)
Leukemia Mononuclear	17 (34%)	16 (32%)	16 (32%)	14 (28%)
Lymphoma Malignant				2 (4%)
Mesothelioma Benign	1 (2%)		1 (2%)	1 (2%)
Mesothelioma Malignant		1 (2%)	3 (6%)	

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	2 MG/KG	6 MG/KG	18 MG/KG
Tumor Summary for Males				
Total Animals with Primary Neoplasms (b)	50	50	50	49
Total Primary Neoplasms	139	127	131	119
Total Animals with Benign Neoplasms	46	47	50	48
Total Benign Neoplasms	111	103	108	99
Total Animals with Malignant Neoplasms	23	21	19	16
Total Malignant Neoplasms	27	24	22	19
Total Animals with Metastatic Neoplasms	3	2	1	
Total Metastatic Neoplasms	9	2	9	
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

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	17	16	17	14
Natural Death	4	2	9	5
Survivors				
Terminal Sacrifice	29	32	24	31
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma		1 (2%)	1 (2%)	
Mesentery	(14)	(12)	(12)	(12)
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Tooth	(1)	(0)	(0)	(0)
Odontoma	1 (100%)			
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	1 (2%)		1 (2%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Adenoma			1 (2%)	
Parathyroid Gland	(46)	(48)	(48)	(48)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	35 (70%)	22 (44%)	26 (52%)	27 (54%)
Pars Intermedia, Adenoma		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	8 (16%)	4 (8%)	5 (10%)	4 (8%)
C-cell, Carcinoma			1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(49)
Adenoma	6 (12%)	2 (4%)	3 (6%)	5 (10%)
Ovary	(50)	(50)	(50)	(50)
Thecoma Benign				1 (2%)
Uterus	(50)	(50)	(50)	(50)
Leiomyoma				1 (2%)
Polyp Stromal	2 (4%)	6 (12%)	5 (10%)	4 (8%)
Sarcoma Stromal		1 (2%)	2 (4%)	
Schwannoma Malignant			1 (2%)	
Bilateral, Sarcoma Stromal	1 (2%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(4)	(2)	(3)	(5)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(45)	(49)	(48)	(45)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Adenocarcinoma	2 (4%)			

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Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Adenoma	1 (2%)	5 (10%)	1 (2%)	
Fibroadenoma	11 (22%)	13 (26%)	7 (14%)	7 (14%)
Fibroadenoma, Multiple	3 (6%)	5 (10%)		2 (4%)
Fibrosarcoma				1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma				1 (2%)
Neural Crest Tumor				1 (2%)
Squamous Cell Carcinoma	1 (2%)			
Subcutaneous Tissue, Fibroma				1 (2%)
Subcutaneous Tissue, Fibrosarcoma				1 (2%)
Subcutaneous Tissue, Schwannoma		1 (2%)	1 (2%)	1 (2%)
Malignant				
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma		1 (2%)		
Skeletal Muscle	(1)	(0)	(0)	(1)
Rhabdomyosarcoma	1 (100%)			1 (100%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Peripheral Nerve	(2)	(0)	(0)	(1)
Squamous Cell Carcinoma, Metastatic, Skin	1 (50%)			
Spinal Cord	(1)	(0)	(0)	(1)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	2 (4%)		
Alveolar/Bronchiolar Carcinoma	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Chondroma				1 (2%)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				

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Species/Strain: RATS/F 344

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(2)	(1)	(0)
Adenoma		2 (100%)	1 (100%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Renal Tubule, Carcinoma		1 (2%)		
Urinary Bladder	(50)	(50)	(49)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma			1 (2%)	
Leukemia Mononuclear	10 (20%)	18 (36%)	13 (26%)	15 (30%)

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* Number of animals with any tissue examined microscopically

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FISCHER 344 RATS FEMALE	0 MG/KG	2 MG/KG	6 MG/KG	18 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	48	46	45	44
Total Primary Neoplasms	89	85	70	76
Total Animals with Benign Neoplasms	46	35	37	40
Total Benign Neoplasms	73	63	51	56
Total Animals with Malignant Neoplasms	15	21	19	19
Total Malignant Neoplasms	16	22	19	19
Total Animals with Metastatic Neoplasms	1			
Total Metastatic Neoplasms	1			
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