

TDMS No. 99017 - 05

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

Date Report Requested: 01/13/2010

Test Type: CHRONIC

Diethylamine

Time Report Requested: 11:20:13

Route: RESPIRATORY EXPOSURE WHOLE BODY

CAS Number: 109-89-7

First Dose M/F: 08/25/03 / 08/25/03

Species/Strain: RATS/F 344/N

Lab: BNW

F3_R2

C Number: C99017
Lock Date: 07/24/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.2.0

Test Type: CHRONIC

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CAS Number: 109-89-7

First Dose M/F: 08/25/03 / 08/25/03

Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	19	24	20	13
Natural Death	3	5	5	1
Survivors				
Terminal Sacrifice	28	21	25	36
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(47)	(49)	(50)
Intestine Small, Duodenum	(49)	(49)	(49)	(50)
Adenoma		1 (2%)		
Leiomyoma	1 (2%)			
Intestine Small, Ileum	(48)	(47)	(46)	(49)
Adenoma		1 (2%)		
Intestine Small, Jejunum	(48)	(47)	(48)	(50)
Liver	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Hepatocellular Adenoma			1 (2%)	
Hepatocellular Adenoma, Multiple			1 (2%)	
Mesentery	(10)	(13)	(16)	(10)
Fibrosarcoma			1 (6%)	
Pancreas	(49)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(1)	(0)

CARDIOVASCULAR SYSTEM

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

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Lab: BNW

FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
Blood Vessel	(0)	(0)	(0)	(1)
Heart	(50)	(50)	(50)	(50)

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	6 (12%)	3 (6%)	3 (6%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Ganglioneuroma				1 (2%)
Pheochromocytoma Benign	7 (14%)	3 (6%)	7 (14%)	8 (16%)
Pheochromocytoma Benign, Multiple				1 (2%)
Pheochromocytoma Complex	2 (4%)			
Pheochromocytoma Malignant	1 (2%)		2 (4%)	1 (2%)
Bilateral, Pheochromocytoma Benign		3 (6%)	2 (4%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	8 (16%)	7 (14%)	2 (4%)
Carcinoma	1 (2%)	3 (6%)	2 (4%)	1 (2%)
Pituitary Gland	(50)	(48)	(50)	(50)
Ganglioneuroma	1 (2%)			
Pars Distalis, Adenoma	31 (62%)	32 (67%)	31 (62%)	26 (52%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	7 (14%)	5 (10%)	3 (6%)	9 (18%)
C-cell, Carcinoma	1 (2%)	3 (6%)	1 (2%)	
Follicular Cell, Adenoma		1 (2%)	1 (2%)	

GENERAL BODY SYSTEM

Peritoneum	(0)	(1)	(1)	(1)
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GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma		1 (2%)	2 (4%)	

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Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
Carcinoma	1 (2%)	1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	23 (46%)	23 (46%)	33 (66%)	25 (50%)
Interstitial Cell, Adenoma	13 (26%)	14 (28%)	6 (12%)	18 (36%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(10)	(5)	(10)	(10)
Lymph Node, Bronchial	(4)	(4)	(3)	(5)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (25%)			
Basal Cell Carcinoma, Metastatic, Skin	1 (25%)			
Lymph Node, Mandibular	(0)	(0)	(1)	(1)
Lymph Node, Mediastinal	(30)	(24)	(35)	(29)
Basal Cell Carcinoma, Metastatic, Skin	1 (3%)			
Lymph Node, Mesenteric	(49)	(50)	(50)	(49)
Spleen	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery			1 (2%)	
Thymus	(44)	(43)	(47)	(45)
Thymoma Malignant				1 (2%)

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(49)
Adenoma		1 (2%)		
Carcinoma		1 (2%)		
Fibroadenoma	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Fibroadenoma, Multiple		1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma	1 (2%)	1 (2%)		
Keratoacanthoma		2 (4%)	2 (4%)	1 (2%)
Squamous Cell Carcinoma			1 (2%)	

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Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
Sebaceous Gland, Adenoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Fibroma	1 (2%)	4 (8%)	2 (4%)	
Subcutaneous Tissue, Fibrosarcoma		1 (2%)		
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Lipoma		1 (2%)		1 (2%)
Subcutaneous Tissue, Osteosarcoma		1 (2%)		
Subcutaneous Tissue, Sarcoma		2 (4%)		
Subcutaneous Tissue, Schwannoma Benign				1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Chordoma				1 (2%)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Cranium, Squamous Cell Carcinoma, Metastatic, Skin			1 (2%)	
Tibia, Osteosarcoma				1 (2%)
Skeletal Muscle	(0)	(1)	(1)	(1)
Fibrous Histiocytoma, Metastatic, Skin		1 (100%)		

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
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RESPIRATORY SYSTEM

Larynx	(50)	(50)	(50)	(50)
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		1 (2%)		
Alveolar/Bronchiolar Carcinoma	1 (2%)		1 (2%)	2 (4%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)		
Basal Cell Carcinoma, Metastatic, Skin	1 (2%)			
Carcinoma, Metastatic, Mammary Gland		1 (2%)		
Carcinoma, Metastatic, Zymbal'S Gland				1 (2%)

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Species/Strain: RATS/F 344/N

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FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
Chordoma, Metastatic, Bone				1 (2%)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla				1 (2%)
Squamous Cell Carcinoma, Metastatic, Skin			1 (2%)	
Nose	(49)	(50)	(50)	(50)
Pleura	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(49)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(43)	(39)	(41)	(40)
Adenoma	2 (5%)	1 (3%)		
Carcinoma		3 (8%)		2 (5%)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Lipoma		1 (2%)		
Urinary Bladder	(50)	(50)	(49)	(50)
Hemangiosarcoma	1 (2%)			
Transitional Epithelium, Papilloma	1 (2%)	1 (2%)		

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				2 (4%)
Leukemia Mononuclear	25 (50%)	18 (36%)	33 (66%)	24 (48%)
Mesothelioma Malignant		3 (6%)	1 (2%)	

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* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS MALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	49	50	50	49
Total Primary Neoplasms	132	152	146	132
Total Animals with Benign Neoplasms	44	48	49	48
Total Benign Neoplasms	97	113	104	97
Total Animals with Malignant Neoplasms	31	31	37	32
Total Malignant Neoplasms	35	39	42	35
Total Animals with Metastatic Neoplasms	2	2	2	3
Total Metastatic Neoplasms	4	5	4	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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First Dose M/F: 08/25/03 / 08/25/03

Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS FEMALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	17	15	18	15
Natural Death	2	4	2	
Survivors				
Moribund Sacrifice			1	1
Terminal Sacrifice	31	31	29	34
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Intestine Large, Colon	(49)	(47)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	1 (2%)			
Mesentery	(16)	(15)	(18)	(10)
Carcinoma, Metastatic, Uncertain Primary Site	1 (6%)			
Pancreas	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(2)	(0)	(1)
Squamous Cell Papilloma		1 (50%)		

CARDIOVASCULAR SYSTEM

Heart	(50)	(50)	(50)	(50)
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ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	5 (10%)	2 (4%)	6 (12%)
Bilateral, Adenoma		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)	2 (4%)	1 (2%)

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Pheochromocytoma Malignant		1 (2%)	1 (2%)	1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Carcinoma			2 (4%)	
Parathyroid Gland	(43)	(42)	(48)	(48)
Adenoma	1 (2%)			
Pituitary Gland	(50)	(50)	(50)	(50)
Carcinoma	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Pars Distalis, Adenoma	29 (58%)	33 (66%)	36 (72%)	23 (46%)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Adenoma	4 (8%)	6 (12%)	3 (6%)	6 (12%)
C-cell, Carcinoma		1 (2%)		1 (2%)
Follicular Cell, Adenoma		1 (2%)		

GENERAL BODY SYSTEM

Tissue NOS	(1)	(0)	(0)	(0)
Mediastinum, Carcinoma, Metastatic, Uncertain Primary Site	1 (100%)			

GENITAL SYSTEM

Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	2 (4%)	3 (6%)	2 (4%)
Carcinoma			1 (2%)	
Ovary	(50)	(50)	(50)	(50)
Granulosa Cell Tumor Malignant			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			1 (2%)
Polyp Stromal	8 (16%)	9 (18%)	7 (14%)	9 (18%)
Polyp Stromal, Multiple		2 (4%)		1 (2%)
Sarcoma Stromal		1 (2%)		
Cervix, Polyp Stromal			1 (2%)	
Endometrium, Deciduoma Benign		1 (2%)		
Vagina	(1)	(0)	(0)	(0)

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FISCHER 344 RATS FEMALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(3)	(0)	(1)	(1)
Lymph Node, Bronchial	(4)	(1)	(5)	(7)
Lymph Node, Mandibular	(2)	(0)	(1)	(2)
Lymph Node, Mediastinal	(33)	(27)	(25)	(29)
Carcinoma, Metastatic, Thyroid Gland		1 (4%)		
Fibrosarcoma, Metastatic, Skin			1 (4%)	
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(48)	(44)	(40)	(47)
Thymoma Nos	1 (2%)			

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Carcinoma	7 (14%)	3 (6%)	1 (2%)	2 (4%)
Carcinoma, Multiple	1 (2%)		1 (2%)	
Fibroadenoma	18 (36%)	16 (32%)	17 (34%)	19 (38%)
Fibroadenoma, Multiple	9 (18%)	9 (18%)	8 (16%)	5 (10%)
Fibrosarcoma, Metastatic, Skin		1 (2%)		
Duct, Carcinoma	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma				1 (2%)
Basal Cell Carcinoma		1 (2%)		
Fibrosarcoma		1 (2%)		
Keratoacanthoma	1 (2%)			
Neural Crest Tumor				1 (2%)
Subcutaneous Tissue, Fibroma	1 (2%)		1 (2%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	

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Species/Strain: RATS/F 344/N

Lab: BNW

FISCHER 344 RATS FEMALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Vertebra, Osteosarcoma			1 (2%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pituitary Gland	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Granular Cell Tumor Malignant		1 (2%)		
Spinal Cord	(0)	(0)	(1)	(0)
Osteosarcoma, Metastatic, Bone			1 (100%)	

RESPIRATORY SYSTEM

Larynx	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma				1 (2%)
Carcinoma, Metastatic, Clitoral Gland			1 (2%)	
Carcinoma, Metastatic, Thyroid Gland		1 (2%)		1 (2%)
Carcinoma, Metastatic, Zymbal'S Gland		1 (2%)		
Nose	(50)	(49)	(50)	(50)
Pleura	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(40)	(38)	(42)	(33)
Carcinoma		2 (5%)		

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Lab: BNW

FISCHER 344 RATS FEMALE

CONTROL

31 PPM

62.5 PPM

125 PPM

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				1 (2%)
Leukemia Mononuclear	15 (30%)	10 (20%)	15 (30%)	11 (22%)

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* Number of animals with any tissue examined microscopically

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FISCHER 344 RATS FEMALE	CONTROL	31 PPM	62.5 PPM	125 PPM
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	48	48	48	46
Total Primary Neoplasms	108	110	107	95
Total Animals with Benign Neoplasms	43	45	46	40
Total Benign Neoplasms	81	88	82	76
Total Animals with Malignant Neoplasms	24	18	22	16
Total Malignant Neoplasms	26	22	25	18
Total Animals with Metastatic Neoplasms	3	4	4	2
Total Metastatic Neoplasms	4	6	4	2
Total Animals with Malignant Neoplasms Uncertain Primary Site	1			
Total Animals with Neoplasms Uncertain- Benign or Malignant	1			1
Total Uncertain Neoplasms	1			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