

TDMS No. 88123 - 05

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

FORMAMIDE

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Final 1 Rats

Date Report Reqsted: 12/05/2005

Time Report Reqsted: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

C Number: C88123B
Lock Date: 11/20/2003
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

Test Type: CHRONIC

Time Report Requested: 14:23:30

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	24	15	22	18
Natural Death		8	2	3
Survivors				
Terminal Sacrifice	26	27	26	29
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(49)	(50)	(50)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas		1 (2%)		
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)	1 (2%)		
Hepatocellular Adenoma		1 (2%)	1 (2%)	1 (2%)
Hepatocellular Carcinoma				2 (4%)
Ito Cell Tumor Benign				1 (2%)
Mesentery	(10)	(12)	(7)	(10)
Carcinoma, Metastatic, Pancreas		1 (8%)		
Oral Mucosa	(22)	(27)	(29)	(20)
Squamous Cell Carcinoma		1 (4%)		
Pancreas	(50)	(50)	(50)	(50)
Acinus, Carcinoma		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(1)	(0)	(0)
Squamous Cell Papilloma		1 (100%)		
Tooth	(25)	(32)	(30)	(25)

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

Test Type: CHRONIC

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CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Epicardium, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (2%)			
Pericardium, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (2%)			
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	7 (14%)	9 (18%)	1 (2%)	6 (12%)
Pheochromocytoma Malignant		1 (2%)	1 (2%)	1 (2%)
Bilateral, Pheochromocytoma Benign	2 (4%)		1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	2 (4%)		4 (8%)	2 (4%)
Carcinoma	1 (2%)			
Parathyroid Gland	(48)	(49)	(49)	(49)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	11 (22%)	15 (30%)	21 (42%)	18 (36%)
Pars Intermedia, Adenoma		1 (2%)		
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma		1 (2%)		
C-cell, Adenoma	6 (12%)	5 (10%)	6 (12%)	2 (4%)
C-cell, Carcinoma		1 (2%)		
Follicular Cell, Carcinoma	1 (2%)		1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				

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

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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Coagulating Gland	(0)	(1)	(1)	(0)
Epididymis	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)		2 (4%)	2 (4%)
Carcinoma	1 (2%)	3 (6%)	2 (4%)	2 (4%)
Prostate	(50)	(50)	(50)	(50)
Adenoma		3 (6%)	2 (4%)	
Seminal Vesicle	(50)	(50)	(50)	(49)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	32 (64%)	41 (82%)	44 (88%)	38 (76%)
Interstitial Cell, Adenoma	12 (24%)	7 (14%)	2 (4%)	7 (14%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(7)	(8)	(8)	(5)
Fibrous Histiocytoma, Metastatic, Skin	1 (14%)			
Lymph Node, Mandibular	(0)	(1)	(0)	(3)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Spleen	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Osteosarcoma, Metastatic, Skin			1 (2%)	
Thymus	(49)	(45)	(47)	(48)
Thymoma Malignant				1 (2%)

INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(48)	(50)	(50)
Adenoma	1 (2%)			
Carcinoma		1 (2%)		
Fibroadenoma	2 (4%)	4 (8%)		1 (2%)
Fibroma	1 (2%)			
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)		3 (6%)	
Keratoacanthoma	8 (16%)	3 (6%)	4 (8%)	2 (4%)
Squamous Cell Papilloma	1 (2%)			
Pinna, Neural Crest Tumor			1 (2%)	

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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Subcutaneous Tissue, Fibroma	5 (10%)	4 (8%)	2 (4%)	2 (4%)
Subcutaneous Tissue, Fibroma, Multiple	1 (2%)		1 (2%)	
Subcutaneous Tissue, Fibrosarcoma		1 (2%)		
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Osteosarcoma			1 (2%)	
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)			1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Chordoma	1 (2%)	1 (2%)	1 (2%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant		1 (2%)		
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma		2 (4%)	2 (4%)	2 (4%)
Alveolar/Bronchiolar Carcinoma	1 (2%)	2 (4%)		
Carcinoma, Metastatic, Pancreas		1 (2%)		
Chordoma, Metastatic, Bone	1 (2%)	1 (2%)	1 (2%)	
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)	1 (2%)		
Osteosarcoma, Metastatic, Skin			1 (2%)	
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla			1 (2%)	
Mediastinum, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Sarcoma			1 (2%)	
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				

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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(1)	(1)
Carcinoma			1 (100%)	1 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin	1 (2%)			
Stromal Nephroma			1 (2%)	
Renal Tubule, Adenoma	1 (2%)			
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)	2 (4%)		2 (4%)
Leukemia Mononuclear	15 (30%)	14 (28%)	17 (34%)	18 (36%)
Mesothelioma Malignant	2 (4%)	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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Route: GAVAGE

Species/Strain: RATS/F 344

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Time Report Requested: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

FISCHER 344 RATS MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	48	50	49	50
Total Primary Neoplasms	120	129	125	113
Total Animals with Benign Neoplasms	45	50	48	49
Total Benign Neoplasms	94	97	97	84
Total Animals with Malignant Neoplasms	25	27	26	25
Total Malignant Neoplasms	26	32	27	29
Total Animals with Metastatic Neoplasms	3	3	3	1
Total Metastatic Neoplasms	13	6	4	1
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant			1	
Total Uncertain Neoplasms			1	

*** 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

Test Type: CHRONIC

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CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	10	16	14	14
Natural Death	2	4	2	4
Survivors				
Natural Death		1		
Terminal Sacrifice	38	29	34	32
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Lipoma			1 (2%)	
Intestine Large, Cecum	(50)	(49)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(49)
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma	1 (2%)		1 (2%)	
Hepatocellular Adenoma, Multiple	1 (2%)			
Mesentery	(18)	(16)	(12)	(9)
Oral Mucosa	(15)	(9)	(12)	(7)
Gingival, Squamous Cell Carcinoma	1 (7%)			
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Adenoma				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma			1 (2%)	
Stomach, Glandular	(50)	(50)	(50)	(50)
Tongue	(0)	(0)	(1)	(0)
Tooth	(19)	(11)	(11)	(14)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)

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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Parathyroid Gland	(46)	(47)	(46)	(47)
Adenoma			1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	22 (44%)	21 (42%)	15 (30%)	15 (30%)
Pars Distalis, Carcinoma	2 (4%)		1 (2%)	
Pars Intermedia, Carcinoma			1 (2%)	
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma	1 (2%)	1 (2%)		
C-cell, Adenoma	4 (8%)	7 (14%)	6 (12%)	5 (10%)
C-cell, Carcinoma		1 (2%)		1 (2%)
Follicular Cell, Adenoma		2 (4%)	1 (2%)	3 (6%)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(49)
Adenoma	2 (4%)	1 (2%)	4 (8%)	3 (6%)
Carcinoma			1 (2%)	
Ovary	(50)	(50)	(50)	(50)
Granulosa-Theca Tumor Benign		1 (2%)		
Uterus	(50)	(50)	(50)	(50)
Carcinoma			2 (4%)	
Polyp Stromal	7 (14%)	7 (14%)	5 (10%)	10 (20%)
Sarcoma		1 (2%)	1 (2%)	1 (2%)
Sarcoma Stromal			1 (2%)	
Schwannoma Malignant	1 (2%)			

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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Cervix, Sarcoma Stromal				1 (2%)
Vagina	(0)	(2)	(0)	(0)
Leiomyosarcoma		1 (50%)		
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(6)	(5)	(3)	(2)
Deep Cervical, Carcinoma, Metastatic,				1 (50%)
Thyroid Gland				
Lymph Node, Mandibular	(1)	(0)	(1)	(1)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Thymus	(48)	(47)	(47)	(46)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma	2 (4%)	1 (2%)	1 (2%)	
Fibroadenoma	19 (38%)	17 (34%)	14 (28%)	20 (40%)
Fibroadenoma, Multiple	14 (28%)	7 (14%)	4 (8%)	5 (10%)
Fibroma	1 (2%)	1 (2%)		
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma	1 (2%)			1 (2%)
Basal Cell Carcinoma		1 (2%)		
Fibroma		1 (2%)		
Keratoacanthoma	2 (4%)	1 (2%)		1 (2%)
Squamous Cell Papilloma		1 (2%)		
Trichoepithelioma	1 (2%)			
Subcutaneous Tissue, Fibroma	1 (2%)			
Subcutaneous Tissue, Schwannoma			1 (2%)	
Malignant				
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma				1 (2%)
Skeletal Muscle	(1)	(0)	(1)	(0)

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Route: GAVAGE

Species/Strain: RATS/F 344

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Time Report Requested: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pituitary Gland	2 (4%)		1 (2%)	
Granular Cell Tumor Benign	1 (2%)			
Meningioma Malignant				1 (2%)
Neuroblastoma			1 (2%)	
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)		1 (2%)
Alveolar/Bronchiolar Carcinoma	1 (2%)			
Mediastinum, Alveolar/Bronchiolar Carcinoma	1 (2%)			
Nose	(50)	(50)	(50)	(50)
Astrocytoma Malignant, Metastatic, Brain			1 (2%)	
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Zymbal's Gland	(0)	(0)	(0)	(1)
Carcinoma				1 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Renal Tubule, Adenoma			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)

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

TDMS No. 88123 - 05

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

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Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Leukemia Granulocytic			1 (2%)	
Leukemia Mononuclear	10 (20%)	11 (22%)	12 (24%)	11 (22%)
Lymphoma Malignant		1 (2%)		
Mesothelioma Malignant	2 (4%)			

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

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

FISCHER 344 RATS FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	49	46	40	46
Total Primary Neoplasms	100	87	78	82
Total Animals with Benign Neoplasms	43	39	31	41
Total Benign Neoplasms	80	70	54	65
Total Animals with Malignant Neoplasms	15	16	20	16
Total Malignant Neoplasms	20	17	24	17
Total Animals with Metastatic Neoplasms	3		2	1
Total Metastatic Neoplasms	3		2	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