

TDMS No. 00117 - 66

Test Type: CHRONIC-LIFETIME

Route: DOSED FEED

Species/Strain: RATS/SD

C Number: C00117C

Lock Date: 10/31/2005

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

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

Aspartame

CAS Number: 22839-47-0

Pathologist: LAURIOLA, M.

Date Report Reqsted: 05/30/2006

Time Report Reqsted: 12:08:21

First Dose M/F: 06/27/97 / 06/27/97

Lab: CRC

Test Type: CHRONIC-LIFETIME

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Pathologist: LAURIOLA, M.

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SPRAGUE-DAWLEY RATS MALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Disposition Summary						
Animals Initially in Study	150	150	150	150	100	100
Early Deaths						
Natural Death	150	150	150	150	100	100
Survivors						
Animals Examined Microscopically	150	150	150	150	100	100
ALIMENTARY SYSTEM						
Esophagus	(150)	(150)	(150)	(150)	(100)	(100)
Intestine Large, Colon	(149)	(149)	(148)	(149)	(100)	(100)
Leiomyosarcoma	1 (1%)					1 (1%)
Polyp Adenomatous				1 (1%)		
Intestine Large, Rectum	(149)	(150)	(149)	(150)	(100)	(100)
Leiomyoma			2 (1%)			
Polyp Adenomatous		2 (1%)				
Intestine Small, Duodenum	(149)	(149)	(147)	(150)	(100)	(100)
Polyp Adenomatous					1 (1%)	
Intestine Small, Ileum	(149)	(149)	(148)	(149)	(100)	(100)
Intestine Small, Jejunum	(149)	(149)	(148)	(149)	(100)	(100)
Adenocarcinoma			1 (1%)			
Fibroma	1 (1%)					
Liver	(148)	(149)	(149)	(150)	(100)	(100)
Adenocarcinoma, Metastatic, Adrenal Cortex	1 (1%)					
Cholangioma			4 (3%)	2 (1%)	2 (2%)	1 (1%)
Hemangiosarcoma						1 (1%)
Hemangiosarcoma, Metastatic, Spleen	1 (1%)					
Hepatocellular Adenoma				1 (1%)		
Hepatocellular Carcinoma				1 (1%)		
Osteosarcoma, Metastatic, Bone	1 (1%)					
Schwannoma Malignant, Metastatic, Peripheral Nerve						
Oral Mucosa	(150)	(150)	(150)	(149)	(100)	(100)
Squamous Cell Carcinoma			2 (1%)			
Squamous Cell Papilloma				1 (1%)	1 (1%)	1 (1%)
Pancreas	(149)	(149)	(149)	(150)	(100)	(100)

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SPRAGUE-DAWLEY RATS MALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Pharynx	(150)	(150)	(148)	(147)	(99)	(100)
Salivary Glands	(150)	(150)	(148)	(148)	(99)	(99)
Carcinoma			1 (1%)			
Submandibular Gland, Liposarcoma	1 (1%)			1 (1%)		
Stomach, Forestomach	(148)	(149)	(149)	(150)	(100)	(100)
Squamous Cell Carcinoma		1 (1%)				1 (1%)
Squamous Cell Papilloma	1 (1%)		2 (1%)	3 (2%)	2 (2%)	3 (3%)
Stomach, Glandular	(148)	(149)	(149)	(149)	(100)	(100)
Neoplasm Nos		1 (1%)				
Tongue	(150)	(150)	(146)	(148)	(99)	(99)
Tooth	(2)	(0)	(0)	(2)	(0)	(1)
CARDIOVASCULAR SYSTEM						
Heart	(150)	(150)	(149)	(150)	(100)	(100)
Myxoma	1 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)	
Schwannoma Benign			1 (1%)	1 (1%)		
Schwannoma Malignant	1 (1%)	1 (1%)			1 (1%)	1 (1%)
ENDOCRINE SYSTEM						
Adrenal Cortex	(149)	(149)	(149)	(150)	(100)	(100)
Left, Adenocarcinoma	1 (1%)					
Left, Adenoma		1 (1%)		1 (1%)	3 (3%)	1 (1%)
Right, Adenoma	4 (3%)	1 (1%)	1 (1%)	3 (2%)	2 (2%)	1 (1%)
Adrenal Medulla	(149)	(149)	(149)	(150)	(100)	(100)
Bilateral, Pheochromocytoma Benign		2 (1%)	3 (2%)	3 (2%)	7 (7%)	4 (4%)
Left, Neuroblastoma	1 (1%)					
Left, Pheochromocytoma Benign	10 (7%)	16 (11%)	11 (7%)	7 (5%)	8 (8%)	12 (12%)
Left, Pheochromocytoma Malignant						1 (1%)
Right, Pheochromocytoma Benign	8 (5%)	2 (1%)	11 (7%)	5 (3%)	4 (4%)	5 (5%)
Right, Pheochromocytoma Malignant					1 (1%)	3 (3%)
Islets, Pancreatic	(149)	(148)	(149)	(150)	(100)	(100)
Adenoma	7 (5%)	3 (2%)	10 (7%)	5 (3%)	7 (7%)	6 (6%)
Parathyroid Gland	(140)	(149)	(140)	(148)	(99)	(100)
Adenoma		1 (1%)				
Pituitary Gland	(149)	(149)	(148)	(147)	(100)	(99)
Adenocarcinoma	1 (1%)	5 (3%)	1 (1%)	6 (4%)	2 (2%)	1 (1%)
Adenoma	1 (1%)				1 (1%)	

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Lab: CRC

SPRAGUE-DAWLEY RATS MALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (1%)			
Squamous Cell Carcinoma, Metastatic, Ear Pars Distalis, Adenocarcinoma					1 (1%)	
Pars Distalis, Adenoma	65 (44%)	57 (38%)	55 (37%)	54 (37%)	52 (52%)	45 (45%)
Thyroid Gland	(145)	(149)	(147)	(148)	(99)	(100)
Fibroangioma		1 (1%)				
C-cell, Adenocarcinoma	1 (1%)					
C-cell, Adenoma	3 (2%)	4 (3%)	6 (4%)	6 (4%)	2 (2%)	5 (5%)
C-cell, Carcinoma			2 (1%)	2 (1%)	3 (3%)	
Follicular Cell, Adenoma				1 (1%)	1 (1%)	
GENERAL BODY SYSTEM						
Peritoneum	(15)	(11)	(7)	(13)	(10)	(17)
Fibroangioma						1 (6%)
Hemangiosarcoma				1 (8%)		
Neoplasm Nos	1 (7%)					1 (6%)
Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (14%)			
Tissue NOS	(64)	(35)	(33)	(82)	(55)	(54)
Fibroma					1 (2%)	
GENITAL SYSTEM						
Epididymis	(149)	(150)	(149)	(148)	(99)	(100)
Prostate	(149)	(150)	(147)	(150)	(100)	(99)
Adenoma	1 (1%)				2 (2%)	2 (2%)
Seminal Vesicle	(0)	(0)	(1)	(1)	(0)	(0)
Rhabdomyosarcoma			1 (100%)			
Testes	(149)	(149)	(148)	(149)	(100)	(100)
Bilateral, Interstitial Cell, Adenoma	1 (1%)		1 (1%)			2 (2%)
Bilateral, Interstitial Cell, Interstitial Stromal Tumor	1 (1%)					
Interstitial Cell, Adenocarcinoma						
Interstitial Cell, Adenoma		5 (3%)	2 (1%)	6 (4%)	2 (2%)	1 (1%)
HEMATOPOIETIC SYSTEM						

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SPRAGUE-DAWLEY RATS MALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Bone Marrow	(1)	(1)	(0)	(0)	(1)	(1)
Lymph Node	(150)	(150)	(150)	(150)	(100)	(100)
Inguinal, Fibroangioma						1 (1%)
Mandibular, Osteosarcoma, Metastatic, Ear						
Mandibular, Schwannoma Malignant, Metastatic, Peripheral Nerve						
Mediastinal, Fibroangioma			1 (1%)			
Mediastinal, Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (1%)			
Mediastinal, Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland						1 (1%)
Mesenteric, Pancreatic, Leiomyosarcoma, Metastatic, Intestine Large, Colon	1 (1%)					
Mesenteric, Fibroangioma					2 (2%)	
Renal, Pheochromocytoma Malignant, Metastatic, Adrenal Medulla						1 (1%)
Spleen	(148)	(149)	(147)	(150)	(100)	(100)
Fibroangioma			1 (1%)	1 (1%)		1 (1%)
Fibroma			1 (1%)		1 (1%)	
Fibrosarcoma						1 (1%)
Hemangiosarcoma	1 (1%)			1 (1%)		
Thymus	(148)	(148)	(144)	(149)	(98)	(98)
Fibroangioma				1 (1%)		
Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (1%)			
Thymoma Benign		1 (1%)				
Thymoma Malignant	1 (1%)	1 (1%)				
INTEGUMENTARY SYSTEM						
Mammary Gland	(149)	(150)	(150)	(150)	(100)	(100)
Adenocarcinoma		1 (1%)	2 (1%)	1 (1%)	1 (1%)	
Adenoma			1 (1%)			
Fibroadenoma	5 (3%)	1 (1%)	6 (4%)	2 (1%)	3 (3%)	6 (6%)
Fibrolipoma	3 (2%)			1 (1%)		
Fibroma	1 (1%)	1 (1%)	2 (1%)	2 (1%)	1 (1%)	1 (1%)
Lipoma						1 (1%)
Skin	(149)	(150)	(150)	(149)	(100)	(100)

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Fibroma	1 (1%)	1 (1%)				
Lip, Squamous Cell Papilloma			1 (1%)			
Subcutaneous Tissue, Adenoma						1 (1%)
Subcutaneous Tissue, Fibroangioma						
Subcutaneous Tissue, Fibrolipoma	2 (1%)	2 (1%)	1 (1%)	3 (2%)	1 (1%)	2 (2%)
Subcutaneous Tissue, Fibroma	1 (1%)	3 (2%)	5 (3%)	1 (1%)	1 (1%)	1 (1%)
Subcutaneous Tissue, Fibrosarcoma	1 (1%)			1 (1%)		
Subcutaneous Tissue, Lipoma	2 (1%)	2 (1%)	4 (3%)	6 (4%)	1 (1%)	1 (1%)
Subcutaneous Tissue, Lipoma, Multiple			1 (1%)	2 (1%)		
Subcutaneous Tissue, Liposarcoma		1 (1%)				
MUSCULOSKELETAL SYSTEM						
Bone	(2)	(1)	(1)	(2)	(0)	(0)
Osteosarcoma	1 (50%)	1 (100%)				
Femur, Osteosarcoma	1 (50%)		1 (100%)			
Rib, Osteosarcoma				1 (50%)		
Bone, Cranium	(150)	(150)	(150)	(150)	(100)	(99)
Chondroma				1 (1%)	1 (1%)	
Osteoma		4 (3%)	2 (1%)	1 (1%)	3 (3%)	
Osteosarcoma	5 (3%)	7 (5%)	5 (3%)	9 (6%)	5 (5%)	2 (2%)
Skeletal Muscle	(150)	(150)	(149)	(150)	(100)	(100)
Diaphragm, Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (1%)			
NERVOUS SYSTEM						
Brain	(149)	(148)	(149)	(147)	(100)	(99)
Meningioma Benign			2 (1%)	1 (1%)		2 (2%)
Meningioma Malignant				1 (1%)		
Neoplasm Nos					1 (1%)	
Oligodendroglioma Nos				1 (1%)		1 (1%)
Schwannoma Malignant, Metastatic, Peripheral Nerve						
Cerebrum, Meninges, Neoplasm Nos					1 (1%)	
Cerebrum, Oligodendroglioma Nos		2 (1%)				1 (1%)
Meninges, Meningioma Benign	2 (1%)	1 (1%)	1 (1%)	1 (1%)	2 (2%)	3 (3%)
Peripheral Nerve	(1)	(2)	(4)	(2)	(2)	(3)
Schwannoma Benign			1 (25%)			

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Schwannoma Malignant Spinal, Schwannoma Malignant	1 (100%)	1 (50%)	1 (25%) 2 (50%)	2 (100%)	2 (100%)	3 (100%)
RESPIRATORY SYSTEM						
Larynx	(150)	(150)	(148)	(148)	(99)	(100)
Lung	(150)	(150)	(149)	(150)	(100)	(100)
Alveolar/Bronchiolar Adenoma				1 (1%)		
Fibroangioma		1 (1%)				1 (1%)
Fibroma			1 (1%)			
Fibrous Histiocytoma		1 (1%)				
Hemangiosarcoma						1 (1%)
Hemangiosarcoma, Metastatic, Liver						1 (1%)
Osteosarcoma, Metastatic, Bone, Cranium		1 (1%)				
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (1%)				
Rhabdomyosarcoma, Metastatic, Seminal Vesicle				1 (1%)		
Schwannoma Malignant, Metastatic, Peripheral Nerve						
Squamous Cell Carcinoma		1 (1%)				
Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland						1 (1%)
Bronchus, Adenoma						
Bronchus, Squamous Cell Carcinoma			1 (1%)			
Nose	(150)	(150)	(150)	(149)	(100)	(100)
Olfactory Epithelium, Adenoma				1 (1%)	2 (2%)	
Respiratory Epithelium, Adenoma		1 (1%)				1 (1%)
Respiratory Epithelium, Squamous Cell Carcinoma						
Sinus, Squamous Cell Carcinoma	1 (1%)					
Pleura	(150)	(150)	(149)	(150)	(100)	(100)
Neoplasm Nos				1 (1%)		
Trachea	(150)	(150)	(149)	(150)	(100)	(100)
SPECIAL SENSES SYSTEM						
Ear	(150)	(150)	(149)	(150)	(100)	(100)
Squamous Cell Carcinoma	5 (3%)	3 (2%)	3 (2%)	7 (5%)	7 (7%)	2 (2%)

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Left, Squamous Cell Carcinoma						
Eye	(1)	(1)	(0)	(1)	(1)	(0)
Harderian Gland	(150)	(150)	(150)	(146)	(100)	(100)
Lacrimal Gland	(1)	(0)	(0)	(0)	(0)	(0)
Zymbal's Gland	(150)	(150)	(149)	(148)	(99)	(100)
Left, Squamous Cell Carcinoma	2 (1%)	1 (1%)	2 (1%)		1 (1%)	3 (3%)
Right, Squamous Cell Carcinoma			1 (1%)		1 (1%)	
URINARY SYSTEM						
Kidney	(150)	(149)	(149)	(150)	(100)	(100)
Bilateral, Rhabdomyosarcoma, Metastatic, Seminal Vesicle			1 (1%)			
Left, Pelvis Transitional Epithelium, Carcinoma				1 (1%)		1 (1%)
Left, Pelvis Transitional Epithelium, Papilloma			1 (1%)		1 (1%)	
Left, Renal Tubule, Adenoma	1 (1%)					
Left, Fibroangioma		1 (1%)				
Pelvis, Right Transitional Epithelium, Carcinoma					1 (1%)	
Pelvis, Right Transitional Epithelium, Papilloma			1 (1%)			
Urinary Bladder	(150)	(150)	(147)	(150)	(100)	(100)
Papilloma						1 (1%)
Transitional Epithelium, Carcinoma					2 (2%)	
Transitional Epithelium, Papilloma		1 (1%)				
SYSTEMIC LESIONS						
Multiple Organs	*(150)	*(150)	*(150)	*(150)	*(100)	*(100)
Histiocytic Sarcoma	8 (5%)	4 (3%)	2 (1%)	10 (7%)	3 (3%)	6 (6%)
Leukemia Granulocytic	1 (1%)	2 (1%)			1 (1%)	
Leukemia Lymphoblastic	1 (1%)				1 (1%)	
Leukemia Lymphocytic					1 (1%)	
Leukemia Monocytic	2 (1%)	2 (1%)	1 (1%)	7 (5%)	3 (3%)	1 (1%)
Leukemia Myeloid	1 (1%)	2 (1%)			1 (1%)	
Lymphoma Lympho-Immunoblastic	19 (13%)	12 (8%)	22 (15%)	15 (10%)	8 (8%)	13 (13%)
Lymphoma Lymphoblastic		3 (2%)				

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Lymphoma Lymphocytic				1 (1%)		
Lymphoma Malignant	2 (1%)			2 (1%)	1 (1%)	1 (1%)
Lymphoma Malignant Lymphocytic	1 (1%)			3 (2%)	1 (1%)	1 (1%)
Mesothelioma Malignant	2 (1%)		1 (1%)			1 (1%)

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SPRAGUE-DAWLEY RATS MALE

100000 PPM

Disposition Summary

Animals Initially in Study	100
Early Deaths	
Natural Death	100
Survivors	
Animals Examined Microscopically	100

ALIMENTARY SYSTEM

Esophagus	(99)
Intestine Large, Colon	(98)
Leiomyosarcoma	
Polyp Adenomatous	
Intestine Large, Rectum	(100)
Leiomyoma	
Polyp Adenomatous	
Intestine Small, Duodenum	(98)
Polyp Adenomatous	
Intestine Small, Ileum	(98)
Intestine Small, Jejunum	(98)
Adenocarcinoma	
Fibroma	
Liver	(100)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Cholangioma	
Hemangiosarcoma	
Hemangiosarcoma, Metastatic, Spleen	
Hepatocellular Adenoma	
Hepatocellular Carcinoma	1 (1%)
Osteosarcoma, Metastatic, Bone	
Schwannoma Malignant, Metastatic, Peripheral Nerve	1 (1%)
Oral Mucosa	(100)
Squamous Cell Carcinoma	1 (1%)
Squamous Cell Papilloma	
Pancreas	(99)

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SPRAGUE-DAWLEY RATS MALE	100000 PPM
Pharynx	(99)
Salivary Glands	(99)
Carcinoma	
Submandibular Gland, Liposarcoma	
Stomach, Forestomach	(100)
Squamous Cell Carcinoma	
Squamous Cell Papilloma	3 (3%)
Stomach, Glandular	(100)
Neoplasm Nos	
Tongue	(99)
Tooth	(4)
CARDIOVASCULAR SYSTEM	
Heart	(100)
Myxoma	
Schwannoma Benign	
Schwannoma Malignant	1 (1%)
ENDOCRINE SYSTEM	
Adrenal Cortex	(100)
Left, Adenocarcinoma	
Left, Adenoma	
Right, Adenoma	2 (2%)
Adrenal Medulla	(100)
Bilateral, Pheochromocytoma Benign	3 (3%)
Left, Neuroblastoma	
Left, Pheochromocytoma Benign	11 (11%)
Left, Pheochromocytoma Malignant	1 (1%)
Right, Pheochromocytoma Benign	5 (5%)
Right, Pheochromocytoma Malignant	1 (1%)
Islets, Pancreatic	(99)
Adenoma	9 (9%)
Parathyroid Gland	(99)
Adenoma	
Pituitary Gland	(98)
Adenocarcinoma	1 (1%)
Adenoma	2 (2%)

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SPRAGUE-DAWLEY RATS MALE

100000 PPM

Rhabdomyosarcoma, Metastatic, Seminal Vesicle	
Squamous Cell Carcinoma, Metastatic, Ear	
Pars Distalis, Adenocarcinoma	1 (1%)
Pars Distalis, Adenoma	33 (34%)
Thyroid Gland	(100)
Fibroangioma	
C-cell, Adenocarcinoma	
C-cell, Adenoma	5 (5%)
C-cell, Carcinoma	
Follicular Cell, Adenoma	

GENERAL BODY SYSTEM

Peritoneum	(14)
Fibroangioma	
Hemangiosarcoma	
Neoplasm Nos	1 (7%)
Rhabdomyosarcoma, Metastatic, Seminal Vesicle	
Tissue NOS	(33)
Fibroma	

GENITAL SYSTEM

Epididymis	(96)
Prostate	(97)
Adenoma	1 (1%)
Seminal Vesicle	(1)
Rhabdomyosarcoma	
Testes	(97)
Bilateral, Interstitial Cell, Adenoma	
Bilateral, Interstitial Cell, Interstitial Stromal Tumor	
Interstitial Cell, Adenocarcinoma	1 (1%)
Interstitial Cell, Adenoma	1 (1%)

HEMATOPOIETIC SYSTEM

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SPRAGUE-DAWLEY RATS MALE

100000 PPM

Bone Marrow	(1)
Lymph Node	(100)
Inguinal, Fibroangioma	
Mandibular, Osteosarcoma, Metastatic, Ear	1 (1%)
Mandibular, Schwannoma Malignant, Metastatic, Peripheral Nerve	2 (2%)
Mediastinal, Fibroangioma	
Mediastinal, Rhabdomyosarcoma, Metastatic, Seminal Vesicle	
Mediastinal, Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland	
Mesenteric, Pancreatic, Leiomyosarcoma, Metastatic, Intestine Large, Colon	
Mesenteric, Fibroangioma	
Renal, Pheochromocytoma Malignant, Metastatic, Adrenal Medulla	
Spleen	(99)
Fibroangioma	4 (4%)
Fibroma	
Fibrosarcoma	
Hemangiosarcoma	2 (2%)
Thymus	(94)
Fibroangioma	
Rhabdomyosarcoma, Metastatic, Seminal Vesicle	
Thymoma Benign	1 (1%)
Thymoma Malignant	

INTEGUMENTARY SYSTEM

Mammary Gland	(100)
Adenocarcinoma	1 (1%)
Adenoma	1 (1%)
Fibroadenoma	2 (2%)
Fibrolipoma	1 (1%)
Fibroma	1 (1%)
Lipoma	
Skin	(100)

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS MALE

100000 PPM

Fibroma	
Lip, Squamous Cell Papilloma	
Subcutaneous Tissue, Adenoma	
Subcutaneous Tissue, Fibroangioma	1 (1%)
Subcutaneous Tissue, Fibrolipoma	
Subcutaneous Tissue, Fibroma	1 (1%)
Subcutaneous Tissue, Fibrosarcoma	
Subcutaneous Tissue, Lipoma	
Subcutaneous Tissue, Lipoma, Multiple	
Subcutaneous Tissue, Liposarcoma	

MUSCULOSKELETAL SYSTEM

Bone	(5)
Osteosarcoma	
Femur, Osteosarcoma	
Rib, Osteosarcoma	
Bone, Cranium	(99)
Chondroma	
Osteoma	
Osteosarcoma	3 (3%)
Skeletal Muscle	(93)
Diaphragm, Rhabdomyosarcoma,	
Metastatic, Seminal Vesicle	

NERVOUS SYSTEM

Brain	(99)
Meningioma Benign	
Meningioma Malignant	
Neoplasm Nos	
Oligodendroglioma Nos	
Schwannoma Malignant, Metastatic,	1 (1%)
Peripheral Nerve	
Cerebrum, Meninges, Neoplasm Nos	
Cerebrum, Oligodendroglioma Nos	1 (1%)
Meninges, Meningioma Benign	1 (1%)
Peripheral Nerve	(4)
Schwannoma Benign	

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Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS MALE

100000 PPM

Schwannoma Malignant
Spinal, Schwannoma Malignant 4 (100%)

RESPIRATORY SYSTEM

Larynx (100)
Lung (100)
Alveolar/Bronchiolar Adenoma
Fibroangioma
Fibroma
Fibrous Histiocytoma
Hemangiosarcoma 1 (1%)
Hemangiosarcoma, Metastatic, Liver
Osteosarcoma, Metastatic, Bone, Cranium
Osteosarcoma, Metastatic, Uncertain
Primary Site
Rhabdomyosarcoma, Metastatic, Seminal
Vesicle
Schwannoma Malignant, Metastatic,
Peripheral Nerve 1 (1%)
Squamous Cell Carcinoma
Squamous Cell Carcinoma, Metastatic,
Zymbal'S Gland
Bronchus, Adenoma 1 (1%)
Bronchus, Squamous Cell Carcinoma
Nose (100)
Olfactory Epithelium, Adenoma
Respiratory Epithelium, Adenoma
Respiratory Epithelium, Squamous Cell
Carcinoma 1 (1%)
Sinus, Squamous Cell Carcinoma
Pleura (100)
Neoplasm Nos
Trachea (100)

SPECIAL SENSES SYSTEM

Ear (100)
Squamous Cell Carcinoma 2 (2%)

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Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

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CAS Number: 22839-47-0

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Species/Strain: RATS/SD

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Lab: CRC

SPRAGUE-DAWLEY RATS MALE

100000 PPM

Left, Squamous Cell Carcinoma	1 (1%)
Eye	(0)
Harderian Gland	(100)
Lacrimal Gland	(0)
Zymbal's Gland	(99)
Left, Squamous Cell Carcinoma	1 (1%)
Right, Squamous Cell Carcinoma	

URINARY SYSTEM

Kidney	(100)
Bilateral, Rhabdomyosarcoma, Metastatic, Seminal Vesicle	
Left, Pelvis Transitional Epithelium, Carcinoma	
Left, Pelvis Transitional Epithelium, Papilloma	
Left, Renal Tubule, Adenoma	
Left, Fibroangioma	
Pelvis, Right Transitional Epithelium, Carcinoma	1 (1%)
Pelvis, Right Transitional Epithelium, Papilloma	
Urinary Bladder	(98)
Papilloma	
Transitional Epithelium, Carcinoma	
Transitional Epithelium, Papilloma	

SYSTEMIC LESIONS

Multiple Organs	*(100)
Histiocytic Sarcoma	4 (4%)
Leukemia Granulocytic	1 (1%)
Leukemia Lymphoblastic	
Leukemia Lymphocytic	
Leukemia Monocytic	1 (1%)
Leukemia Myeloid	1 (1%)
Lymphoma Lympho-Immunoblastic	24 (24%)
Lymphoma Lymphoblastic	

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* Number of animals with any tissue examined microscopically

TDMS No. 00117 - 66

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

Date Report Reqsted: 05/30/2006

Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Reqsted: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS MALE

100000 PPM

Lymphoma Lymphocytic

Lymphoma Malignant

Lymphoma Malignant Lymphocytic

Mesothelioma Malignant

1 (1%)

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Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS MALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	114	109	119	114	83	86
Total Primary Neoplasms	186	169	195	201	167	161
Total Animals with Benign Neoplasms	93	82	99	87	77	71
Total Benign Neoplasms	121	116	143	126	118	113
Total Animals with Malignant Neoplasms	53	44	48	60	34	38
Total Malignant Neoplasms	63	50	52	73	47	45
Total Animals with Metastatic Neoplasms	5	2	1		1	3
Total Metastatic Neoplasms	7	2	7		1	4
Total Animals with Malignant Neoplasms Uncertain Primary Site		1				
Total Animals with Neoplasms Uncertain-Benign or Malignant	2	3		2	2	3
Total Uncertain Neoplasms	2	3		2	2	3

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-LIFETIME

Aspartame

Time Report Reqsted: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS MALE

100000 PPM

Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	82
Total Primary Neoplasms	148
Total Animals with Benign Neoplasms	66
Total Benign Neoplasms	89
Total Animals with Malignant Neoplasms	43
Total Malignant Neoplasms	57
Total Animals with Metastatic Neoplasms	4
Total Metastatic Neoplasms	6
Total Animals with Malignant Neoplasms Uncertain Primary Site	
Total Animals with Neoplasms Uncertain-Benign or Malignant	2
Total Uncertain Neoplasms	2

*** 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-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Disposition Summary						
Animals Initially in Study	150	150	150	150	100	100
Early Deaths						
Natural Death	150	150	150	150	100	100
Survivors						
Animals Examined Microscopically	150	150	150	150	100	100
ALIMENTARY SYSTEM						
Esophagus	(150)	(150)	(149)	(149)	(99)	(99)
Intestine Large, Colon	(149)	(148)	(148)	(147)	(99)	(99)
Adenocarcinoma				1 (1%)		
Intestine Large, Rectum	(150)	(148)	(149)	(148)	(100)	(99)
Adenocarcinoma	1 (1%)				1 (1%)	
Leiomyoma	1 (1%)					
Polyp Adenomatous	1 (1%)			1 (1%)	1 (1%)	2 (2%)
Intestine Small, Duodenum	(149)	(149)	(148)	(148)	(99)	(99)
Adenocarcinoma	1 (1%)					
Intestine Small, Ileum	(149)	(148)	(148)	(149)	(99)	(99)
Intestine Small, Jejunum	(149)	(148)	(148)	(149)	(99)	(99)
Liver	(150)	(150)	(149)	(149)	(99)	(99)
Adenocarcinoma, Metastatic, Adrenal Cortex	1 (1%)	2 (1%)	2 (1%)	1 (1%)		1 (1%)
Adenocarcinoma, Metastatic, Intestine Large, Colon				1 (1%)		
Cholangiocarcinoma					1 (1%)	
Cholangioma	1 (1%)		1 (1%)			2 (2%)
Fibroangioma					1 (1%)	
Hemangiosarcoma		1 (1%)				
Hepatocellular Adenoma	2 (1%)	1 (1%)				
Hepatocellular Carcinoma			1 (1%)			
Leiomyosarcoma, Metastatic, Stomach, Glandular				1 (1%)		
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		2 (1%)		1 (1%)		1 (1%)
Bile Duct, Cholangioma	2 (1%)		1 (1%)			
Mesentery	(1)	(0)	(72)	(3)	(2)	(2)

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Test Type: CHRONIC-LIFETIME

Aspartame

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Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Oral Mucosa	(150)	(150)	(150)	(150)	(100)	(100)
Squamous Cell Carcinoma	2 (1%)		4 (3%)	1 (1%)	1 (1%)	
Squamous Cell Papilloma		1 (1%)				
Pancreas	(150)	(149)	(147)	(149)	(99)	(99)
Adenoma			1 (1%)			1 (1%)
Carcinoid Tumor Malignant, Metastatic, Stomach, Glandular						
Pharynx	(150)	(150)	(149)	(148)	(99)	(100)
Neoplasm Nos					1 (1%)	
Squamous Cell Carcinoma	1 (1%)					
Salivary Glands	(150)	(150)	(149)	(150)	(100)	(100)
Adenoma, Atypical	1 (1%)					
Stomach, Forestomach	(150)	(150)	(148)	(150)	(99)	(99)
Neoplasm Nos			1 (1%)			
Squamous Cell Papilloma	4 (3%)	1 (1%)	1 (1%)		3 (3%)	
Stomach, Glandular	(150)	(150)	(148)	(150)	(99)	(99)
Carcinoid Tumor Malignant						
Leiomyosarcoma				1 (1%)		
Tongue	(150)	(150)	(149)	(150)	(99)	(100)
Squamous Cell Carcinoma						1 (1%)
Squamous Cell Papilloma					1 (1%)	
Tooth	(3)	(2)	(77)	(1)	(4)	(3)
CARDIOVASCULAR SYSTEM						
Heart	(149)	(150)	(150)	(149)	(99)	(99)
Adenocarcinoma, Metastatic, Mammary Gland			1 (1%)			
Myxoma		2 (1%)	1 (1%)			
Schwannoma Benign			1 (1%)			
Schwannoma Malignant					1 (1%)	
ENDOCRINE SYSTEM						
Adrenal Cortex	(150)	(150)	(150)	(150)	(100)	(99)
Bilateral, Adenoma		1 (1%)		2 (1%)		2 (2%)
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site			1 (1%)			
Left, Adenocarcinoma	2 (1%)	1 (1%)	1 (1%)	2 (1%)	2 (2%)	1 (1%)

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Aspartame

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First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Left, Adenoma	1 (1%)	2 (1%)	6 (4%)	4 (3%)	3 (3%)	
Right, Adenocarcinoma	1 (1%)	1 (1%)	1 (1%)			1 (1%)
Right, Adenocarcinoma, Metastatic, Ovary				1 (1%)		
Right, Adenoma	3 (2%)	7 (5%)	3 (2%)	5 (3%)	4 (4%)	
Adrenal Medulla	(149)	(150)	(149)	(150)	(100)	(99)
Ganglioneuroma	1 (1%)					
Pheochromocytoma Benign	1 (1%)					
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site			1 (1%)			
Bilateral, Pheochromocytoma Benign	13 (9%)	2 (1%)	6 (4%)	8 (5%)	4 (4%)	8 (8%)
Bilateral, Pheochromocytoma Malignant				1 (1%)		
Left, Ganglioneuroma			1 (1%)			
Left, Pheochromocytoma Benign	15 (10%)	16 (11%)	10 (7%)	19 (13%)	13 (13%)	9 (9%)
Left, Pheochromocytoma Malignant		4 (3%)	1 (1%)	1 (1%)		4 (4%)
Right, Adenocarcinoma, Metastatic, Ovary				1 (1%)		
Right, Pheochromocytoma Benign	7 (5%)	8 (5%)	6 (4%)	10 (7%)	7 (7%)	7 (7%)
Right, Pheochromocytoma Malignant			1 (1%)	1 (1%)		1 (1%)
Islets, Pancreatic	(150)	(149)	(147)	(149)	(99)	(99)
Adenoma	1 (1%)	4 (3%)	1 (1%)	2 (1%)		1 (1%)
Carcinoid Tumor Malignant, Metastatic, Stomach, Glandular						
Carcinoma			1 (1%)			
Neoplasm Nos						
Parathyroid Gland	(129)	(148)	(148)	(150)	(99)	(100)
Adenoma		2 (1%)	1 (1%)	1 (1%)		
Pituitary Gland	(148)	(150)	(148)	(150)	(100)	(100)
Adenocarcinoma		1 (1%)	3 (2%)	3 (2%)	1 (1%)	3 (3%)
Adenoma	1 (1%)				1 (1%)	2 (2%)
Pars Distalis, Adenoma	50 (34%)	29 (19%)	34 (23%)	37 (25%)	26 (26%)	33 (33%)
Pars Intermedia, Adenoma						
Thyroid Gland	(147)	(150)	(149)	(150)	(99)	(100)
Bilateral, C-cell, Adenoma	1 (1%)	1 (1%)		1 (1%)		
Bilateral, C-cell, Carcinoma				1 (1%)		
C-cell, Adenocarcinoma						
C-cell, Adenoma	6 (4%)	4 (3%)	7 (5%)	7 (5%)	7 (7%)	2 (2%)
C-cell, Carcinoma	2 (1%)	2 (1%)	3 (2%)	1 (1%)		2 (2%)
Follicular Cell, Adenoma	1 (1%)					1 (1%)

GENERAL BODY SYSTEM

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Aspartame

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First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Peritoneum	(47)	(12)	(24)	(35)	(13)	(22)
Adenocarcinoma, Metastatic, Adrenal Cortex			1 (4%)			
Adenocarcinoma, Metastatic, Ovary		1 (8%)				
Fibrolipoma	1 (2%)					
Hemangiosarcoma				1 (3%)		
Neoplasm Nos						
Schwannoma Malignant, Metastatic, Uterus			1 (4%)			
Tissue NOS	(86)	(132)	(115)	(76)	(70)	(84)
Fibroangioma					1 (1%)	
Lipoma					1 (1%)	1 (1%)
Squamous Cell Carcinoma	1 (1%)					
Abdominal, Hemangiosarcoma			1 (1%)			
Mediastinum, Adenocarcinoma, Metastatic, Adrenal Cortex			1 (1%)			
Mediastinum, Adenocarcinoma, Metastatic, Ovary			1 (1%)			
Mediastinum, Liposarcoma	1 (1%)					
GENITAL SYSTEM						
Ovary	(150)	(148)	(149)	(148)	(99)	(99)
Adenocarcinoma		1 (1%)	1 (1%)	1 (1%)		1 (1%)
Cystadenoma	5 (3%)	4 (3%)	2 (1%)	8 (5%)	1 (1%)	
Fibroangioma				1 (1%)		3 (3%)
Fibroma						
Granulosa Cell Tumor Benign		1 (1%)				
Granulosa-Theca Tumor Benign		1 (1%)	1 (1%)	2 (1%)		
Neoplasm Nos					1 (1%)	
Sertoli Cell Tumor Benign	1 (1%)					
Sertoli Cell Tumor Malignant				1 (1%)		
Thecoma Benign	1 (1%)		1 (1%)			
Bilateral, Fibroangioma						
Left, Fibroangioma					1 (1%)	
Oviduct	(150)	(149)	(149)	(148)	(99)	(99)
Uterus	(150)	(147)	(149)	(148)	(99)	(99)
Adenocarcinoma	3 (2%)		1 (1%)	3 (2%)	1 (1%)	4 (4%)
Adenocarcinoma, Metastatic, Ovary		1 (1%)				

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Test Type: CHRONIC-LIFETIME

Aspartame

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Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Adenoma	2 (1%)					
Fibroangioma	3 (2%)	1 (1%)		2 (1%)	1 (1%)	
Fibroma						2 (2%)
Hemangiosarcoma				1 (1%)		
Leiomyoma				1 (1%)		
Leiomyosarcoma	1 (1%)		1 (1%)			1 (1%)
Polyp	1 (1%)					
Polyp, Multiple	1 (1%)					
Polyp Stromal	28 (19%)	51 (35%)	35 (23%)	23 (16%)	28 (28%)	39 (39%)
Polyp Stromal, Multiple	8 (5%)					
Sarcoma		1 (1%)				
Schwannoma Malignant	5 (3%)	2 (1%)	4 (3%)	3 (2%)	4 (4%)	1 (1%)
Squamous Cell Carcinoma				2 (1%)	1 (1%)	
Cervix, Fibroangioma						1 (1%)
Cervix, Squamous Cell Carcinoma					1 (1%)	
Endometrium, Adenoma		1 (1%)		1 (1%)		
Endometrium, Squamous Cell Carcinoma			1 (1%)			
Vagina	(149)	(147)	(149)	(147)	(99)	(99)
Fibroangioma				1 (1%)		
Fibroma				1 (1%)		
Hemangiosarcoma				1 (1%)		
Polyp		2 (1%)				1 (1%)
Schwannoma Benign			1 (1%)			
Schwannoma Malignant	1 (1%)					
Squamous Cell Papilloma			1 (1%)			

HEMATOPOIETIC SYSTEM

Bone Marrow	(1)	(0)	(0)	(1)	(0)	(1)
Lymph Node	(150)	(149)	(150)	(150)	(100)	(100)
Axillary, Inguinal, Liposarcoma, Metastatic, Mammary Gland			1 (1%)			
Axillary, Adenocarcinoma, Metastatic, Mammary Gland	1 (1%)					
Lumbar, Mediastinal, Leiomyosarcoma, Metastatic, Stomach, Glandular				1 (1%)		
Lumbar, Adenocarcinoma, Metastatic, Intestine Large, Rectum					1 (1%)	
Lumbar, Adenocarcinoma, Metastatic,			1 (1%)			

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Test Type: CHRONIC-LIFETIME

Aspartame

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CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Mammary Gland						
Lumbar, Schwannoma Malignant, Metastatic, Uterus					1 (1%)	
Mandibular, Liposarcoma, Metastatic, Tissue Nos	1 (1%)					
Mandibular, Squamous Cell Carcinoma, Metastatic, Ear	1 (1%)					
Mandibular, Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland				1 (1%)		1 (1%)
Mediastinal, Adenocarcinoma, Metastatic, Adrenal Cortex			1 (1%)			
Mediastinal, Adenocarcinoma, Metastatic, Ovary			1 (1%)	1 (1%)		
Mediastinal, Carcinosarcoma, Metastatic, Mammary Gland		1 (1%)				
Mediastinal, Hemangioma			1 (1%)			
Mediastinal, Osteosarcoma, Metastatic, Uncertain Primary Site			1 (1%)			
Mesenteric, Fibroangioma		1 (1%)				
Lymph Node, Mandibular	(10)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mediastinal	(9)	(0)	(0)	(0)	(0)	(0)
Lymph Node, Mesenteric	(8)	(0)	(0)	(0)	(0)	(0)
Spleen	(150)	(149)	(146)	(149)	(99)	(98)
Adenocarcinoma, Metastatic, Adrenal Cortex			1 (1%)	1 (1%)		1 (1%)
Adenocarcinoma, Metastatic, Mammary Gland			1 (1%)			
Fibroangioma		1 (1%)		1 (1%)		2 (2%)
Fibroma		1 (1%)	2 (1%)		1 (1%)	1 (1%)
Hemangiosarcoma	1 (1%)					
Thymus	(149)	(150)	(147)	(149)	(99)	(100)
Adenocarcinoma, Metastatic, Adrenal Cortex			1 (1%)			
Thymoma Benign	2 (1%)	7 (5%)	4 (3%)	6 (4%)	5 (5%)	6 (6%)
Thymoma Malignant	1 (1%)	1 (1%)				
INTEGUMENTARY SYSTEM						
Mammary Gland	(150)	(150)	(150)	(150)	(99)	(99)

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Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Adenocarcinoma	7 (5%)	9 (6%)	14 (9%)	12 (8%)	6 (6%)	17 (17%)
Adenocarcinoma, Multiple	1 (1%)	6 (4%)	2 (1%)		1 (1%)	1 (1%)
Adenoma	1 (1%)		2 (1%)			2 (2%)
Carcinosarcoma		1 (1%)				
Fibroadenoma	60 (40%)	48 (32%)	54 (36%)	45 (30%)	34 (34%)	33 (33%)
Fibroadenoma, Multiple	28 (19%)	18 (12%)	34 (23%)	20 (13%)	21 (21%)	21 (21%)
Fibrolipoma	1 (1%)				1 (1%)	
Fibroma	1 (1%)	2 (1%)	1 (1%)	3 (2%)	3 (3%)	5 (5%)
Fibroma, Multiple				1 (1%)		
Fibrosarcoma						1 (1%)
Lipoma	1 (1%)				1 (1%)	1 (1%)
Liposarcoma		1 (1%)	1 (1%)			
Neoplasm Nos		1 (1%)				
Skin	(150)	(150)	(146)	(149)	(99)	(100)
Squamous Cell Papilloma		1 (1%)				
Interscapular Brown Fat Pad, Fibrosarcoma, Lipomatous						
Lip, Squamous Cell Carcinoma						
Subcutaneous Tissue, Fibroangioma		1 (1%)				
Subcutaneous Tissue, Fibrolipoma	1 (1%)					
Subcutaneous Tissue, Fibroma		1 (1%)	1 (1%)		1 (1%)	1 (1%)
Subcutaneous Tissue, Fibromyxoma					1 (1%)	
Subcutaneous Tissue, Fibrosarcoma	1 (1%)	2 (1%)	1 (1%)	1 (1%)		
Subcutaneous Tissue, Liposarcoma	1 (1%)	1 (1%)				
Subcutaneous Tissue, Rhabdomyosarcoma	1 (1%)					

MUSCULOSKELETAL SYSTEM

Bone	(2)	(0)	(2)	(1)	(1)	(0)
Osteosarcoma			1 (50%)		1 (100%)	
Femur, Osteosarcoma	1 (50%)		1 (50%)	1 (100%)		
Pelvis, Osteosarcoma	1 (50%)					
Bone, Cranium	(149)	(150)	(149)	(150)	(100)	(100)
Chondroma					1 (1%)	
Osteoma		1 (1%)	1 (1%)	1 (1%)	1 (1%)	
Osteosarcoma	7 (5%)	9 (6%)	3 (2%)	4 (3%)	3 (3%)	3 (3%)
Mandible, Osteosarcoma						
Skeletal Muscle	(148)	(150)	(149)	(150)	(99)	(99)

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Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Diaphragm, Adenocarcinoma, Metastatic, Intestine Large, Colon				1 (1%)		
Diaphragm, Adenocarcinoma, Metastatic, Ovary		1 (1%)				
Diaphragm, Sertoli Cell Tumor Malignant, Metastatic, Ovary				1 (1%)		
NERVOUS SYSTEM						
Brain	(150)	(145)	(150)	(150)	(100)	(100)
Glioma Malignant, Mixed Neoplasm Nos				1 (1%)		1 (1%)
Oligodendroglioma Nos		1 (1%)			2 (2%)	
Cerebellum, Astrocytoma Nos						
Meninges, Meningioma Benign		1 (1%)	2 (1%)	2 (1%)	1 (1%)	1 (1%)
Peripheral Nerve	(0)	(2)	(0)	(5)	(1)	(2)
Schwannoma Benign				2 (40%)		
Schwannoma Malignant		1 (50%)		1 (20%)	1 (100%)	1 (50%)
Spinal, Schwannoma Malignant		1 (50%)		2 (40%)		
RESPIRATORY SYSTEM						
Larynx	(149)	(150)	(149)	(150)	(97)	(100)
Lung	(150)	(150)	(148)	(149)	(99)	(99)
Adenocarcinoma, Metastatic, Adrenal Cortex		1 (1%)	1 (1%)			1 (1%)
Adenocarcinoma, Metastatic, Mammary Gland		1 (1%)	2 (1%)	1 (1%)	2 (2%)	
Alveolar/Bronchiolar Adenoma				2 (1%)		
Carcinosarcoma, Metastatic, Mammary Gland		1 (1%)				
Fibroangioma				2 (1%)		
Liposarcoma, Metastatic, Mammary Gland			1 (1%)			
Osteosarcoma, Metastatic, Bone	1 (1%)		1 (1%)			
Osteosarcoma, Metastatic, Uncertain Primary Site			1 (1%)		1 (1%)	
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		3 (2%)			1 (1%)	2 (2%)
Schwannoma Malignant, Metastatic,					1 (1%)	

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SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Uterus						
Squamous Cell Carcinoma			1 (1%)			1 (1%)
Squamous Cell Carcinoma, Metastatic, Oral Mucosa						
Squamous Cell Carcinoma, Metastatic, Uncertain Primary Site	1 (1%)					
Bronchiole, Adenoma						1 (1%)
Bronchus, Adenoma						1 (1%)
Nose	(150)	(150)	(150)	(150)	(100)	(100)
Olfactory Epithelium, Adenoma		2 (1%)	1 (1%)	1 (1%)		
Olfactory Epithelium, Esthesioneuroblastoma						
Respiratory Epithelium, Adenoma					2 (2%)	
Pleura	(150)	(150)	(147)	(149)	(99)	(99)
Adenocarcinoma, Metastatic, Adrenal Cortex			1 (1%)			
Neoplasm Nos				1 (1%)	2 (2%)	1 (1%)
Trachea	(150)	(149)	(149)	(150)	(99)	(100)
SPECIAL SENSES SYSTEM						
Ear	(149)	(150)	(150)	(149)	(100)	(100)
Papilloma		1 (1%)	1 (1%)			1 (1%)
Squamous Cell Carcinoma	9 (6%)	4 (3%)	2 (1%)		7 (7%)	7 (7%)
Harderian Gland	(150)	(150)	(149)	(150)	(100)	(100)
Lacrimal Gland	(2)	(1)	(0)	(0)	(2)	(0)
Zymbal's Gland	(149)	(150)	(150)	(149)	(100)	(100)
Left, Squamous Cell Carcinoma	2 (1%)	1 (1%)				
Right, Carcinoma		1 (1%)				
Right, Squamous Cell Carcinoma				3 (2%)	2 (1%)	2 (2%)
Right, Squamous Cell Carcinoma						1 (1%)
URINARY SYSTEM						
Kidney	(150)	(150)	(150)	(150)	(100)	(99)
Bilateral, Pelvis Transitional Epithelium, Carcinoma				1 (1%)	1 (1%)	
Bilateral, Osteosarcoma, Metastatic, Bone				1 (1%)		
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site			1 (1%)			

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SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
Left, Pelvis Transitional Epithelium, Carcinoma		1 (1%)	1 (1%)	2 (1%)	2 (2%)	2 (2%)
Left, Pelvis Transitional Epithelium, Papilloma	1 (1%)	2 (1%)	1 (1%)	1 (1%)	1 (1%)	1 (1%)
Left, Renal Tubule, Adenoma						
Left, Renal Tubule, Carcinoma			1 (1%)			
Left, Transitional Epithelium, Papilloma					1 (1%)	
Left, Stromal Nephroma				1 (1%)		
Pelvis, Right Transitional Epithelium, Carcinoma			2 (1%)			1 (1%)
Pelvis, Right Transitional Epithelium, Papilloma		1 (1%)	1 (1%)	1 (1%)	1 (1%)	
Pelvis, Right, Papilloma					1 (1%)	
Renal Tubule, Right, Adenoma, Cystic				1 (1%)		
Right, Adenocarcinoma, Metastatic, Mammary Gland			1 (1%)			
Right, Squamous Cell Carcinoma, Metastatic, Lung						1 (1%)
Ureter	(1)	(0)	(71)	(2)	(2)	(2)
Urethra	(1)	(0)	(71)	(2)	(2)	(2)
Urinary Bladder	(149)	(147)	(149)	(147)	(99)	(99)
Transitional Epithelium, Carcinoma				1 (1%)		

SYSTEMIC LESIONS

Multiple Organs	*(150)	*(150)	*(150)	*(150)	*(100)	*(100)
Histiocytic Sarcoma	4 (3%)	6 (4%)	9 (6%)	8 (5%)	10 (10%)	8 (8%)
Leukemia Granulocytic				1 (1%)		2 (2%)
Leukemia Lymphoblastic				2 (1%)		
Leukemia Lymphocytic				2 (1%)		
Leukemia Monocytic		2 (1%)	5 (3%)	4 (3%)	2 (2%)	4 (4%)
Leukemia Myeloid				1 (1%)		1 (1%)
Lymphoma Lympho-Immunoblastic	5 (3%)	6 (4%)	8 (5%)	8 (5%)	3 (3%)	10 (10%)
Lymphoma Lymphoblastic	2 (1%)	3 (2%)	7 (5%)	4 (3%)	2 (2%)	2 (2%)
Lymphoma Lymphocytic	2 (1%)	5 (3%)	2 (1%)	1 (1%)	2 (2%)	
Lymphoma Malignant	1 (1%)	2 (1%)	1 (1%)			2 (2%)
Lymphoma Malignant Lymphocytic	1 (1%)				2 (2%)	3 (3%)
Mesothelioma Malignant		1 (1%)	4 (3%)	3 (2%)		2 (2%)

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Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Disposition Summary

Animals Initially in Study	100
Early Deaths	
Natural Death	100
Survivors	
Animals Examined Microscopically	100

ALIMENTARY SYSTEM

Esophagus	(100)
Intestine Large, Colon	(98)
Adenocarcinoma	
Intestine Large, Rectum	(98)
Adenocarcinoma	
Leiomyoma	
Polyp Adenomatous	
Intestine Small, Duodenum	(98)
Adenocarcinoma	
Intestine Small, Ileum	(98)
Intestine Small, Jejunum	(98)
Liver	(100)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Adenocarcinoma, Metastatic, Intestine Large, Colon	
Cholangiocarcinoma	
Cholangioma	4 (4%)
Fibroangioma	
Hemangiosarcoma	
Hepatocellular Adenoma	
Hepatocellular Carcinoma	
Leiomyosarcoma, Metastatic, Stomach, Glandular	
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla	
Bile Duct, Cholangioma	
Mesentery	(1)

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Oral Mucosa	(100)
Squamous Cell Carcinoma	1 (1%)
Squamous Cell Papilloma	2 (2%)
Pancreas	(99)
Adenoma	
Carcinoid Tumor Malignant, Metastatic, Stomach, Glandular	1 (1%)
Pharynx	(100)
Neoplasm Nos	
Squamous Cell Carcinoma	
Salivary Glands	(100)
Adenoma, Atypical	
Stomach, Forestomach	(100)
Neoplasm Nos	
Squamous Cell Papilloma	2 (2%)
Stomach, Glandular	(100)
Carcinoid Tumor Malignant	1 (1%)
Leiomyosarcoma	
Tongue	(100)
Squamous Cell Carcinoma	
Squamous Cell Papilloma	
Tooth	(3)

CARDIOVASCULAR SYSTEM

Heart	(99)
Adenocarcinoma, Metastatic, Mammary Gland	
Myxoma	2 (2%)
Schwannoma Benign	1 (1%)
Schwannoma Malignant	

ENDOCRINE SYSTEM

Adrenal Cortex	(100)
Bilateral, Adenoma	
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site	
Left, Adenocarcinoma	

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SPRAGUE-DAWLEY RATS FEMALE	100000 PPM
Left, Adenoma	4 (4%)
Right, Adenocarcinoma	1 (1%)
Right, Adenocarcinoma, Metastatic, Ovary	
Right, Adenoma	4 (4%)
Adrenal Medulla	(100)
Ganglioneuroma	
Pheochromocytoma Benign	1 (1%)
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site	
Bilateral, Pheochromocytoma Benign	5 (5%)
Bilateral, Pheochromocytoma Malignant	
Left, Ganglioneuroma	
Left, Pheochromocytoma Benign	15 (15%)
Left, Pheochromocytoma Malignant	
Right, Adenocarcinoma, Metastatic, Ovary	
Right, Pheochromocytoma Benign	8 (8%)
Right, Pheochromocytoma Malignant	
Islets, Pancreatic	(99)
Adenoma	
Carcinoid Tumor Malignant, Metastatic, Stomach, Glandular	1 (1%)
Carcinoma	
Neoplasm Nos	1 (1%)
Parathyroid Gland	(95)
Adenoma	
Pituitary Gland	(98)
Adenocarcinoma	
Adenoma	5 (5%)
Pars Distalis, Adenoma	26 (27%)
Pars Intermedia, Adenoma	1 (1%)
Thyroid Gland	(100)
Bilateral, C-cell, Adenoma	1 (1%)
Bilateral, C-cell, Carcinoma	
C-cell, Adenocarcinoma	1 (1%)
C-cell, Adenoma	4 (4%)
C-cell, Carcinoma	1 (1%)
Follicular Cell, Adenoma	1 (1%)

GENERAL BODY SYSTEM

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Peritoneum	(20)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Adenocarcinoma, Metastatic, Ovary	
Fibrolipoma	
Hemangiosarcoma	
Neoplasm Nos	1 (5%)
Schwannoma Malignant, Metastatic, Uterus	
Tissue NOS	(68)
Fibroangioma	
Lipoma	
Squamous Cell Carcinoma	
Abdominal, Hemangiosarcoma	
Mediastinum, Adenocarcinoma, Metastatic, Adrenal Cortex	
Mediastinum, Adenocarcinoma, Metastatic, Ovary	
Mediastinum, Liposarcoma	

GENITAL SYSTEM

Ovary	(100)
Adenocarcinoma	1 (1%)
Cystadenoma	1 (1%)
Fibroangioma	2 (2%)
Fibroma	1 (1%)
Granulosa Cell Tumor Benign	
Granulosa-Theca Tumor Benign	2 (2%)
Neoplasm Nos	
Sertoli Cell Tumor Benign	
Sertoli Cell Tumor Malignant	
Thecoma Benign	
Bilateral, Fibroangioma	1 (1%)
Left, Fibroangioma	
Oviduct	(100)
Uterus	(100)
Adenocarcinoma	2 (2%)
Adenocarcinoma, Metastatic, Ovary	

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Adenoma	
Fibroangioma	1 (1%)
Fibroma	
Hemangiosarcoma	
Leiomyoma	
Leiomyosarcoma	
Polyp	
Polyp, Multiple	
Polyp Stromal	42 (42%)
Polyp Stromal, Multiple	
Sarcoma	
Schwannoma Malignant	3 (3%)
Squamous Cell Carcinoma	
Cervix, Fibroangioma	
Cervix, Squamous Cell Carcinoma	
Endometrium, Adenoma	
Endometrium, Squamous Cell Carcinoma	
Vagina	(100)
Fibroangioma	
Fibroma	
Hemangiosarcoma	
Polyp	1 (1%)
Schwannoma Benign	
Schwannoma Malignant	
Squamous Cell Papilloma	

HEMATOPOIETIC SYSTEM

Bone Marrow	(0)
Lymph Node	(100)
Axillary, Inguinal, Liposarcoma, Metastatic, Mammary Gland	
Axillary, Adenocarcinoma, Metastatic, Mammary Gland	
Lumbar, Mediastinal, Leiomyosarcoma, Metastatic, Stomach, Glandular	
Lumbar, Adenocarcinoma, Metastatic, Intestine Large, Rectum	
Lumbar, Adenocarcinoma, Metastatic,	

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Mammary Gland	
Lumbar, Schwannoma Malignant, Metastatic, Uterus	
Mandibular, Liposarcoma, Metastatic, Tissue Nos	
Mandibular, Squamous Cell Carcinoma, Metastatic, Ear	
Mandibular, Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland	
Mediastinal, Adenocarcinoma, Metastatic, Adrenal Cortex	
Mediastinal, Adenocarcinoma, Metastatic, Ovary	
Mediastinal, Carcinosarcoma, Metastatic, Mammary Gland	
Mediastinal, Hemangioma	
Mediastinal, Osteosarcoma, Metastatic, Uncertain Primary Site	
Mesenteric, Fibroangioma	
Lymph Node, Mandibular	(0)
Lymph Node, Mediastinal	(0)
Lymph Node, Mesenteric	(0)
Spleen	(100)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Adenocarcinoma, Metastatic, Mammary Gland	
Fibroangioma	2 (2%)
Fibroma	
Hemangiosarcoma	
Thymus	(99)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Thymoma Benign	2 (2%)
Thymoma Malignant	

INTEGUMENTARY SYSTEM

Mammary Gland	(100)
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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Adenocarcinoma	7 (7%)
Adenocarcinoma, Multiple	
Adenoma	
Carcinosarcoma	
Fibroadenoma	38 (38%)
Fibroadenoma, Multiple	20 (20%)
Fibrolipoma	
Fibroma	1 (1%)
Fibroma, Multiple	
Fibrosarcoma	
Lipoma	
Liposarcoma	
Neoplasm Nos	2 (2%)
Skin	(98)
Squamous Cell Papilloma	
Interscapular Brown Fat Pad,	1 (1%)
Fibrosarcoma, Lipomatous	
Lip, Squamous Cell Carcinoma	1 (1%)
Subcutaneous Tissue, Fibroangioma	
Subcutaneous Tissue, Fibrolipoma	
Subcutaneous Tissue, Fibroma	
Subcutaneous Tissue, Fibromyxoma	
Subcutaneous Tissue, Fibrosarcoma	
Subcutaneous Tissue, Liposarcoma	
Subcutaneous Tissue,	
Rhabdomyosarcoma	

MUSCULOSKELETAL SYSTEM

Bone	(3)
Osteosarcoma	
Femur, Osteosarcoma	
Pelvis, Osteosarcoma	
Bone, Cranium	(100)
Chondroma	
Osteoma	2 (2%)
Osteosarcoma	3 (3%)
Mandible, Osteosarcoma	1 (1%)
Skeletal Muscle	(99)

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Diaphragm, Adenocarcinoma, Metastatic,
Intestine Large, Colon
Diaphragm, Adenocarcinoma, Metastatic,
Ovary
Diaphragm, Sertoli Cell Tumor Malignant,
Metastatic, Ovary

NERVOUS SYSTEM

Brain	(100)
Glioma Malignant, Mixed	
Neoplasm Nos	
Oligodendroglioma Nos	
Cerebellum, Astrocytoma Nos	1 (1%)
Meninges, Meningioma Benign	1 (1%)
Peripheral Nerve	(2)
Schwannoma Benign	
Schwannoma Malignant	1 (50%)
Spinal, Schwannoma Malignant	1 (50%)

RESPIRATORY SYSTEM

Larynx	(100)
Lung	(100)
Adenocarcinoma, Metastatic, Adrenal	
Cortex	
Adenocarcinoma, Metastatic, Mammary	
Gland	
Alveolar/Bronchiolar Adenoma	
Carcinosarcoma, Metastatic, Mammary	
Gland	
Fibroangioma	
Liposarcoma, Metastatic, Mammary Gland	
Osteosarcoma, Metastatic, Bone	
Osteosarcoma, Metastatic, Uncertain	
Primary Site	
Pheochromocytoma Malignant, Metastatic,	
Adrenal Medulla	
Schwannoma Malignant, Metastatic,	

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Uterus	
Squamous Cell Carcinoma	
Squamous Cell Carcinoma, Metastatic, Oral Mucosa	1 (1%)
Squamous Cell Carcinoma, Metastatic, Uncertain Primary Site	
Bronchiole, Adenoma	
Bronchus, Adenoma	
Nose	(100)
Olfactory Epithelium, Adenoma	2 (2%)
Olfactory Epithelium, Esthesioneuroblastoma	1 (1%)
Respiratory Epithelium, Adenoma	
Pleura	(99)
Adenocarcinoma, Metastatic, Adrenal Cortex	
Neoplasm Nos	
Trachea	(100)

SPECIAL SENSES SYSTEM

Ear	(100)
Papilloma	
Squamous Cell Carcinoma	6 (6%)
Harderian Gland	(100)
Lacrimal Gland	(0)
Zymbal's Gland	(100)
Left, Squamous Cell Carcinoma	
Right, Carcinoma	
Right, Squamous Cell Carcinoma	1 (1%)

URINARY SYSTEM

Kidney	(100)
Bilateral, Pelvis Transitional Epithelium, Carcinoma	
Bilateral, Osteosarcoma, Metastatic, Bone	
Bilateral, Osteosarcoma, Metastatic, Uncertain Primary Site	

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SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Left, Pelvis Transitional Epithelium, Carcinoma	3 (3%)
Left, Pelvis Transitional Epithelium, Papilloma	3 (3%)
Left, Renal Tubule, Adenoma	1 (1%)
Left, Renal Tubule, Carcinoma	
Left, Transitional Epithelium, Papilloma	
Left, Stromal Nephroma	
Pelvis, Right Transitional Epithelium, Carcinoma	1 (1%)
Pelvis, Right Transitional Epithelium, Papilloma	
Pelvis, Right, Papilloma	
Renal Tubule, Right, Adenoma, Cystic	
Right, Adenocarcinoma, Metastatic, Mammary Gland	
Right, Squamous Cell Carcinoma, Metastatic, Lung	
Ureter	(1)
Urethra	(0)
Urinary Bladder	(98)
Transitional Epithelium, Carcinoma	

SYSTEMIC LESIONS

Multiple Organs	*(100)
Histiocytic Sarcoma	7 (7%)
Leukemia Granulocytic	2 (2%)
Leukemia Lymphoblastic	
Leukemia Lymphocytic	
Leukemia Monocytic	2 (2%)
Leukemia Myeloid	2 (2%)
Lymphoma Lympho-Immunoblastic	11 (11%)
Lymphoma Lymphoblastic	1 (1%)
Lymphoma Lymphocytic	2 (2%)
Lymphoma Malignant	
Lymphoma Malignant Lymphocytic	
Mesothelioma Malignant	

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

* Number of animals with any tissue examined microscopically

Test Type: CHRONIC-LIFETIME

Aspartame

Time Report Requested: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE	0 PPM	80 PPM	400 PPM	2000 PPM	10000 PPM	50000 PPM
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	131	127	135	129	90	93
Total Primary Neoplasms	330	311	323	315	247	285
Total Animals with Benign Neoplasms	123	112	120	121	85	87
Total Benign Neoplasms	260	231	228	226	181	194
Total Animals with Malignant Neoplasms	55	64	70	67	40	58
Total Malignant Neoplasms	70	78	94	87	60	89
Total Animals with Metastatic Neoplasms	6	8	9	9	6	6
Total Metastatic Neoplasms	6	17	26	14	7	8
Total Animals with Malignant Neoplasms Uncertain Primary Site	1		1		1	
Total Animals with Neoplasms Uncertain-Benign or Malignant		2	1	2	6	2
Total Uncertain Neoplasms		2	1	2	6	2

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-LIFETIME

Aspartame

Time Report Reqsted: 12:08:21

Route: DOSED FEED

CAS Number: 22839-47-0

First Dose M/F: 06/27/97 / 06/27/97

Species/Strain: RATS/SD

Pathologist: LAURIOLA, M.

Lab: CRC

SPRAGUE-DAWLEY RATS FEMALE

100000 PPM

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	94
Total Primary Neoplasms	279
Total Animals with Benign Neoplasms	88
Total Benign Neoplasms	209
Total Animals with Malignant Neoplasms	51
Total Malignant Neoplasms	65
Total Animals with Metastatic Neoplasms	2
Total Metastatic Neoplasms	3
Total Animals with Malignant Neoplasms Uncertain Primary Site	
Total Animals with Neoplasms Uncertain-Benign or Malignant	4
Total Uncertain Neoplasms	5

*** 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