

Test Type: CHRONIC

TEF evaluation (PCB 118)

Time Report Requested: 10:22:40

Route: GAVAGE

CAS Number: 31508-00-6

First Dose M/F: NA / 03/26/04

Species/Strain: RATS/SD

Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Disposition Summary						
Animals Initially in Study	80	30	30	80	80	80
Early Deaths						
Dosing Accident				1		
Moribund Sacrifice	27			22	22	17
Natural Death	4	2		9	5	5
Survivors						
Terminal Sacrifice	21			20	25	30
Animals Examined Microscopically	52	2		52	52	52
ALIMENTARY SYSTEM						
Esophagus	(51)	(2)	(0)	(52)	(52)	(52)
Intestine Large, Cecum	(52)	(2)	(0)	(51)	(51)	(52)
Intestine Large, Colon	(52)	(2)	(0)	(52)	(52)	(52)
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Intestine Large, Rectum	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Ovary						
Intestine Small, Duodenum	(52)	(2)	(0)	(52)	(52)	(52)
Intestine Small, Ileum	(52)	(2)	(0)	(51)	(50)	(52)
Intestine Small, Jejunum	(52)	(2)	(0)	(52)	(50)	(52)
Liver	(52)	(2)	(0)	(51)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	
Cholangiocarcinoma						
Cholangiocarcinoma, Multiple						
Cholangioma	1 (2%)					
Hepatocellular Adenoma				1 (2%)	1 (2%)	4 (8%)
Hepatocellular Adenoma, Multiple						
Hepatocellular Carcinoma						
Hepatocholangioma						
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Mesentery	(2)	(0)	(0)	(1)	(3)	(3)
Carcinoma, Metastatic, Ovary						
Carcinoma, Metastatic, Uterus					2 (67%)	
Fibroma				1 (100%)		

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

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Schwannoma Malignant					1 (33%)	
Oral Mucosa	(1)	(0)	(0)	(0)	(1)	(1)
Squamous Cell Carcinoma					1 (100%)	
Pancreas	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Ovary					2 (4%)	
Carcinoma, Metastatic, Uterus						
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Acinus, Adenoma						2 (4%)
Acinus, Carcinoma						
Salivary Glands	(51)	(2)	(0)	(51)	(52)	(51)
Stomach, Forestomach	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Ovary						
Stomach, Glandular	(52)	(2)	(0)	(52)	(52)	(52)
Adenoma				1 (2%)		
Carcinoma, Metastatic, Ovary						
Sarcoma				1 (2%)		
Tooth	(10)	(0)	(0)	(5)	(5)	(5)
Odontoma	1 (10%)					
CARDIOVASCULAR SYSTEM						
Blood Vessel	(52)	(2)	(0)	(52)	(52)	(52)
Heart	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Ovary						
Schwannoma Benign						
ENDOCRINE SYSTEM						
Adrenal Cortex	(52)	(2)	(0)	(52)	(52)	(51)
Adenoma	2 (4%)			2 (4%)		2 (4%)
Carcinoma	1 (2%)					
Carcinoma, Metastatic, Ovary						
Carcinoma, Metastatic, Thyroid Gland	1 (2%)					
Adrenal Medulla	(52)	(2)	(0)	(52)	(52)	(52)
Pheochromocytoma Benign	3 (6%)			1 (2%)	3 (6%)	2 (4%)
Pheochromocytoma Complex					1 (2%)	
Pheochromocytoma Malignant					1 (2%)	1 (2%)
Bilateral, Pheochromocytoma Benign						

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Islets, Pancreatic	(52)	(2)	(0)	(52)	(52)	(52)
Adenoma				2 (4%)	1 (2%)	3 (6%)
Carcinoma					1 (2%)	
Parathyroid Gland	(47)	(2)	(0)	(46)	(47)	(50)
Adenoma						
Carcinoma, Metastatic, Thyroid Gland				1 (2%)		
Pituitary Gland	(52)	(2)	(0)	(52)	(52)	(52)
Pars Distalis, Adenoma	16 (31%)			24 (46%)	18 (35%)	24 (46%)
Pars Distalis, Adenoma, Multiple	1 (2%)					
Pars Distalis, Carcinoma	2 (4%)			1 (2%)		
Thyroid Gland	(51)	(2)	(0)	(51)	(51)	(51)
Bilateral, Adenoma					1 (2%)	
Bilateral, C-cell, Adenoma						1 (2%)
C-cell, Adenoma	9 (18%)			5 (10%)	5 (10%)	11 (22%)
C-cell, Adenoma, Multiple						1 (2%)
C-cell, Carcinoma	2 (4%)			1 (2%)		1 (2%)
Follicular Cell, Adenoma	1 (2%)			1 (2%)		

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(52)	(2)	(0)	(52)	(51)	(52)
Adenoma						1 (2%)
Carcinoma				1 (2%)		
Ovary	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	
Granulosa-Theca Tumor Malignant					2 (4%)	
Luteoma	1 (2%)					
Thecoma Benign						
Bilateral, Adamantinoma Malignant, Metastatic, Ovary						
Bilateral, Carcinoma, Metastatic, Ovary						
Uterus	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma	2 (4%)			2 (4%)	1 (2%)	3 (6%)
Hemangiosarcoma						
Polyp Stromal	3 (6%)			6 (12%)	5 (10%)	10 (19%)

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
Sarcoma						1 (2%)
Schwannoma Malignant	1 (2%)			1 (2%)		1 (2%)
Squamous Cell Carcinoma					3 (6%)	1 (2%)
Bilateral, Polyp Stromal					1 (2%)	
Vagina	(7)	(0)	(0)	(0)	(0)	(1)
Polyp						1 (100%)
Polyp, Multiple	1 (14%)					
Schwannoma Malignant						
Squamous Cell Carcinoma	1 (14%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(52)	(2)	(0)	(52)	(52)	(52)
Lymph Node	(0)	(0)	(0)	(2)	(1)	(1)
Lymph Node, Mandibular	(51)	(2)	(0)	(51)	(52)	(51)
Lymph Node, Mesenteric	(52)	(2)	(0)	(51)	(52)	(52)
Carcinoma, Metastatic, Ovary						
Carcinoma, Metastatic, Uterus						
Spleen	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	
Thymus	(51)	(2)	(0)	(51)	(51)	(50)
Thymoma Malignant				1 (2%)		
INTEGUMENTARY SYSTEM						
Mammary Gland	(52)	(2)	(0)	(51)	(52)	(52)
Adenoma					1 (2%)	2 (4%)
Carcinoma	2 (4%)			6 (12%)	7 (13%)	4 (8%)
Fibroadenoma	16 (31%)			18 (35%)	17 (33%)	19 (37%)
Fibroadenoma, Multiple	9 (17%)			11 (22%)	10 (19%)	14 (27%)
Skin	(52)	(2)	(0)	(51)	(52)	(52)
Fibroma	2 (4%)				1 (2%)	
Hemangiosarcoma	1 (2%)					
Keratoacanthoma	1 (2%)			1 (2%)		
Schwannoma Malignant	1 (2%)			1 (2%)		1 (2%)
Squamous Cell Papilloma						2 (4%)
Pinna, Neural Crest Tumor					1 (2%)	
Subcutaneous Tissue, Schwannoma	1 (2%)					
Malignant, Metastatic, Uterus						

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
MUSCULOSKELETAL SYSTEM						
Skeletal Muscle	(0)	(0)	(0)	(1)	(0)	(0)
Carcinoma, Metastatic, Uterus				1 (100%)		
Schwannoma Malignant						
NERVOUS SYSTEM						
Brain	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Pituitary Gland	2 (4%)				1 (2%)	
Ependymoma Malignant						
Glioma Malignant						
Meningioma Malignant						
Oligodendroglioma Malignant				1 (2%)		
Spinal Cord	(0)	(0)	(0)	(0)	(1)	(0)
Schwannoma Malignant					1 (100%)	
RESPIRATORY SYSTEM						
Lung	(51)	(2)	(0)	(52)	(52)	(52)
Alveolar/Bronchiolar Carcinoma, Multiple						1 (2%)
Carcinoma, Metastatic, Mammary Gland					1 (2%)	
Carcinoma, Metastatic, Ovary						
Carcinoma, Metastatic, Thyroid Gland	1 (2%)					
Carcinoma, Metastatic, Uncertain Primary Site						1 (2%)
Carcinoma, Metastatic, Uterus					1 (2%)	
Cystic Keratinizing Epithelioma						
Cystic Keratinizing Epithelioma, Multiple						
Nose	(52)	(2)	(0)	(52)	(52)	(52)
Trachea	(51)	(2)	(0)	(52)	(52)	(52)
SPECIAL SENSES SYSTEM						
Eye	(52)	(2)	(0)	(52)	(52)	(52)
Harderian Gland	(52)	(2)	(0)	(52)	(52)	(52)

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
URINARY SYSTEM						
Kidney	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	
Mesenchymal Tumor Malignant				1 (2%)		
Nephroblastoma					1 (2%)	
Ureter	(0)	(0)	(0)	(0)	(0)	(0)
Carcinoma, Metastatic, Ovary						
Urinary Bladder	(52)	(2)	(0)	(52)	(52)	(52)
Carcinoma, Metastatic, Uterus					1 (2%)	
Sarcoma, Metastatic, Uterus						1 (2%)
SYSTEMIC LESIONS						
Multiple Organs	*(52)	*(2)		*(52)	*(52)	*(52)
Adenolipoma						1 (2%)
Histiocytic Sarcoma	1 (2%)					
Lymphoma Malignant	2 (4%)			1 (2%)	2 (4%)	2 (4%)

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* Number of animals with any tissue examined microscopically

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
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Disposition Summary

Animals Initially in Study	80	80
Early Deaths		
Dosing Accident		
Moribund Sacrifice	16	16
Natural Death	8	11
Survivors		
Terminal Sacrifice	28	25
Animals Examined Microscopically	52	52

ALIMENTARY SYSTEM

Esophagus	(52)	(52)
Intestine Large, Cecum	(52)	(48)
Intestine Large, Colon	(52)	(48)
Schwannoma Malignant, Metastatic, Uterus		
Intestine Large, Rectum	(52)	(50)
Carcinoma, Metastatic, Ovary	1 (2%)	
Intestine Small, Duodenum	(52)	(48)
Intestine Small, Ileum	(52)	(47)
Intestine Small, Jejunum	(52)	(48)
Liver	(52)	(49)
Carcinoma, Metastatic, Uterus	1 (2%)	
Cholangiocarcinoma	3 (6%)	6 (12%)
Cholangiocarcinoma, Multiple		30 (61%)
Cholangioma		
Hepatocellular Adenoma	8 (15%)	10 (20%)
Hepatocellular Adenoma, Multiple	4 (8%)	14 (29%)
Hepatocellular Carcinoma		1 (2%)
Hepatocholangioma		4 (8%)
Schwannoma Malignant, Metastatic, Uterus		
Mesentery	(9)	(9)
Carcinoma, Metastatic, Ovary	1 (11%)	
Carcinoma, Metastatic, Uterus	2 (22%)	
Fibroma		

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Schwannoma Malignant		
Oral Mucosa	(1)	(3)
Squamous Cell Carcinoma		2 (67%)
Pancreas	(52)	(47)
Carcinoma, Metastatic, Ovary	1 (2%)	
Carcinoma, Metastatic, Uterus	1 (2%)	
Schwannoma Malignant, Metastatic, Uterus		
Acinus, Adenoma	3 (6%)	1 (2%)
Acinus, Carcinoma		1 (2%)
Salivary Glands	(52)	(51)
Stomach, Forestomach	(52)	(51)
Carcinoma, Metastatic, Ovary	1 (2%)	
Stomach, Glandular	(52)	(51)
Adenoma		
Carcinoma, Metastatic, Ovary	1 (2%)	
Sarcoma		
Tooth	(4)	(7)
Odontoma		
CARDIOVASCULAR SYSTEM		
Blood Vessel	(52)	(51)
Heart	(52)	(50)
Carcinoma, Metastatic, Ovary	1 (2%)	
Schwannoma Benign	1 (2%)	
ENDOCRINE SYSTEM		
Adrenal Cortex	(52)	(49)
Adenoma		4 (8%)
Carcinoma		
Carcinoma, Metastatic, Ovary	1 (2%)	
Carcinoma, Metastatic, Thyroid Gland		
Adrenal Medulla	(52)	(49)
Pheochromocytoma Benign	1 (2%)	
Pheochromocytoma Complex		
Pheochromocytoma Malignant	1 (2%)	
Bilateral, Pheochromocytoma Benign	1 (2%)	

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Islets, Pancreatic	(52)	(47)
Adenoma		
Carcinoma		
Parathyroid Gland	(50)	(47)
Adenoma		1 (2%)
Carcinoma, Metastatic, Thyroid Gland		
Pituitary Gland	(52)	(52)
Pars Distalis, Adenoma	17 (33%)	4 (8%)
Pars Distalis, Adenoma, Multiple		
Pars Distalis, Carcinoma		
Thyroid Gland	(52)	(49)
Bilateral, Adenoma		
Bilateral, C-cell, Adenoma	1 (2%)	
C-cell, Adenoma	4 (8%)	6 (12%)
C-cell, Adenoma, Multiple		
C-cell, Carcinoma		
Follicular Cell, Adenoma	1 (2%)	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(51)	(49)
Adenoma		
Carcinoma	1 (2%)	
Ovary	(52)	(48)
Carcinoma, Metastatic, Uterus	1 (2%)	
Granulosa-Theca Tumor Malignant		
Luteoma		
Thecoma Benign	1 (2%)	
Bilateral, Adamantinoma Malignant,	1 (2%)	
Metastatic, Ovary		
Bilateral, Carcinoma, Metastatic, Ovary	1 (2%)	
Uterus	(52)	(49)
Carcinoma	4 (8%)	3 (6%)
Hemangiosarcoma	1 (2%)	
Polyp Stromal	6 (12%)	5 (10%)

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
Sarcoma		
Schwannoma Malignant		1 (2%)
Squamous Cell Carcinoma	1 (2%)	
Bilateral, Polyp Stromal	2 (4%)	1 (2%)
Vagina	(1)	(0)
Polyp		
Polyp, Multiple		
Schwannoma Malignant	1 (100%)	
Squamous Cell Carcinoma		
HEMATOPOIETIC SYSTEM		
Bone Marrow	(52)	(52)
Lymph Node	(0)	(2)
Lymph Node, Mandibular	(52)	(51)
Lymph Node, Mesenteric	(52)	(47)
Carcinoma, Metastatic, Ovary	1 (2%)	
Carcinoma, Metastatic, Uterus	1 (2%)	
Spleen	(52)	(47)
Carcinoma, Metastatic, Uterus	1 (2%)	
Thymus	(50)	(49)
Thymoma Malignant		
INTEGUMENTARY SYSTEM		
Mammary Gland	(52)	(50)
Adenoma	1 (2%)	
Carcinoma	1 (2%)	2 (4%)
Fibroadenoma	15 (29%)	8 (16%)
Fibroadenoma, Multiple	5 (10%)	
Skin	(52)	(51)
Fibroma	1 (2%)	
Hemangiosarcoma		
Keratoacanthoma		
Schwannoma Malignant		1 (2%)
Squamous Cell Papilloma		
Pinna, Neural Crest Tumor		
Subcutaneous Tissue, Schwannoma		
Malignant, Metastatic, Uterus		

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
MUSCULOSKELETAL SYSTEM		
Skeletal Muscle	(1)	(0)
Carcinoma, Metastatic, Uterus	1 (100%)	
Schwannoma Malignant		
NERVOUS SYSTEM		
Brain	(52)	(52)
Carcinoma, Metastatic, Pituitary Gland		
Ependymoma Malignant		
Glioma Malignant	1 (2%)	
Meningioma Malignant	1 (2%)	
Oligodendroglioma Malignant		
Spinal Cord	(0)	(1)
Schwannoma Malignant		
RESPIRATORY SYSTEM		
Lung	(52)	(50)
Alveolar/Bronchiolar Carcinoma, Multiple		
Carcinoma, Metastatic, Mammary Gland		
Carcinoma, Metastatic, Ovary	1 (2%)	
Carcinoma, Metastatic, Thyroid Gland		
Carcinoma, Metastatic, Uncertain		
Primary Site		
Carcinoma, Metastatic, Uterus	1 (2%)	
Cystic Keratinizing Epithelioma		12 (24%)
Cystic Keratinizing Epithelioma, Multiple		8 (16%)
Nose	(52)	(52)
Trachea	(52)	(52)
SPECIAL SENSES SYSTEM		
Eye	(52)	(52)
Harderian Gland	(52)	(52)

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SPRAGUE-DAWLEY RATS FEMALE	1000 UG/KG	4600 UG/KG
URINARY SYSTEM		
Kidney	(52)	(50)
Carcinoma, Metastatic, Uterus	1 (2%)	
Mesenchymal Tumor Malignant		
Nephroblastoma		
Ureter	(1)	(0)
Carcinoma, Metastatic, Ovary	1 (100%)	
Urinary Bladder	(52)	(50)
Carcinoma, Metastatic, Uterus		
Sarcoma, Metastatic, Uterus		
SYSTEMIC LESIONS		
Multiple Organs	*(52)	*(52)
Adenolipoma		
Histiocytic Sarcoma		
Lymphoma Malignant	1 (2%)	3 (6%)

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Lab: BAT

SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	10 UG/KG	30 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	48		43		47	47
Total Primary Neoplasms	83		93		88	116
Total Animals with Benign Neoplasms	43		39		37	45
Total Benign Neoplasms	67		74		64	99
Total Animals with Malignant Neoplasms	15		18		23	13
Total Malignant Neoplasms	16		19		23	16
Total Animals with Metastatic Neoplasms	4		1		3	2
Total Metastatic Neoplasms	8		1		11	2
Total Animals with Malignant Neoplasms Uncertain Primary Site						1
Total Animals with Neoplasms Uncertain-Benign or Malignant					1	
Total Uncertain Neoplasms					1	

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b - Primary tumors: all tumors except metastatic tumors

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SPRAGUE-DAWLEY RATS FEMALE

1000 UG/KG

4600 UG/KG

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	45	45
Total Primary Neoplasms	88	128
Total Animals with Benign Neoplasms	41	36
Total Benign Neoplasms	72	78
Total Animals with Malignant Neoplasms	16	39
Total Malignant Neoplasms	16	50
Total Animals with Metastatic Neoplasms	4	
Total Metastatic Neoplasms	22	
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