

TDMS No. 20304 - 01

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

Date Report Requested: 06/26/2008

Test Type: CHRONIC

TEF evaluation (PCB 118)

Time Report Requested: 12:05:16

Route: GAVAGE

CAS Number: 31508-00-6

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

Species/Strain: RATS/SD

Lab: BAT

F1_R8

C Number: C20304

Lock Date: 10/12/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: 25022 ACCK 25021 TSAC 25020 NATD

25019 MSAC 25018 DACC

Removal Date Range: ALL

Treatment Groups: Include 001 0 UG/KG Include 004 100 UG/KG Include 005 220 UG/KG

Include 006 460 UG/KG Include 007 1000 UG/KG Include 008 4600 UG/KG

Include 009 4600 UG/KG STOP

Study Gender: Female

TDMSE Version: 2.0.0

Test Type: CHRONIC

TEF evaluation (PCB 118)

Time Report Requested: 12:05:16

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	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Disposition Summary						
Animals Initially in Study	80	80	80	80	80	80
Early Deaths						
Accidently Killed						
Dosing Accident		1				
Moribund Sacrifice	27	22	22	17	16	16
Natural Death	4	9	5	5	8	11
Survivors						
Moribund Sacrifice						
Terminal Sacrifice	21	20	25	30	28	25
Animals Examined Microscopically	52	52	52	52	52	52

ALIMENTARY SYSTEM

Esophagus	(51)	(52)	(52)	(52)	(52)	(52)
Intestine Large, Cecum	(52)	(51)	(51)	(52)	(52)	(48)
Intestine Large, Colon	(52)	(52)	(52)	(52)	(52)	(48)
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Intestine Large, Rectum	(52)	(52)	(52)	(52)	(52)	(50)
Carcinoma, Metastatic, Ovary					1 (2%)	
Intestine Small, Duodenum	(52)	(52)	(52)	(52)	(52)	(48)
Carcinoma, Metastatic, Uterus						
Intestine Small, Ileum	(52)	(51)	(50)	(52)	(52)	(47)
Carcinoma, Metastatic, Uterus						
Intestine Small, Jejunum	(52)	(52)	(50)	(52)	(52)	(48)
Liver	(52)	(51)	(52)	(52)	(52)	(49)
Carcinoma, Metastatic, Uterus			1 (2%)		1 (2%)	
Cholangiocarcinoma					3 (6%)	
Cholangiocarcinoma, Multiple						6 (12%)
Cholangioma	1 (2%)					30 (61%)
Hepatocellular Adenoma		1 (2%)	1 (2%)	4 (8%)	8 (15%)	10 (20%)
Hepatocellular Adenoma, Multiple					4 (8%)	14 (29%)
Hepatocellular Carcinoma						1 (2%)
Hepatocholangioma						4 (8%)
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					

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	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Mesentery	(2)	(1)	(3)	(3)	(9)	(9)
Carcinoma, Metastatic, Ovary					1 (11%)	
Carcinoma, Metastatic, Uterus			2 (67%)		2 (22%)	
Fibroma		1 (100%)				
Schwannoma Malignant			1 (33%)			
Oral Mucosa	(1)	(0)	(1)	(1)	(1)	(3)
Squamous Cell Carcinoma			1 (100%)			2 (67%)
Pancreas	(52)	(52)	(52)	(52)	(52)	(47)
Carcinoma, Metastatic, Ovary					1 (2%)	
Carcinoma, Metastatic, Uterus			2 (4%)		1 (2%)	
Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
Acinus, Adenoma				2 (4%)	3 (6%)	1 (2%)
Acinus, Carcinoma						1 (2%)
Salivary Glands	(51)	(51)	(52)	(51)	(52)	(51)
Stomach, Forestomach	(52)	(52)	(52)	(52)	(52)	(51)
Carcinoma, Metastatic, Ovary					1 (2%)	
Squamous Cell Carcinoma						
Squamous Cell Papilloma						
Stomach, Glandular	(52)	(52)	(52)	(52)	(52)	(51)
Adenoma		1 (2%)				
Carcinoma, Metastatic, Ovary					1 (2%)	
Carcinoma, Metastatic, Uterus						
Sarcoma		1 (2%)				
Tongue	(0)	(0)	(0)	(0)	(0)	(0)
Tooth	(10)	(5)	(5)	(5)	(4)	(7)
Odontoma	1 (10%)					
CARDIOVASCULAR SYSTEM						
Blood Vessel	(52)	(52)	(52)	(52)	(52)	(51)
Heart	(52)	(52)	(52)	(52)	(52)	(50)
Carcinoma, Metastatic, Ovary					1 (2%)	
Schwannoma Benign					1 (2%)	
ENDOCRINE SYSTEM						
Adrenal Cortex	(52)	(52)	(52)	(51)	(52)	(49)
Adenoma	2 (4%)	2 (4%)		2 (4%)		4 (8%)

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Carcinoma	1 (2%)					
Carcinoma, Metastatic, Ovary					1 (2%)	
Carcinoma, Metastatic, Thyroid Gland	1 (2%)					
Carcinoma, Metastatic, Uterus						
Granulosa Cell Tumor Malignant, Metastatic, Ovary						
Adrenal Medulla	(52)	(52)	(52)	(52)	(52)	(49)
Pheochromocytoma Benign	3 (6%)	1 (2%)	3 (6%)	2 (4%)	1 (2%)	
Pheochromocytoma Complex			1 (2%)			
Pheochromocytoma Malignant			1 (2%)	1 (2%)	1 (2%)	
Bilateral, Pheochromocytoma Benign					1 (2%)	
Islets, Pancreatic	(52)	(52)	(52)	(52)	(52)	(47)
Adenoma		2 (4%)	1 (2%)	3 (6%)		
Carcinoma			1 (2%)			
Parathyroid Gland	(47)	(46)	(47)	(50)	(50)	(47)
Adenoma						1 (2%)
Carcinoma, Metastatic, Thyroid Gland		1 (2%)				
Pituitary Gland	(52)	(52)	(52)	(52)	(52)	(52)
Pars Distalis, Adenoma	16 (31%)	24 (46%)	18 (35%)	24 (46%)	17 (33%)	4 (8%)
Pars Distalis, Adenoma, Multiple	1 (2%)					
Pars Distalis, Carcinoma	2 (4%)	1 (2%)				
Thyroid Gland	(51)	(51)	(51)	(51)	(52)	(49)
Bilateral, Adenoma			1 (2%)			
Bilateral, C-cell, Adenoma				1 (2%)	1 (2%)	
C-cell, Adenoma	9 (18%)	5 (10%)	5 (10%)	11 (22%)	4 (8%)	6 (12%)
C-cell, Adenoma, Multiple				1 (2%)		
C-cell, Carcinoma	2 (4%)	1 (2%)		1 (2%)		
Follicular Cell, Adenoma	1 (2%)	1 (2%)			1 (2%)	
Follicular Cell, Carcinoma						

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(52)	(52)	(51)	(52)	(51)	(49)
Adenoma				1 (2%)		
Carcinoma		1 (2%)			1 (2%)	

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Ovary	(52)	(52)	(52)	(52)	(52)	(48)
Carcinoma, Metastatic, Uterus			1 (2%)		1 (2%)	
Granulosa Cell Tumor Malignant			2 (4%)			
Granulosa-Theca Tumor Malignant						
Luteoma	1 (2%)					
Thecoma Benign					1 (2%)	
Bilateral, Adamantinoma Malignant, Metastatic, Ovary					1 (2%)	
Bilateral, Carcinoma, Metastatic, Ovary					1 (2%)	
Uterus	(52)	(52)	(52)	(52)	(52)	(49)
Carcinoma	2 (4%)	2 (4%)	1 (2%)	3 (6%)	4 (8%)	3 (6%)
Hemangiosarcoma					1 (2%)	
Polyp Stromal	3 (6%)	6 (12%)	5 (10%)	10 (19%)	6 (12%)	5 (10%)
Sarcoma				1 (2%)		
Schwannoma Malignant	1 (2%)	1 (2%)		1 (2%)		1 (2%)
Squamous Cell Carcinoma			3 (6%)	1 (2%)	1 (2%)	
Bilateral, Polyp Stromal			1 (2%)		2 (4%)	1 (2%)
Vagina	(7)	(0)	(0)	(1)	(1)	(0)
Polyp				1 (100%)		
Polyp, Multiple	1 (14%)					
Schwannoma Malignant					1 (100%)	
Squamous Cell Carcinoma	1 (14%)					
HEMATOPOIETIC SYSTEM						
Bone Marrow	(52)	(52)	(52)	(52)	(52)	(52)
Lymph Node	(0)	(2)	(1)	(1)	(0)	(2)
Renal, Carcinoma, Metastatic, Uterus						
Lymph Node, Mandibular	(51)	(51)	(52)	(51)	(52)	(51)
Lymph Node, Mesenteric	(52)	(51)	(52)	(52)	(52)	(47)
Carcinoma, Metastatic, Ovary					1 (2%)	
Carcinoma, Metastatic, Uterus					1 (2%)	
Spleen	(52)	(52)	(52)	(52)	(52)	(47)
Carcinoma, Metastatic, Uterus			1 (2%)		1 (2%)	
Thymus	(51)	(51)	(51)	(50)	(50)	(49)
Thymoma Malignant		1 (2%)				
INTEGUMENTARY SYSTEM						

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Mammary Gland	(52)	(51)	(52)	(52)	(52)	(50)
Adenoma			1 (2%)	2 (4%)	1 (2%)	
Carcinoma	2 (4%)	6 (12%)	7 (13%)	4 (8%)	1 (2%)	2 (4%)
Fibroadenoma	16 (31%)	18 (35%)	17 (33%)	19 (37%)	15 (29%)	8 (16%)
Fibroadenoma, Multiple	9 (17%)	11 (22%)	10 (19%)	14 (27%)	5 (10%)	
Skin	(52)	(51)	(52)	(52)	(52)	(51)
Fibroma	2 (4%)		1 (2%)		1 (2%)	
Hemangiosarcoma	1 (2%)					
Keratoacanthoma	1 (2%)	1 (2%)				
Schwannoma Malignant	1 (2%)	1 (2%)		1 (2%)		1 (2%)
Squamous Cell Papilloma				2 (4%)		
Pinna, Neural Crest Tumor			1 (2%)			
Subcutaneous Tissue, Schwannoma Malignant, Metastatic, Uterus	1 (2%)					
MUSCULOSKELETAL SYSTEM						
Bone	(52)	(52)	(52)	(52)	(52)	(52)
Skeletal Muscle	(0)	(1)	(0)	(0)	(1)	(0)
Carcinoma, Metastatic, Uterus					1 (100%)	
Granulosa Cell Tumor Malignant, Metastatic, Ovary						
Schwannoma Malignant		1 (100%)				
NERVOUS SYSTEM						
Brain	(52)	(52)	(52)	(52)	(52)	(52)
Carcinoma, Metastatic, Pituitary Gland	2 (4%)					
Ependymoma Malignant			1 (2%)			
Glioma Malignant					1 (2%)	
Meningioma Malignant					1 (2%)	
Oligodendroglioma Malignant		1 (2%)				
Spinal Cord	(0)	(0)	(1)	(0)	(0)	(1)
Schwannoma Malignant			1 (100%)			
RESPIRATORY SYSTEM						
Lung	(51)	(52)	(52)	(52)	(52)	(50)
Alveolar/Bronchiolar Carcinoma, Multiple				1 (2%)		

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SPRAGUE-DAWLEY RATS FEMALE	0 UG/KG	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Carcinoma, Metastatic, Mammary Gland			1 (2%)			
Carcinoma, Metastatic, Ovary					1 (2%)	
Carcinoma, Metastatic, Thyroid Gland	1 (2%)					
Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)		
Carcinoma, Metastatic, Uterus			1 (2%)		1 (2%)	
Cystic Keratinizing Epithelioma						12 (24%)
Cystic Keratinizing Epithelioma, Multiple						8 (16%)
Nose	(52)	(52)	(52)	(52)	(52)	(52)
Trachea	(51)	(52)	(52)	(52)	(52)	(52)
SPECIAL SENSES SYSTEM						
Eye	(52)	(52)	(52)	(52)	(52)	(52)
Harderian Gland	(52)	(52)	(52)	(52)	(52)	(52)
URINARY SYSTEM						
Kidney	(52)	(52)	(52)	(52)	(52)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)		1 (2%)	
Granulosa Cell Tumor Malignant, Metastatic, Ovary						
Mesenchymal Tumor Malignant		1 (2%)				
Nephroblastoma			1 (2%)			
Renal Tubule, Carcinoma						
Ureter	(0)	(0)	(0)	(0)	(1)	(0)
Carcinoma, Metastatic, Ovary					1 (100%)	
Urinary Bladder	(52)	(52)	(52)	(52)	(52)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)			
Sarcoma, Metastatic, Uterus				1 (2%)		
SYSTEMIC LESIONS						
Multiple Organs	*(52)	*(52)	*(52)	*(52)	*(52)	*(52)
Adenolipoma				1 (2%)		
Histiocytic Sarcoma	1 (2%)					
Lymphoma Malignant	2 (4%)	1 (2%)	2 (4%)	2 (4%)	1 (2%)	3 (6%)

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* Number of animals with any tissue examined microscopically

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SPRAGUE-DAWLEY RATS FEMALE

4600 UG/KG STOP

Disposition Summary

Animals Initially in Study	50
Early Deaths	
Accidentally Killed	1
Dosing Accident	
Moribund Sacrifice	18
Natural Death	6
Survivors	
Moribund Sacrifice	1
Terminal Sacrifice	24
Animals Examined Microscopically	50

ALIMENTARY SYSTEM

Esophagus	(50)
Intestine Large, Cecum	(49)
Intestine Large, Colon	(49)
Schwannoma Malignant, Metastatic, Uterus	
Intestine Large, Rectum	(49)
Carcinoma, Metastatic, Ovary	
Intestine Small, Duodenum	(49)
Carcinoma, Metastatic, Uterus	1 (2%)
Intestine Small, Ileum	(49)
Carcinoma, Metastatic, Uterus	2 (4%)
Intestine Small, Jejunum	(49)
Liver	(49)
Carcinoma, Metastatic, Uterus	2 (4%)
Cholangiocarcinoma	12 (24%)
Cholangiocarcinoma, Multiple	17 (35%)
Cholangioma	
Hepatocellular Adenoma	
Hepatocellular Adenoma, Multiple	1 (2%)
Hepatocellular Carcinoma	
Hepatocholangioma	
Schwannoma Malignant, Metastatic, Uterus	

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SPRAGUE-DAWLEY RATS FEMALE

4600 UG/KG STOP

Mesentery	(9)
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Uterus	4 (44%)
Fibroma	
Schwannoma Malignant	
Oral Mucosa	(0)
Squamous Cell Carcinoma	
Pancreas	(49)
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Uterus	4 (8%)
Schwannoma Malignant, Metastatic, Uterus	
Acinus, Adenoma	
Acinus, Carcinoma	
Salivary Glands	(50)
Stomach, Forestomach	(49)
Carcinoma, Metastatic, Ovary	
Squamous Cell Carcinoma	1 (2%)
Squamous Cell Papilloma	1 (2%)
Stomach, Glandular	(49)
Adenoma	
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Uterus	1 (2%)
Sarcoma	
Tongue	(1)
Tooth	(7)
Odontoma	

CARDIOVASCULAR SYSTEM

Blood Vessel	(50)
Heart	(50)
Carcinoma, Metastatic, Ovary	
Schwannoma Benign	

ENDOCRINE SYSTEM

Adrenal Cortex	(49)
Adenoma	1 (2%)

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Carcinoma	
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Thyroid Gland	
Carcinoma, Metastatic, Uterus	2 (4%)
Granulosa Cell Tumor Malignant, Metastatic, Ovary	1 (2%)
Adrenal Medulla	(49)
Pheochromocytoma Benign	2 (4%)
Pheochromocytoma Complex	
Pheochromocytoma Malignant	
Bilateral, Pheochromocytoma Benign	
Islets, Pancreatic	(49)
Adenoma	
Carcinoma	
Parathyroid Gland	(49)
Adenoma	
Carcinoma, Metastatic, Thyroid Gland	
Pituitary Gland	(50)
Pars Distalis, Adenoma	12 (24%)
Pars Distalis, Adenoma, Multiple	
Pars Distalis, Carcinoma	1 (2%)
Thyroid Gland	(50)
Bilateral, Adenoma	
Bilateral, C-cell, Adenoma	
C-cell, Adenoma	5 (10%)
C-cell, Adenoma, Multiple	
C-cell, Carcinoma	
Follicular Cell, Adenoma	
Follicular Cell, Carcinoma	1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(48)
Adenoma	
Carcinoma	

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Ovary	(49)
Carcinoma, Metastatic, Uterus	3 (6%)
Granulosa Cell Tumor Malignant	1 (2%)
Granulosa-Theca Tumor Malignant	
Luteoma	
Thecoma Benign	
Bilateral, Adamantinoma Malignant, Metastatic, Ovary	
Bilateral, Carcinoma, Metastatic, Ovary	
Uterus	(49)
Carcinoma	11 (22%)
Hemangiosarcoma	
Polyp Stromal	3 (6%)
Sarcoma	
Schwannoma Malignant	2 (4%)
Squamous Cell Carcinoma	1 (2%)
Bilateral, Polyp Stromal	1 (2%)
Vagina	(0)
Polyp	
Polyp, Multiple	
Schwannoma Malignant	
Squamous Cell Carcinoma	

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)
Lymph Node	(1)
Renal, Carcinoma, Metastatic, Uterus	1 (100%)
Lymph Node, Mandibular	(50)
Lymph Node, Mesenteric	(49)
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Uterus	
Spleen	(49)
Carcinoma, Metastatic, Uterus	3 (6%)
Thymus	(50)
Thymoma Malignant	

INTEGUMENTARY SYSTEM

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Mammary Gland	(50)
Adenoma	
Carcinoma	2 (4%)
Fibroadenoma	12 (24%)
Fibroadenoma, Multiple	5 (10%)
Skin	(50)
Fibroma	1 (2%)
Hemangiosarcoma	
Keratoacanthoma	
Schwannoma Malignant	
Squamous Cell Papilloma	
Pinna, Neural Crest Tumor	
Subcutaneous Tissue, Schwannoma	
Malignant, Metastatic, Uterus	

MUSCULOSKELETAL SYSTEM

Bone	(50)
Skeletal Muscle	(2)
Carcinoma, Metastatic, Uterus	1 (50%)
Granulosa Cell Tumor Malignant, Metastatic, Ovary	1 (50%)
Schwannoma Malignant	

NERVOUS SYSTEM

Brain	(50)
Carcinoma, Metastatic, Pituitary Gland	1 (2%)
Ependymoma Malignant	
Glioma Malignant	
Meningioma Malignant	
Oligodendroglioma Malignant	
Spinal Cord	(0)
Schwannoma Malignant	

RESPIRATORY SYSTEM

Lung	(50)
Alveolar/Bronchiolar Carcinoma, Multiple	

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Carcinoma, Metastatic, Mammary Gland	
Carcinoma, Metastatic, Ovary	
Carcinoma, Metastatic, Thyroid Gland	1 (2%)
Carcinoma, Metastatic, Uncertain Primary Site	
Carcinoma, Metastatic, Uterus	2 (4%)
Cystic Keratinizing Epithelioma	
Cystic Keratinizing Epithelioma, Multiple	
Nose	(50)
Trachea	(50)

SPECIAL SENSES SYSTEM

Eye	(50)
Harderian Gland	(50)

URINARY SYSTEM

Kidney	(49)
Carcinoma, Metastatic, Uterus	1 (2%)
Granulosa Cell Tumor Malignant, Metastatic, Ovary	1 (2%)
Mesenchymal Tumor Malignant	
Nephroblastoma	
Renal Tubule, Carcinoma	1 (2%)
Ureter	(2)
Carcinoma, Metastatic, Ovary	
Urinary Bladder	(49)
Carcinoma, Metastatic, Uterus	1 (2%)
Sarcoma, Metastatic, Uterus	

SYSTEMIC LESIONS

Multiple Organs	*(50)
Adenolipoma	
Histiocytic Sarcoma	
Lymphoma 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

TEF evaluation (PCB 118)

Time Report Requested: 12:05:16

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	100 UG/KG	220 UG/KG	460 UG/KG	1000 UG/KG	4600 UG/KG
Tumor Summary for Females						
Total Animals with Primary Neoplasms (b)	48	43	47	47	45	45
Total Primary Neoplasms	83	93	88	116	88	128
Total Animals with Benign Neoplasms	43	39	37	45	41	36
Total Benign Neoplasms	67	74	64	99	72	78
Total Animals with Malignant Neoplasms	15	18	23	13	16	39
Total Malignant Neoplasms	16	19	23	16	16	50
Total Animals with Metastatic Neoplasms	4	1	3	2	4	
Total Metastatic Neoplasms	8	1	11	2	22	
Total Animals with Malignant Neoplasms Uncertain Primary Site				1		
Total Animals with Neoplasms Uncertain-Benign or Malignant			1			
Total Uncertain Neoplasms			1			

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

TEF evaluation (PCB 118)

Time Report Requested: 12:05:16

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

4600 UG/KG STOP

Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	44
Total Primary Neoplasms	94
Total Animals with Benign Neoplasms	30
Total Benign Neoplasms	44
Total Animals with Malignant Neoplasms	37
Total Malignant Neoplasms	50
Total Animals with Metastatic Neoplasms	9
Total Metastatic Neoplasms	33
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