

TDMS No. 99031 - 03

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

Date Report Requested: 01/17/2011

Test Type: CHRONIC

Ginkgo biloba extract

Time Report Requested: 12:22:19

Route: GAVAGE

CAS Number: 90045-36-6

First Dose M/F: 03/23/05 / 03/24/05

Species/Strain: RATS/F 344/N

Lab: BAT

F1_R2

C Number: C99031
Lock Date: 05/21/2008
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.3.0
PWG Approval Date: NONE

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CAS Number: 90045-36-6

First Dose M/F: 03/23/05 / 03/24/05

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	7	8	10	14
Natural Death	5	5	9	20
Survivors				
Terminal Sacrifice	38	37	31	16
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(49)	(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)	(49)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Leiomyoma	1 (2%)			
Schwannoma Malignant		1 (2%)		
Liver	(50)	(50)	(50)	(50)
Hepatocellular Adenoma		2 (4%)	3 (6%)	
Hepatocellular Adenoma, Multiple		1 (2%)		
Ito Cell Tumor Benign		1 (2%)		
Osteosarcoma, Metastatic, Bone			1 (2%)	
Mesentery	(4)	(4)	(8)	(5)
Hemangioma		1 (25%)		
Hemangiosarcoma			1 (13%)	
Pancreas	(50)	(50)	(50)	(50)
Acinus, Adenoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)

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

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	11 (22%)	4 (8%)	4 (8%)	6 (12%)
Pheochromocytoma Benign, Multiple				1 (2%)
Pheochromocytoma Complex				1 (2%)
Pheochromocytoma Malignant	1 (2%)	1 (2%)		1 (2%)
Bilateral, Pheochromocytoma Benign		2 (4%)	1 (2%)	
Bilateral, Pheochromocytoma Malignant	1 (2%)			
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	2 (4%)	1 (2%)	1 (2%)
Carcinoma			1 (2%)	1 (2%)
Parathyroid Gland	(47)	(48)	(48)	(47)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	38 (76%)	28 (56%)	25 (50%)	18 (36%)
Pars Distalis, Adenoma, Multiple		2 (4%)		1 (2%)
Pars Distalis, Carcinoma				1 (2%)
Pars Intermedia, Adenoma	1 (2%)	1 (2%)		1 (2%)
Thyroid Gland	(50)	(50)	(49)	(45)
C-cell, Adenoma	10 (20%)	9 (18%)	10 (20%)	1 (2%)
C-cell, Carcinoma	1 (2%)	2 (4%)	2 (4%)	
Follicle, Adenoma	2 (4%)	1 (2%)	3 (6%)	5 (11%)

GENERAL BODY SYSTEM

None

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

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
GENITAL SYSTEM				
Coagulating Gland	(0)	(0)	(1)	(0)
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Adenoma	4 (8%)	3 (6%)		3 (6%)
Carcinoma			1 (2%)	2 (4%)
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(50)	(50)	(50)	(50)
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	26 (52%)	29 (58%)	26 (52%)	27 (54%)
Interstitial Cell, Adenoma	11 (22%)	8 (16%)	13 (26%)	12 (24%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(48)	(50)
Lymph Node	(2)	(2)	(9)	(10)
Mediastinal, Carcinoma, Metastatic, Thyroid Gland			1 (11%)	
Lymph Node, Mandibular	(0)	(0)	(1)	(0)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma			2 (4%)	
Osteosarcoma, Metastatic, Bone			1 (2%)	
Thymus	(47)	(50)	(47)	(47)
Thymoma Benign	1 (2%)			1 (2%)

INTEGUMENTARY SYSTEM

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

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Subcutaneous Tissue, Fibroma	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma				3 (6%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)			
Subcutaneous Tissue, Schwannoma Malignant	1 (2%)		2 (4%)	

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteosarcoma			2 (4%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Peripheral Nerve	(0)	(0)	(0)	(1)
Spinal Cord	(0)	(0)	(0)	(1)

RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Alveolar/Bronchiolar Carcinoma			1 (2%)	1 (2%)
Carcinoma, Metastatic, Thyroid Gland	1 (2%)	1 (2%)	1 (2%)	
Cystic Keratinizing Epithelioma			1 (2%)	
Osteosarcoma, Metastatic, Bone			1 (2%)	
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla	1 (2%)	1 (2%)		
Nose	(50)	(49)	(49)	(50)
Pleura	(0)	(0)	(1)	(0)
Trachea	(50)	(50)	(50)	(50)

SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Zymbal's Gland Carcinoma	(1) 1 (100%)	(0)	(0)	(1) 1 (100%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Lipoma	1 (2%)			
Renal Tubule, Adenoma			1 (2%)	1 (2%)
Transitional Epithelium, Carcinoma		1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organ	*(50)	*(50)	*(50)	*(50)
Leukemia Mononuclear	9 (18%)	12 (24%)	22 (44%)	21 (42%)
Mesothelioma Malignant	3 (6%)	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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FISCHER 344 RATS MALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	50	48	50	49
Total Primary Neoplasms	135	120	131	121
Total Animals with Benign Neoplasms	50	48	49	48
Total Benign Neoplasms	117	101	96	88
Total Animals with Malignant Neoplasms	13	17	30	29
Total Malignant Neoplasms	18	19	35	33
Total Animals with Metastatic Neoplasms	3	3	2	
Total Metastatic Neoplasms	3	3	5	
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

*** END OF MALE ***

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

b - Primary tumors: all tumors except metastatic tumors

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Disposition Summary

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident				1
Moribund Sacrifice	9	13	7	4
Natural Death	4	10	6	13
Survivors				
Natural Death			1	
Terminal Sacrifice	37	27	36	32
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)	
Intestine Large, Cecum	(50)	(50)	(50)	(49)
Intestine Large, Colon	(50)	(50)	(50)	(49)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(49)
Schwannoma Malignant	1 (2%)			
Intestine Small, Ileum	(50)	(50)	(50)	(49)
Carcinoma, Metastatic, Uterus			1 (2%)	
Intestine Small, Jejunum	(50)	(50)	(50)	(49)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)	
Mesentery	(10)	(2)	(8)	(11)
Oral Mucosa	(0)	(0)	(1)	(0)
Squamous Cell Papilloma			1 (100%)	
Pancreas	(50)	(50)	(50)	(48)
Carcinoma, Metastatic, Uterus			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Stomach, Glandular	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)

ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma			1 (2%)	
Carcinoma		1 (2%)		
Carcinoma, Metastatic, Uterus			1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	2 (4%)	2 (4%)		2 (4%)
Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			1 (2%)
Parathyroid Gland	(38)	(47)	(43)	(35)
Adenoma	1 (3%)			
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	33 (66%)	27 (54%)	22 (44%)	16 (32%)
Pars Distalis, Adenoma, Multiple	1 (2%)	1 (2%)		
Pars Distalis, Carcinoma	2 (4%)			2 (4%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(49)	(50)	(49)	(49)
Bilateral, C-cell, Adenoma	1 (2%)			
C-cell, Adenoma	10 (20%)	8 (16%)	8 (16%)	5 (10%)
C-cell, Carcinoma		1 (2%)	1 (2%)	1 (2%)
Follicle, Adenoma	1 (2%)		3 (6%)	1 (2%)
Follicle, Carcinoma			1 (2%)	1 (2%)

GENERAL BODY SYSTEM

None

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Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(50)	(50)
Adenoma	5 (10%)	5 (10%)	4 (8%)	7 (14%)
Carcinoma			1 (2%)	
Bilateral, Adenoma		3 (6%)		1 (2%)
Ovary	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)	
Granulosa Cell Tumor Benign		1 (2%)	1 (2%)	
Schwannoma Malignant, Metastatic, Intestine Small, Duodenum	1 (2%)			
Tubulostromal Adenoma	1 (2%)			
Uterus	(50)	(50)	(50)	(50)
Carcinoma			1 (2%)	
Polyp Stromal	3 (6%)	8 (16%)	8 (16%)	9 (18%)
Schwannoma Malignant Endometrium, Adenoma	1 (2%)			1 (2%)
Vagina	(0)	(2)	(0)	(0)
Schwannoma Malignant		2 (100%)		
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(3)	(3)	(3)	(4)
Mediastinal, Carcinoma, Metastatic, Thyroid Gland		1 (33%)		
Lymph Node, Mesenteric	(50)	(50)	(50)	(49)
Carcinoma, Metastatic, Uterus			1 (2%)	
Spleen	(50)	(50)	(50)	(50)
Thymus	(50)	(48)	(49)	(48)
Thymoma Benign	1 (2%)			
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Fibroadenoma	13 (26%)	22 (44%)	21 (42%)	10 (20%)
Fibroadenoma, Multiple	10 (20%)	9 (18%)	10 (20%)	4 (8%)
Skin	(50)	(50)	(50)	(50)
Keratoacanthoma				1 (2%)
Squamous Cell Carcinoma	1 (2%)			
Subcutaneous Tissue, Fibroma	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Subcutaneous Tissue, Fibrosarcoma			1 (2%)	1 (2%)
Subcutaneous Tissue, Schwannoma Malignant		1 (2%)	1 (2%)	1 (2%)

MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(0)	(1)	(0)
Carcinoma, Metastatic, Uterus			1 (100%)	

NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant		1 (2%)		
Granular Cell Tumor Malignant				1 (2%)
Peripheral Nerve	(1)	(0)	(0)	(0)
Spinal Cord	(1)	(0)	(0)	(0)

RESPIRATORY SYSTEM

Larynx	(0)	(0)	(0)	(1)
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)		3 (6%)	
Astrocytoma Malignant, Metastatic, Brain		1 (2%)		
Carcinoma, Metastatic, Adrenal Cortex		1 (2%)		
Carcinoma, Metastatic, Uterus			1 (2%)	
Granular Cell Tumor Malignant, Metastatic, Brain				1 (2%)
Nose	(49)	(49)	(50)	(46)

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FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Respiratory Epithelium, Adenoma Trachea	(50)	(50)	2 (4%) (50)	(50)
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SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)

URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Uterus			1 (2%)	
Mesenchymal Tumor Malignant				1 (2%)
Renal Tubule, Adenoma				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(49)
Carcinoma, Metastatic, Uterus			1 (2%)	

SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma				1 (2%)
Leukemia Mononuclear	8 (16%)	8 (16%)	7 (14%)	5 (10%)

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* Number of animals with any tissue examined microscopically

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FISCHER 344 RATS FEMALE	0 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	49	47	48	42
Total Primary Neoplasms	102	101	99	75
Total Animals with Benign Neoplasms	47	43	46	37
Total Benign Neoplasms	89	87	86	60
Total Animals with Malignant Neoplasms	12	14	12	13
Total Malignant Neoplasms	13	14	13	15
Total Animals with Metastatic Neoplasms	1	3	1	1
Total Metastatic Neoplasms	1	3	11	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