

TDMS No. 88105 - 03

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

ISOEUGENOL

CAS Number: 97-54-1

Pathologist: Blackshear, P. - GRUMBEIN, S.

F1_R2

Date Report Reqsted: 09/28/2006

Time Report Reqsted: 17:46:24

First Dose M/F: 04/22/02 / 04/23/02

Lab: BNW

C Number: C88105
Lock Date: 01/21/2005
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

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Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		2
Moribund Sacrifice	14	9	14	11
Natural Death	1	6	3	7
Survivors				
Terminal Sacrifice	35	34	33	30
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(46)	(50)	(45)
Intestine Large, Colon	(50)	(46)	(50)	(47)
Adenoma				1 (2%)
Carcinoma			1 (2%)	
Intestine Large, Rectum	(50)	(46)	(50)	(48)
Intestine Small, Duodenum	(50)	(46)	(50)	(45)
Intestine Small, Ileum	(50)	(46)	(50)	(45)
Intestine Small, Jejunum	(50)	(46)	(50)	(45)
Leiomyoma	1 (2%)			
Liver	(50)	(50)	(50)	(48)
Hemangiosarcoma	1 (2%)			
Hepatocellular Adenoma	1 (2%)			2 (4%)
Mesentery	(12)	(18)	(7)	(11)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle		1 (6%)		
Oral Mucosa	(1)	(0)	(1)	(3)
Gingival, Squamous Cell Carcinoma	1 (100%)		1 (100%)	1 (33%)
Pharyngeal, Squamous Cell Carcinoma				1 (33%)
Pancreas	(50)	(50)	(50)	(49)
Rhabdomyosarcoma, Metastatic, Skeletal Muscle		1 (2%)		
Acinus, Adenoma	7 (14%)	1 (2%)	1 (2%)	4 (8%)
Acinus, Adenoma, Multiple				1 (2%)
Acinus, Carcinoma	1 (2%)			

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

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Salivary Glands	(50)	(50)	(49)	(50)
Schwannoma Malignant				1 (2%)
Stomach, Forestomach	(50)	(49)	(50)	(49)
Squamous Cell Papilloma				1 (2%)
Stomach, Glandular	(50)	(46)	(50)	(45)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung				1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Adenoma				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign	4 (8%)	9 (18%)	9 (18%)	7 (14%)
Pheochromocytoma Complex		1 (2%)		
Pheochromocytoma Malignant	3 (6%)		1 (2%)	1 (2%)
Bilateral, Pheochromocytoma Benign	1 (2%)	1 (2%)		
Islets, Pancreatic	(50)	(49)	(50)	(49)
Adenoma	4 (8%)	1 (2%)	1 (2%)	3 (6%)
Pituitary Gland	(50)	(48)	(47)	(47)
Pars Distalis, Adenoma	19 (38%)	13 (27%)	19 (40%)	15 (32%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(50)	(49)	(50)	(47)
Bilateral, C-cell, Adenoma				1 (2%)
C-cell, Adenoma	9 (18%)	12 (24%)	8 (16%)	5 (11%)
C-cell, Adenoma, Multiple			1 (2%)	
C-cell, Carcinoma	6 (12%)	3 (6%)	3 (6%)	2 (4%)
Follicular Cell, Adenoma	1 (2%)			
Follicular Cell, Carcinoma	1 (2%)	2 (4%)	2 (4%)	1 (2%)
GENERAL BODY SYSTEM				
None				

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(49)	(50)	(50)
Adenoma	2 (4%)	3 (6%)	4 (8%)	5 (10%)
Carcinoma	2 (4%)	3 (6%)	1 (2%)	4 (8%)
Prostate	(50)	(49)	(50)	(50)
Adenoma		2 (4%)	2 (4%)	1 (2%)
Adenoma, Multiple			1 (2%)	
Chemodectoma Benign		1 (2%)		
Seminal Vesicle	(50)	(49)	(50)	(49)
Adenoma			1 (2%)	
Testes	(50)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	40 (80%)	40 (80%)	37 (74%)	41 (82%)
Interstitial Cell, Adenoma	6 (12%)	3 (6%)	7 (14%)	3 (6%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(49)	(50)	(50)
Lymph Node	(3)	(4)	(4)	(4)
Deep Cervical, Carcinoma, Metastatic,	2 (67%)			
Thyroid Gland				
Mediastinal, Schwannoma Malignant,				1 (25%)
Metastatic, Salivary Glands				
Lymph Node, Mesenteric	(50)	(48)	(50)	(47)
Spleen	(50)	(46)	(50)	(47)
Hemangiosarcoma	1 (2%)			
Leiomyoma				1 (2%)
Thymus	(47)	(43)	(49)	(48)
Thymoma Benign				1 (2%)
Thymoma Malignant				1 (2%)
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(49)	(50)	(50)
Carcinoma				2 (4%)
Fibroadenoma	4 (8%)	3 (6%)	1 (2%)	1 (2%)
Skin	(50)	(50)	(50)	(50)
Basal Cell Adenoma				1 (2%)

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Basal Cell Carcinoma	1 (2%)		2 (4%)	
Keratoacanthoma	7 (14%)	5 (10%)	1 (2%)	1 (2%)
Squamous Cell Papilloma				1 (2%)
Sebaceous Gland, Adenoma	1 (2%)			
Subcutaneous Tissue, Fibroma	5 (10%)	1 (2%)	6 (12%)	2 (4%)
Subcutaneous Tissue, Fibrosarcoma	1 (2%)	1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma			2 (4%)	
Subcutaneous Tissue, Lipoma	2 (4%)			
Subcutaneous Tissue, Sarcoma	1 (2%)	1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hemangiosarcoma			2 (4%)	
Osteoma		1 (2%)		
Osteosarcoma	2 (4%)	1 (2%)		
Vertebra, Chordoma				1 (2%)
Skeletal Muscle	(0)	(2)	(0)	(1)
Rhabdomyosarcoma		1 (50%)		
Sarcoma		1 (50%)		
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Glioma Malignant		1 (2%)	1 (2%)	
Oligodendroglioma Malignant	1 (2%)			
Peripheral Nerve	(0)	(1)	(1)	(0)
Schwannoma Malignant			1 (100%)	
Spinal Cord	(0)	(1)	(1)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	3 (6%)	2 (4%)	2 (4%)
Alveolar/Bronchiolar Carcinoma	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Carcinoma, Metastatic, Preputial Gland		1 (2%)		
Carcinoma, Metastatic, Thyroid Gland	2 (4%)			
Carcinoma, Metastatic, Zymbal'S Gland	1 (2%)			

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FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hemangiosarcoma	1 (2%)		1 (2%)	
Osteosarcoma, Metastatic, Bone	2 (4%)			
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla			1 (2%)	
Sarcoma, Metastatic, Skin		1 (2%)		
Schwannoma Malignant, Metastatic, Salivary Glands				1 (2%)
Nose	(50)	(48)	(49)	(49)
Pleura	(0)	(0)	(0)	(2)
Trachea	(50)	(49)	(50)	(48)
SPECIAL SENSES SYSTEM				
Eye	(50)	(46)	(50)	(45)
Harderian Gland	(50)	(47)	(50)	(45)
Zymbal's Gland	(2)	(1)	(0)	(0)
Carcinoma	2 (100%)	1 (100%)		
URINARY SYSTEM				
Kidney	(50)	(48)	(50)	(49)
Hemangiosarcoma	1 (2%)			
Transitional Epithelium, Papilloma		1 (2%)		
Urinary Bladder	(50)	(48)	(50)	(47)
Transitional Epithelium, Papilloma				1 (2%)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		1 (2%)
Leukemia Mononuclear	10 (20%)	11 (22%)	14 (28%)	7 (14%)
Mesothelioma Malignant	3 (6%)	1 (2%)	2 (4%)	4 (8%)

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* Number of animals with any tissue examined microscopically

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Pathologist: Blackshear, P. - GRUMBEIN, S.

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First Dose M/F: 04/22/02 / 04/23/02

Lab: BNW

FISCHER 344 RATS MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	50	47	46	50
Total Primary Neoplasms	158	131	136	131
Total Animals with Benign Neoplasms	49	46	46	49
Total Benign Neoplasms	118	100	101	102
Total Animals with Malignant Neoplasms	29	25	27	25
Total Malignant Neoplasms	40	31	35	29
Total Animals with Metastatic Neoplasms	5	3	1	2
Total Metastatic Neoplasms	7	4	1	3
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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Lab: BNW

FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident		1		
Moribund Sacrifice	15	8	9	9
Natural Death	2	6	7	10
Survivors				
Moribund Sacrifice				1
Terminal Sacrifice	33	35	34	30
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(48)	(47)	(48)
Intestine Large, Rectum	(49)	(48)	(47)	(48)
Intestine Small, Ileum	(49)	(47)	(45)	(45)
Liver	(50)	(50)	(50)	(50)
Mesentery	(11)	(11)	(11)	(14)
Schwannoma Malignant				1 (7%)
Oral Mucosa	(0)	(1)	(0)	(1)
Pharyngeal, Squamous Cell Papilloma		1 (100%)		
Pancreas	(50)	(49)	(48)	(50)
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(49)	(50)
Stomach, Glandular	(50)	(47)	(46)	(47)
Tongue	(0)	(0)	(1)	(0)
Squamous Cell Carcinoma			1 (100%)	
Tooth	(0)	(1)	(0)	(0)
Odontoma		1 (100%)		

CARDIOVASCULAR SYSTEM

Heart	(50)	(50)	(50)	(50)
Schwannoma Malignant, Metastatic, Mesentery				1 (2%)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(47)	(49)
Adenoma		1 (2%)		
Adrenal Medulla	(50)	(50)	(46)	(49)
Pheochromocytoma Benign	2 (4%)	3 (6%)		2 (4%)
Bilateral, Pheochromocytoma Benign		1 (2%)		
Islets, Pancreatic	(50)	(49)	(47)	(49)
Adenoma			1 (2%)	
Parathyroid Gland	(47)	(44)	(48)	(44)
Pituitary Gland	(50)	(48)	(49)	(49)
Pars Distalis, Adenoma	25 (50%)	20 (42%)	20 (41%)	20 (41%)
Pars Intermedia, Adenoma			1 (2%)	
Thyroid Gland	(50)	(46)	(46)	(48)
Bilateral, C-cell, Adenoma		1 (2%)		1 (2%)
Bilateral, C-cell, Carcinoma	1 (2%)			
C-cell, Adenoma	7 (14%)	7 (15%)	7 (15%)	5 (10%)
C-cell, Carcinoma	2 (4%)	2 (4%)	2 (4%)	2 (4%)
Follicular Cell, Adenoma		1 (2%)		
Follicular Cell, Carcinoma	1 (2%)		1 (2%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(48)	(50)	(49)	(50)
Adenoma	3 (6%)	3 (6%)	4 (8%)	5 (10%)
Carcinoma	1 (2%)	2 (4%)		2 (4%)
Bilateral, Carcinoma	1 (2%)			
Ovary	(50)	(50)	(49)	(50)
Cystadenoma		1 (2%)		
Granulosa-Theca Tumor Malignant				1 (2%)
Schwannoma Malignant, Metastatic, Mesentery				1 (2%)
Uterus	(50)	(50)	(49)	(50)

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Deciduoma Benign	1 (2%)			
Polyp Stromal	8 (16%)	15 (30%)	6 (12%)	5 (10%)
Polyp Stromal, Multiple		1 (2%)		
Sarcoma Stromal			1 (2%)	
Vagina	(1)	(0)	(1)	(0)
Polyp	1 (100%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(49)	(49)	(49)
Lymph Node	(0)	(3)	(3)	(3)
Lymph Node, Mesenteric	(50)	(49)	(48)	(49)
Schwannoma Malignant, Metastatic, Mesentery				1 (2%)
Spleen	(50)	(49)	(49)	(49)
Thymus	(47)	(47)	(46)	(49)
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(50)	(50)	(49)
Carcinoma	4 (8%)	1 (2%)	2 (4%)	4 (8%)
Fibroadenoma	17 (35%)	19 (38%)	12 (24%)	13 (27%)
Fibroadenoma, Multiple	9 (18%)	9 (18%)	7 (14%)	5 (10%)
Skin	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma				1 (2%)
Squamous Cell Papilloma			1 (2%)	
Subcutaneous Tissue, Fibroma		1 (2%)		
Subcutaneous Tissue, Lipoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Neural Crest Tumor			1 (2%)	
Subcutaneous Tissue, Sarcoma			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma		1 (2%)		
NERVOUS SYSTEM				

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Brain	(50)	(50)	(50)	(50)
Astrocytoma Malignant			1 (2%)	
Granular Cell Tumor Malignant				1 (2%)
Oligodendroglioma Malignant	1 (2%)			
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	2 (4%)	1 (2%)	4 (8%)
Granulosa-Theca Tumor Malignant, Metastatic, Ovary				1 (2%)
Schwannoma Malignant, Metastatic, Mesentery				1 (2%)
Nose	(50)	(49)	(49)	(49)
Respiratory Epithelium, Adenoma		1 (2%)		
Pleura	(0)	(0)	(0)	(1)
Trachea	(50)	(49)	(48)	(49)
SPECIAL SENSES SYSTEM				
Eye	(49)	(46)	(47)	(48)
Zymbal's Gland	(0)	(1)	(0)	(1)
Carcinoma		1 (100%)		1 (100%)
URINARY SYSTEM				
Kidney	(50)	(49)	(47)	(50)
Transitional Epithelium, Carcinoma			1 (2%)	
Urinary Bladder	(50)	(50)	(48)	(49)
Leiomyoma				1 (2%)
Sarcoma Stromal, Metastatic, Uterus			1 (2%)	
Transitional Epithelium, Papilloma			1 (2%)	
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)		1 (2%)
Leukemia Mononuclear	8 (16%)	5 (10%)	12 (24%)	8 (16%)

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

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ISOEUGENOL

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
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* Number of animals with any tissue examined microscopically

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FISCHER 344 RATS FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	46	46	46	43
Total Primary Neoplasms	93	102	85	83
Total Animals with Benign Neoplasms	41	45	36	40
Total Benign Neoplasms	74	89	62	61
Total Animals with Malignant Neoplasms	18	12	21	20
Total Malignant Neoplasms	19	13	22	22
Total Animals with Metastatic Neoplasms			1	2
Total Metastatic Neoplasms			1	5
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain-Benign or Malignant			1	
Total Uncertain Neoplasms			1	

*** 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