

TDMS No. 88105 - 04

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

Date Report Reqsted: 10/04/2006

Test Type: CHRONIC

ISOEUGENOL

Time Report Reqsted: 13:43:51

Route: GAVAGE

CAS Number: 97-54-1

First Dose M/F: 05/09/02 / 05/08/02

Species/Strain: MICE/B6C3F1

Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

F1_M3

C Number: C88105

Lock Date: 03/10/2005

Cage Range: ALL

Date Range: ALL

Reasons For Removal:	25022 ACCK	25021 TSAC	25020 NATD
	25019 MSAC		

Removal Date Range: ALL

Treatment Groups: Include ALL

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Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE 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				
Moribund Sacrifice	7	10	5	7
Natural Death	4	2	9	16
Survivors				
Terminal Sacrifice	39	38	36	27
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(44)	(47)	(46)	(38)
Intestine Large, Colon	(48)	(49)	(46)	(46)
Carcinoma		1 (2%)		
Intestine Small, Jejunum	(47)	(48)	(46)	(42)
Adenoma			1 (2%)	
Carcinoma			1 (2%)	
Hemangiosarcoma	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)	2 (4%)	1 (2%)	
Hepatoblastoma	3 (6%)			1 (2%)
Hepatoblastoma, Multiple		1 (2%)		1 (2%)
Hepatocellular Adenoma	14 (28%)	9 (18%)	9 (18%)	13 (26%)
Hepatocellular Adenoma, Multiple	10 (20%)	26 (52%)	28 (56%)	20 (40%)
Hepatocellular Carcinoma	6 (12%)	12 (24%)	13 (26%)	14 (28%)
Hepatocellular Carcinoma, Multiple	2 (4%)	6 (12%)	6 (12%)	4 (8%)
Hepatocholangiocarcinoma	2 (4%)	1 (2%)		1 (2%)
Mesentery	(5)	(4)	(4)	(1)
Hepatoblastoma, Metastatic, Liver		1 (25%)		1 (100%)
Pancreas	(50)	(50)	(50)	(49)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(49)	(50)	(49)
Squamous Cell Papilloma		2 (4%)	2 (4%)	
Stomach, Glandular	(50)	(49)	(49)	(44)

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

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Pathologist: Blackshear, P. - GRUMBEIN, S.

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver	2 (4%)			1 (2%)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(49)
Subcapsular, Adenoma	3 (6%)		3 (6%)	
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign				1 (2%)
Islets, Pancreatic	(50)	(50)	(50)	(49)
Pituitary Gland	(50)	(48)	(50)	(48)
Pars Intermedia, Adenoma				1 (2%)
Thyroid Gland	(50)	(49)	(50)	(49)
Follicular Cell, Adenoma		1 (2%)		
Follicular Cell, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Coagulating Gland	(0)	(1)	(0)	(0)
Adenoma		1 (100%)		
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Seminal Vesicle	(49)	(50)	(50)	(48)
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma	2 (4%)	1 (2%)	1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)

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B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hemangiosarcoma		1 (2%)		
Lymph Node	(1)	(0)	(2)	(2)
Bronchial, Hepatocholangiocarcinoma, Metastatic, Liver	1 (100%)			
Pancreatic, Hepatoblastoma, Metastatic, Liver				1 (50%)
Lymph Node, Mandibular	(49)	(49)	(50)	(47)
Lymph Node, Mesenteric	(48)	(50)	(50)	(48)
Spleen	(50)	(50)	(50)	(49)
Hemangiosarcoma		1 (2%)	1 (2%)	
Thymus	(48)	(48)	(48)	(42)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver	2 (4%)			1 (2%)
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Fibrosarcoma		1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)			
Subcutaneous Tissue, Lipoma		1 (2%)		
Subcutaneous Tissue, Sarcoma			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Skeletal Muscle	(1)	(0)	(0)	(0)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
RESPIRATORY SYSTEM				

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Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE MALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Lung	(50)	(49)	(50)	(50)
Alveolar/Bronchiolar Adenoma	5 (10%)	5 (10%)	2 (4%)	8 (16%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)			
Alveolar/Bronchiolar Carcinoma	2 (4%)	7 (14%)	5 (10%)	2 (4%)
Alveolar/Bronchiolar Carcinoma, Multiple			2 (4%)	
Carcinoma, Metastatic, Harderian Gland		1 (2%)	1 (2%)	
Hepatoblastoma, Metastatic, Liver	1 (2%)			1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver		10 (20%)	13 (26%)	12 (24%)
Hepatocholangiocarcinoma, Metastatic, Liver	2 (4%)	1 (2%)		1 (2%)
Nose	(50)	(50)	(50)	(50)
Pleura	(0)	(1)	(0)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (100%)		
SPECIAL SENSES SYSTEM				
Eye	(48)	(48)	(46)	(43)
Harderian Gland	(49)	(50)	(50)	(49)
Adenoma	7 (14%)	4 (8%)	2 (4%)	3 (6%)
Carcinoma	4 (8%)	3 (6%)	2 (4%)	1 (2%)
Bilateral, Adenoma	1 (2%)		1 (2%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(49)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Renal Tubule, Adenoma	1 (2%)			
Renal Tubule, Carcinoma		1 (2%)		1 (2%)
Urinary Bladder	(49)	(50)	(50)	(45)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Lymphoma Malignant			3 (6%)	2 (4%)

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* Number of animals with any tissue examined microscopically

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B6C3F1 MICE 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)	43	48	46	46
Total Primary Neoplasms	67	88	84	74
Total Animals with Benign Neoplasms	33	37	37	36
Total Benign Neoplasms	44	50	49	46
Total Animals with Malignant Neoplasms	20	27	29	28
Total Malignant Neoplasms	23	38	35	28
Total Animals with Metastatic Neoplasms	3	14	14	14
Total Metastatic Neoplasms	11	15	14	18
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: MICE/B6C3F1

Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE 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				
Accidentally Killed	2			1
Moribund Sacrifice	5	7	5	5
Natural Death	8	4	7	11
Survivors				
Terminal Sacrifice	34	39	38	33
Animals Examined Microscopically	49	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(42)	(47)	(47)	(40)
Intestine Large, Cecum	(46)	(47)	(45)	(42)
Intestine Large, Colon	(47)	(47)	(47)	(47)
Intestine Large, Rectum	(47)	(48)	(45)	(46)
Intestine Small, Duodenum	(42)	(47)	(45)	(40)
Intestine Small, Ileum	(45)	(47)	(46)	(44)
Intestine Small, Jejunum	(44)	(48)	(45)	(45)
Liver	(49)	(50)	(49)	(50)
Carcinoma, Metastatic, Uncertain Primary Site		1 (2%)		
Hemangiosarcoma		2 (4%)		
Hepatocellular Adenoma	11 (22%)	7 (14%)	8 (16%)	4 (8%)
Hepatocellular Adenoma, Multiple		3 (6%)	1 (2%)	
Hepatocellular Carcinoma	2 (4%)	8 (16%)	7 (14%)	6 (12%)
Hepatocellular Carcinoma, Multiple	1 (2%)		2 (4%)	
Mesentery	(15)	(14)	(14)	(6)
Pancreas	(47)	(50)	(47)	(49)
Carcinoma, Metastatic, Uncertain Primary Site		1 (2%)		
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(48)	(50)	(49)	(50)
Carcinoma, Metastatic, Uncertain Primary Site		1 (2%)		
Squamous Cell Papilloma	1 (2%)	1 (2%)	5 (10%)	2 (4%)
Squamous Cell Papilloma, Multiple				1 (2%)

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Pathologist: Blackshear, P. - GRUMBEIN, S.

Lab: BNW

B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Stomach, Glandular Adenoma Carcinoma, Metastatic, Uncertain Primary Site	(46) 1 (2%)	(48) 1 (2%)	(47)	(48)
CARDIOVASCULAR SYSTEM				
Blood Vessel Heart	(2) (49)	(1) (50)	(1) (50)	(2) (50)
ENDOCRINE SYSTEM				
Adrenal Cortex Capsule, Adenoma Adrenal Medulla Pheochromocytoma Benign Islets, Pancreatic Pituitary Gland Pars Distalis, Adenoma Thyroid Gland Follicular Cell, Adenoma	(48) (48) (47) (47) 4 (9%) (48)	(50) (50) 1 (2%) (50) (48) (50) (50)	(49) 1 (2%) (49) (48) (50) 4 (8%) (49) 1 (2%)	(50) (50) (49) (50) 1 (2%) (50)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland Fibrosarcoma Ovary Cystadenocarcinoma Cystadenoma Granulosa-Theca Tumor Malignant Tubulostromal Adenoma Bilateral, Cystadenoma Uterus Carcinoma	(47) (48) 2 (4%) 1 (2%) (48)	(49) (50) 1 (2%) 1 (2%) (50)	(49) (50) 1 (2%) 1 (2%) (50)	(48) 1 (2%) (50) 1 (2%) (50)

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

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Route: GAVAGE

Species/Strain: MICE/B6C3F1

CAS Number: 97-54-1

Pathologist: Blackshear, P. - GRUMBEIN, S.

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First Dose M/F: 05/09/02 / 05/08/02

Lab: BNW

B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
Hemangiosarcoma			1 (2%)	1 (2%)
Polyp Stromal			2 (4%)	1 (2%)
Sarcoma Stromal	1 (2%)			
HEMATOPOIETIC SYSTEM				
Bone Marrow	(48)	(49)	(50)	(50)
Hemangiosarcoma				1 (2%)
Lymph Node	(4)	(5)	(3)	(2)
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Lymph Node, Mesenteric	(47)	(49)	(47)	(50)
Sarcoma		1 (2%)		
Spleen	(48)	(50)	(49)	(50)
Hemangiosarcoma	1 (2%)			
Thymus	(47)	(50)	(49)	(47)
INTEGUMENTARY SYSTEM				
Mammary Gland	(48)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Skin	(49)	(50)	(50)	(50)
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)			
Subcutaneous Tissue, Sarcoma	2 (4%)		1 (2%)	
Subcutaneous Tissue, Sarcoma, Multiple	1 (2%)			
MUSCULOSKELETAL SYSTEM				
Bone	(49)	(50)	(50)	(50)
Osteosarcoma	1 (2%)		1 (2%)	1 (2%)
Skeletal Muscle	(0)	(1)	(0)	(0)
Rhabdomyosarcoma		1 (100%)		
NERVOUS SYSTEM				
Brain	(49)	(50)	(50)	(50)
Peripheral Nerve	(2)	(2)	(1)	(0)

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B6C3F1 MICE FEMALE	0 MG/KG	75 MG/KG	150 MG/KG	300 MG/KG
RESPIRATORY SYSTEM				
Lung	(48)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	2 (4%)	1 (2%)	1 (2%)
Alveolar/Bronchiolar Carcinoma		1 (2%)	3 (6%)	1 (2%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)		
Carcinoma, Metastatic, Harderian Gland	1 (2%)	1 (2%)		
Carcinoma, Metastatic, Uterus		1 (2%)		
Hepatocellular Carcinoma, Metastatic, Liver			6 (12%)	3 (6%)
Osteosarcoma, Metastatic, Bone	1 (2%)		1 (2%)	
Sarcoma, Metastatic, Harderian Gland			1 (2%)	
Nose	(48)	(50)	(50)	(50)
Carcinoma, Metastatic, Harderian Gland				1 (2%)
Mast Cell Tumor Malignant, Metastatic, Uncertain Primary Site				1 (2%)
Sarcoma, Metastatic, Harderian Gland			1 (2%)	
SPECIAL SENSES SYSTEM				
Eye	(44)	(47)	(46)	(42)
Sarcoma, Metastatic, Harderian Gland			1 (2%)	
Harderian Gland	(46)	(50)	(49)	(48)
Adenoma	3 (7%)	3 (6%)	2 (4%)	5 (10%)
Carcinoma	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Sarcoma			1 (2%)	
URINARY SYSTEM				
Kidney	(47)	(50)	(49)	(49)
Urinary Bladder	(47)	(49)	(47)	(46)
SYSTEMIC LESIONS				
Multiple Organs	*(49)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	1 (2%)	4 (8%)
Lymphoma Malignant	11 (22%)	10 (20%)	8 (16%)	7 (14%)

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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Lab: BNW

B6C3F1 MICE 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)	34	33	37	26
Total Primary Neoplasms	49	48	54	39
Total Animals with Benign Neoplasms	20	18	22	13
Total Benign Neoplasms	27	18	26	16
Total Animals with Malignant Neoplasms	21	27	25	19
Total Malignant Neoplasms	22	30	28	23
Total Animals with Metastatic Neoplasms	2	3	8	5
Total Metastatic Neoplasms	2	6	10	5
Total Animals with Malignant Neoplasms Uncertain Primary Site		1		1
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