

TDMS No. 88123 - 07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: MICE/B6C3F1

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

FORMAMIDE

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

F1_M3

Date Report Reqsted: 05/04/2006

Time Report Reqsted: 11:47:08

First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

C Number: C88123B
Lock Date: 05/24/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

Test Type: CHRONIC

Time Report Requested: 11:47:08

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 10/04/01 / 10/03/01

Species/Strain: MICE/B6C3F1

Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	4	8	6	14
Natural Death	7		8	3
Survivors				
Terminal Sacrifice	39	42	36	33
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Periesophageal Tissue,		1 (2%)		
Hepatocholangiocarcinoma, Metastatic,				
Liver				
Gallbladder	(45)	(48)	(45)	(46)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas				1 (2%)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Epithelium, Carcinoma		1 (2%)		
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma		3 (6%)		1 (2%)
Liver	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas				1 (2%)
Cholangiocarcinoma			1 (2%)	
Hemangioma				1 (2%)
Hemangiosarcoma	1 (2%)	5 (10%)	6 (12%)	3 (6%)
Hemangiosarcoma, Multiple			1 (2%)	5 (10%)
Hepatoblastoma	1 (2%)	1 (2%)	3 (6%)	
Hepatoblastoma, Multiple				1 (2%)
Hepatocellular Adenoma	17 (34%)	12 (24%)	20 (40%)	18 (36%)
Hepatocellular Adenoma, Multiple	7 (14%)	12 (24%)	5 (10%)	10 (20%)
Hepatocellular Carcinoma	12 (24%)	11 (22%)	9 (18%)	18 (36%)
Hepatocellular Carcinoma, Multiple	3 (6%)	4 (8%)	3 (6%)	1 (2%)

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

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Species/Strain: MICE/B6C3F1

Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Hepatocholangiocarcinoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Mesentery	(3)	(1)	(1)	(1)
Carcinoma, Metastatic, Pancreas				1 (100%)
Oral Mucosa	(7)	(5)	(5)	(7)
Pancreas	(50)	(50)	(50)	(50)
Carcinoma				1 (2%)
Salivary Glands	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma		1 (2%)	1 (2%)	1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pancreas				1 (2%)
Tooth	(15)	(14)	(9)	(2)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Hemangioma	1 (2%)			
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)	1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(49)	(50)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		
Bilateral, Carcinoma, Metastatic, Pancreas				1 (2%)
Subcapsular, Adenoma	2 (4%)	1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)

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Species/Strain: MICE/B6C3F1

Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Hepatoblastoma, Metastatic, Liver				1 (2%)
Pheochromocytoma Malignant	1 (2%)			
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma		1 (2%)		
Parathyroid Gland	(43)	(39)	(46)	(47)
Pituitary Gland	(50)	(50)	(50)	(49)
Pars Distalis, Adenoma	1 (2%)			
Pars Distalis, Carcinoma	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
Follicle, Adenoma		3 (6%)	1 (2%)	1 (2%)
Follicle, Carcinoma	1 (2%)			
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Epididymis	(50)	(50)	(50)	(50)
Preputial Gland	(50)	(50)	(50)	(50)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Prostate	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver			1 (2%)	
Bilateral, Interstitial Cell, Adenoma		1 (2%)		
Interstitial Cell, Adenoma		1 (2%)		1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		1 (2%)
Lymph Node	(4)	(2)	(1)	(1)

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Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Mediastinal, Carcinoma, Metastatic, Pancreas				1 (100%)
Pancreatic, Carcinoma, Metastatic, Pancreas				1 (100%)
Renal, Carcinoma, Metastatic, Pancreas				1 (100%)
Lymph Node, Mandibular	(49)	(48)	(49)	(48)
Lymph Node, Mesenteric	(50)	(47)	(50)	(49)
Carcinoma, Metastatic, Pancreas				1 (2%)
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	2 (4%)	2 (4%)	1 (2%)	3 (6%)
Hemangiosarcoma, Multiple			1 (2%)	
Thymus	(47)	(46)	(50)	(46)
Carcinoma, Metastatic, Pancreas				1 (2%)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Hemangioma				1 (2%)
Subcutaneous Tissue, Hemangiosarcoma				1 (2%)
Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Sarcoma			1 (2%)	
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(0)	(2)
Carcinoma, Metastatic, Pancreas				1 (50%)
Hepatoblastoma, Metastatic, Liver				1 (50%)
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Pituitary Gland	1 (2%)			
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

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B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	8 (16%)	3 (6%)	6 (12%)	1 (2%)
Alveolar/Bronchiolar Adenoma, Multiple	2 (4%)	1 (2%)	1 (2%)	
Alveolar/Bronchiolar Carcinoma	6 (12%)	4 (8%)	4 (8%)	11 (22%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)	2 (4%)	
Carcinoma, Metastatic, Harderian Gland	1 (2%)	2 (4%)	1 (2%)	
Carcinoma, Metastatic, Liver	1 (2%)			
Carcinoma, Metastatic, Pancreas				1 (2%)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Hepatoblastoma, Metastatic, Liver			1 (2%)	1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	4 (8%)	4 (8%)	3 (6%)	6 (12%)
Hepatocellular Carcinoma, Metastatic, Uncertain Primary Site				2 (4%)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)	1 (2%)		1 (2%)
Mediastinum, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Mediastinum, Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Pleura	(1)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	8 (16%)	2 (4%)	4 (8%)
Carcinoma	2 (4%)	2 (4%)	2 (4%)	1 (2%)
Bilateral, Adenoma				1 (2%)
Bilateral, Carcinoma		1 (2%)	1 (2%)	
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)

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Species/Strain: MICE/B6C3F1

Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Carcinoma, Metastatic, Pancreas				1 (2%)
Hepatoblastoma, Metastatic, Liver				1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		
Renal Tubule, Carcinoma				1 (2%)
Renal Tubule, Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	1 (2%)	
Lymphoma Malignant	2 (4%)		2 (4%)	

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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Species/Strain: MICE/B6C3F1

CAS Number: 75-12-7

Pathologist: RYAN, M. - Blackshear, P.

Time Report Requested: 11:47:08

First Dose M/F: 10/04/01 / 10/03/01

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	41	39	43	46
Total Primary Neoplasms	78	85	76	90
Total Animals with Benign Neoplasms	31	29	32	33
Total Benign Neoplasms	45	45	37	39
Total Animals with Malignant Neoplasms	28	27	29	36
Total Malignant Neoplasms	33	40	39	51
Total Animals with Metastatic Neoplasms	8	7	7	11
Total Metastatic Neoplasms	11	11	14	30
Total Animals with Malignant Neoplasms Uncertain Primary Site				2
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: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Dosing Accident			1	
Moribund Sacrifice	7	8	8	8
Natural Death	5	3	10	3
Survivors				
Natural Death		1		
Terminal Sacrifice	38	38	31	39
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(47)	(45)	(46)	(49)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Leiomyosarcoma			1 (2%)	
Intestine Large, Colon	(50)	(50)	(50)	(50)
Intestine Large, Rectum	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Leiomyosarcoma				1 (2%)
Intestine Small, Duodenum	(50)	(50)	(50)	(50)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma			1 (2%)	1 (2%)
Hepatocellular Adenoma	4 (8%)	9 (18%)	11 (22%)	10 (20%)
Hepatocellular Adenoma, Multiple	2 (4%)	3 (6%)	2 (4%)	2 (4%)
Hepatocellular Carcinoma	4 (8%)	3 (6%)		5 (10%)
Hepatocellular Carcinoma, Multiple		1 (2%)		1 (2%)
Mesentery	(8)	(3)	(8)	(2)
Fibrosarcoma	1 (13%)			
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(49)	(49)	(50)	(50)

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Salivary Glands	(49)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Carcinoma		1 (2%)		
Squamous Cell Papilloma	1 (2%)			
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(0)	(0)	(0)	(1)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(49)	(50)	(49)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Hepatocellular Carcinoma, Metastatic, Liver				1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign		2 (4%)		
Pheochromocytoma Malignant				2 (4%)
Islets, Pancreatic	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)	1 (2%)	1 (2%)
Parathyroid Gland	(42)	(32)	(35)	(42)
Pituitary Gland	(50)	(50)	(49)	(50)
Pars Distalis, Adenoma	3 (6%)	1 (2%)	2 (4%)	1 (2%)
Pars Distalis, Adenoma, Multiple			1 (2%)	
Pars Intermedia, Adenoma	1 (2%)	1 (2%)		
Thyroid Gland	(49)	(50)	(50)	(50)
Follicle, Adenoma	2 (4%)	2 (4%)	2 (4%)	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)

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Pathologist: RYAN, M. - Blackshear, P.

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Ovary	(50)	(50)	(50)	(49)
Cystadenoma	1 (2%)	3 (6%)	4 (8%)	1 (2%)
Granulosa Cell Tumor Benign		1 (2%)		
Granulosa Cell Tumor Malignant		1 (2%)		
Hemangioma				1 (2%)
Luteoma				1 (2%)
Teratoma Benign		1 (2%)		
Teratoma Malignant			1 (2%)	
Bilateral, Luteoma		1 (2%)		
Uterus	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Polyp Stromal				2 (4%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(8)	(4)	(6)	(5)
Bronchial, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (17%)	
Mediastinal, Hepatocellular Carcinoma, Metastatic, Liver				1 (20%)
Renal, Teratoma Malignant, Metastatic, Ovary			1 (17%)	
Lymph Node, Mandibular	(49)	(50)	(50)	(50)
Lymph Node, Mesenteric	(50)	(50)	(49)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Spleen	(50)	(49)	(49)	(50)
Hemangiosarcoma	1 (2%)			
Thymus	(49)	(50)	(49)	(50)
Thymoma Benign		1 (2%)		
INTEGUMENTARY SYSTEM				
Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma	2 (4%)	2 (4%)	3 (6%)	
Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Hemangiosarcoma				1 (2%)
Subcutaneous Tissue, Sarcoma	1 (2%)	6 (12%)	4 (8%)	1 (2%)
Subcutaneous Tissue, Sarcoma, Multiple			1 (2%)	

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Osteosarcoma				1 (2%)
Skeletal Muscle	(2)	(5)	(5)	(0)
Fibrosarcoma, Metastatic, Mesentery	1 (50%)			
Hemangiosarcoma	1 (50%)		1 (20%)	
Lipoma		1 (20%)		
Teratoma Malignant, Metastatic, Ovary			1 (20%)	
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
Spinal Cord	(1)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	3 (6%)	2 (4%)	1 (2%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)		1 (2%)	
Alveolar/Bronchiolar Carcinoma	2 (4%)		3 (6%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple				1 (2%)
Carcinoma, Metastatic, Harderian Gland	2 (4%)			
Hepatocellular Carcinoma, Metastatic, Liver	2 (4%)	2 (4%)		3 (6%)
Osteosarcoma, Metastatic, Bone				1 (2%)
Sarcoma, Metastatic, Skin		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Pleura	(0)	(0)	(1)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (100%)	
SPECIAL SENSES SYSTEM				
Eye	(49)	(50)	(49)	(50)
Harderian Gland	(49)	(50)	(50)	(50)
Adenoma	4 (8%)	3 (6%)	2 (4%)	7 (14%)

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
Carcinoma	3 (6%)			1 (2%)
Bilateral, Adenoma			1 (2%)	
Bilateral, Carcinoma	1 (2%)			
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Mesentery	1 (2%)			
Osteosarcoma, Metastatic, Bone				1 (2%)
Perirenal Tissue, Hemangioma				1 (2%)
Perirenal Tissue, Hemangiosarcoma				1 (2%)
Urinary Bladder	(50)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	2 (4%)	2 (4%)	2 (4%)	
Lymphoma Malignant	10 (20%)	6 (12%)	6 (12%)	5 (10%)

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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Species/Strain: MICE/B6C3F1

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	20 MG/KG	40 MG/KG	80 MG/KG
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	36	36	33	35
Total Primary Neoplasms	50	54	51	55
Total Animals with Benign Neoplasms	17	23	23	24
Total Benign Neoplasms	22	31	27	30
Total Animals with Malignant Neoplasms	26	20	22	19
Total Malignant Neoplasms	28	23	24	25
Total Animals with Metastatic Neoplasms	5	3	3	4
Total Metastatic Neoplasms	14	3	4	7
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