

TDMs No. 99007 - 06

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

Date Report Requested: 06/25/2008

Test Type: CHRONIC

Goldenseal root powder

Time Report Requested: 13:40:20

Route: DOSED FEED

CAS Number: GOLDENSEALRT

First Dose M/F: 05/12/03 / 05/12/03

Species/Strain: MICE/B6C3F1

Lab: SRI

C Number: C99007B
Lock Date: 08/29/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice		3	2	3
Natural Death	7	9	3	2
Survivors				
Natural Death		1		
Terminal Sacrifice	43	37	45	45
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Intestine Large, Cecum	(47)	(46)	(48)	(50)
Hemangiosarcoma			1 (2%)	
Intestine Small, Duodenum	(44)	(43)	(47)	(50)
Adenoma		2 (5%)		
Intestine Small, Jejunum	(46)	(43)	(47)	(48)
Carcinoma	1 (2%)	1 (2%)		
Carcinoma, Multiple	1 (2%)			
Liver	(50)	(50)	(50)	(50)
Chemodectoma Malignant, Metastatic, Uncertain Primary Site			1 (2%)	
Hemangiosarcoma		2 (4%)	2 (4%)	1 (2%)
Hemangiosarcoma, Metastatic, Spleen	1 (2%)	1 (2%)		1 (2%)
Hemangiosarcoma, Multiple				1 (2%)
Hepatoblastoma	1 (2%)	2 (4%)	1 (2%)	4 (8%)
Hepatoblastoma, Multiple				2 (4%)
Hepatocellular Adenoma	19 (38%)	11 (22%)	12 (24%)	11 (22%)
Hepatocellular Adenoma, Multiple	3 (6%)	5 (10%)	11 (22%)	18 (36%)
Hepatocellular Carcinoma	6 (12%)	10 (20%)	11 (22%)	10 (20%)
Hepatocellular Carcinoma, Multiple	2 (4%)	4 (8%)	4 (8%)	2 (4%)
Hepatocholangiocarcinoma	1 (2%)		1 (2%)	
Sarcoma, Metastatic, Pancreas			1 (2%)	
Mesentery	(6)	(3)	(12)	(1)
Hepatoblastoma, Metastatic, Liver				1 (100%)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (17%)		1 (8%)	

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

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Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Sarcoma, Metastatic, Pancreas			1 (8%)	
Pancreas	(49)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Sarcoma			1 (2%)	
Acinus, Adenoma	1 (2%)			
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Squamous Cell Papilloma		2 (4%)		
Stomach, Glandular	(50)	(50)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)		
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Capsule, Adenoma	1 (2%)	2 (4%)	1 (2%)	1 (2%)
Extra Adrenal Tissue, Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Extra Adrenal Tissue, Sarcoma, Metastatic, Pancreas			1 (2%)	
Adrenal Medulla	(50)	(50)	(50)	(49)
Pheochromocytoma Benign			1 (2%)	1 (2%)
Islets, Pancreatic	(49)	(50)	(50)	(50)
Parathyroid Gland	(45)	(45)	(47)	(49)
Pituitary Gland	(50)	(49)	(49)	(50)
Pars Intermedia, Adenoma				1 (2%)

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Species/Strain: MICE/B6C3F1

Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Thyroid Gland Follicular Cell, Adenoma	(50) 1 (2%)	(50)	(50) 1 (2%)	(50)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Coagulating Gland	(0)	(1)	(0)	(0)
Epididymis	(50)	(50)	(50)	(50)
Hepatocarcinoma, Metastatic, Liver	1 (2%)		1 (2%)	
Sarcoma, Metastatic, Pancreas			1 (2%)	
Preputial Gland	(50)	(50)	(50)	(50)
Prostate	(50)	(50)	(50)	(50)
Hepatocarcinoma, Metastatic, Liver			1 (2%)	
Seminal Vesicle	(50)	(50)	(50)	(50)
Hepatocarcinoma, Metastatic, Liver	1 (2%)			
Testes	(50)	(50)	(50)	(50)
Interstitial Cell, Adenoma			1 (2%)	
HEMATOPOIETIC SYSTEM				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Hemangiosarcoma, Metastatic, Spleen				1 (2%)
Lymph Node	(2)	(5)	(2)	(2)
Sarcoma, Metastatic, Pancreas			1 (50%)	
Bronchial, Hemangiosarcoma, Metastatic, Spleen		1 (20%)		
Inguinal, Hemangiosarcoma				1 (50%)
Mediastinal, Hepatocarcinoma, Metastatic, Liver	1 (50%)			
Renal, Hepatoblastoma, Metastatic, Liver		1 (20%)		
Lymph Node, Mandibular	(46)	(46)	(50)	(49)
Lymph Node, Mesenteric	(48)	(44)	(49)	(48)

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Lab: SRI

B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Hemangiosarcoma, Metastatic, Spleen		1 (2%)		
Hepatoblastoma, Metastatic, Liver		1 (2%)		
Spleen	(50)	(49)	(50)	(50)
Hemangioma		1 (2%)		
Hemangiosarcoma	1 (2%)	3 (6%)		1 (2%)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Thymus	(44)	(39)	(43)	(41)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
INTEGUMENTARY SYSTEM				
Skin	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Lipoma			1 (2%)	
Subcutaneous Tissue, Hemangioma		1 (2%)		
Subcutaneous Tissue, Sarcoma				1 (2%)
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(0)	(1)	(3)	(0)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (33%)	
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	5 (10%)	7 (14%)	8 (16%)
Alveolar/Bronchiolar Adenoma, Multiple			2 (4%)	
Alveolar/Bronchiolar Carcinoma	6 (12%)	4 (8%)	3 (6%)	
Alveolar/Bronchiolar Carcinoma, Multiple			1 (2%)	
Hemangiosarcoma, Metastatic, Spleen		1 (2%)		

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Hepatoblastoma, Metastatic, Liver		2 (4%)		1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	2 (4%)	3 (6%)	4 (8%)	2 (4%)
Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)		1 (2%)	
Sarcoma, Metastatic, Pancreas			1 (2%)	
Sarcoma, Metastatic, Skin				1 (2%)
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(50)	(50)
SPECIAL SENSES SYSTEM				
Eye	(46)	(50)	(49)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	7 (14%)	11 (22%)	3 (6%)	6 (12%)
Carcinoma	2 (4%)	3 (6%)	2 (4%)	2 (4%)
URINARY SYSTEM				
Kidney	(50)	(50)	(50)	(50)
Hepatoblastoma, Metastatic, Liver		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Capsule, Hepatocholangiocarcinoma, Metastatic, Liver	1 (2%)			
Urinary Bladder	(49)	(50)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		2 (4%)	2 (4%)	
Lymphoma Malignant	1 (2%)	2 (4%)	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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B6C3F1 MICE MALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
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Tumor Summary for Males

Total Animals with Primary Neoplasms (b)	38	42	43	40
Total Primary Neoplasms	60	74	70	72
Total Animals with Benign Neoplasms	28	27	33	36
Total Benign Neoplasms	37	40	40	47
Total Animals with Malignant Neoplasms	20	26	25	19
Total Malignant Neoplasms	23	34	30	25
Total Animals with Metastatic Neoplasms	4	6	6	5
Total Metastatic Neoplasms	11	14	22	7
Total Animals with Malignant Neoplasms Uncertain Primary Site			1	
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: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Disposition Summary				
Animals Initially in Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	4	2	2	3
Natural Death	1	4	12	4
Survivors				
Natural Death	1			
Terminal Sacrifice	44	44	36	43
Animals Examined Microscopically	50	50	50	50
ALIMENTARY SYSTEM				
Gallbladder	(48)	(46)	(39)	(47)
Intestine Large, Cecum	(48)	(46)	(41)	(47)
Intestine Large, Rectum	(48)	(47)	(43)	(47)
Leiomyosarcoma			1 (2%)	
Intestine Small, Ileum	(48)	(46)	(39)	(47)
Intestine Small, Jejunum	(48)	(46)	(43)	(48)
Liver	(50)	(50)	(49)	(50)
Hepatocellular Adenoma	3 (6%)	6 (12%)	6 (12%)	5 (10%)
Hepatocellular Adenoma, Multiple			1 (2%)	2 (4%)
Hepatocellular Carcinoma	3 (6%)	3 (6%)	1 (2%)	1 (2%)
Mesentery	(10)	(6)	(9)	(2)
Pancreas	(48)	(48)	(47)	(50)
Acinus, Adenoma			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(49)	(50)	(48)	(50)
Stomach, Glandular	(49)	(49)	(48)	(50)
CARDIOVASCULAR SYSTEM				
Heart	(50)	(50)	(50)	(50)
ENDOCRINE SYSTEM				
Adrenal Cortex	(50)	(50)	(48)	(50)

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Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Adenoma		1 (2%)		
Capsule, Adenoma		1 (2%)		1 (2%)
Adrenal Medulla	(50)	(50)	(49)	(50)
Pheochromocytoma Benign				1 (2%)
Islets, Pancreatic	(48)	(49)	(48)	(50)
Adenoma	1 (2%)	1 (2%)		
Parathyroid Gland	(45)	(44)	(48)	(47)
Pituitary Gland	(50)	(49)	(49)	(49)
Pars Distalis, Adenoma		2 (4%)	2 (4%)	1 (2%)
Pars Intermedia, Adenoma				1 (2%)
Thyroid Gland	(50)	(50)	(48)	(50)
Follicular Cell, Adenoma		2 (4%)		
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland	(50)	(50)	(49)	(50)
Ovary	(49)	(48)	(50)	(50)
Cystadenoma	3 (6%)	2 (4%)	1 (2%)	
Granulosa Cell Tumor Benign				1 (2%)
Uterus	(50)	(49)	(50)	(50)
Polyp Stromal	2 (4%)	1 (2%)		1 (2%)
HEMATOPOIETIC SYSTEM				
Bone Marrow	(49)	(50)	(50)	(50)
Hemangiosarcoma, Metastatic, Spleen	1 (2%)			
Lymph Node	(6)	(4)	(5)	(4)
Iliac, Sarcoma	1 (17%)			
Lymph Node, Mandibular	(50)	(49)	(48)	(49)
Lymph Node, Mesenteric	(48)	(43)	(48)	(49)
Spleen	(48)	(48)	(47)	(49)
Hemangiosarcoma	1 (2%)		1 (2%)	
Thymus	(49)	(48)	(50)	(48)

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Lab: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
INTEGUMENTARY SYSTEM				
Mammary Gland	(49)	(49)	(48)	(50)
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma		1 (2%)		
Sarcoma			1 (2%)	1 (2%)
Trichoepithelioma	1 (2%)			
Subcutaneous Tissue, Fibrosarcoma	1 (2%)			
Subcutaneous Tissue, Melanoma				1 (2%)
Malignant				
Subcutaneous Tissue, Sarcoma	2 (4%)	1 (2%)		
MUSCULOSKELETAL SYSTEM				
Bone	(50)	(50)	(50)	(50)
Skeletal Muscle	(1)	(1)	(2)	(0)
Rhabdomyosarcoma			1 (50%)	
Sarcoma	1 (100%)			
NERVOUS SYSTEM				
Brain	(50)	(50)	(50)	(50)
RESPIRATORY SYSTEM				
Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	4 (8%)	2 (4%)	5 (10%)	1 (2%)
Alveolar/Bronchiolar Carcinoma	1 (2%)	1 (2%)		1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	1 (2%)			
Sarcoma, Metastatic, Skeletal Muscle			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Trachea	(50)	(50)	(49)	(50)
SPECIAL SENSES SYSTEM				
Eye	(49)	(47)	(41)	(46)
Harderian Gland	(50)	(49)	(50)	(50)

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B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
Adenoma	4 (8%)	1 (2%)	1 (2%)	3 (6%)
Carcinoma	2 (4%)			2 (4%)
Bilateral, Adenoma	1 (2%)		1 (2%)	
URINARY SYSTEM				
Kidney	(50)	(49)	(50)	(50)
Urinary Bladder	(49)	(49)	(50)	(50)
SYSTEMIC LESIONS				
Multiple Organs	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		3 (6%)		1 (2%)
Lymphoma Malignant	6 (12%)	5 (10%)	1 (2%)	10 (20%)

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: SRI

B6C3F1 MICE FEMALE	0 PPM	3000 PPM	9000 PPM	25000 PPM
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Tumor Summary for Females

Total Animals with Primary Neoplasms (b)	26	28	17	25
Total Primary Neoplasms	37	33	24	34
Total Animals with Benign Neoplasms	17	17	13	14
Total Benign Neoplasms	19	19	18	17
Total Animals with Malignant Neoplasms	13	13	6	16
Total Malignant Neoplasms	18	14	6	17
Total Animals with Metastatic Neoplasms	2		1	
Total Metastatic Neoplasms	2		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