

**TDMS No.** 99032 - 04

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

**Date Report Requested:** 10/04/2011

**Test Type:** CHRONIC

Pyrogallol

**Time Report Requested:** 13:47:28

**Route:** SKIN APPLICATION

**CAS Number:** 87-66-1

**First Dose M/F:** 09/21/04 / 09/20/04

**Species/Strain:** MICE/B6C3F1

**Lab:** BAT

F2\_M3

**C Number:** C99032  
**Lock Date:** 03/04/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.4.2.1\_003  
**PWG Approval Date:** 08/24/2010

Test Type: CHRONIC

Pyrogallol

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Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/21/04 / 09/20/04

Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Accidentally Killed</b>				<b>1</b>
<b>Moribund Sacrifice</b>	<b>8</b>	<b>10</b>	<b>10</b>	<b>12</b>
<b>Natural Death</b>	<b>5</b>	<b>4</b>	<b>6</b>	<b>6</b>
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>37</b>	<b>36</b>	<b>34</b>	<b>31</b>
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(49)	(49)	(50)	(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)
Intestine Small, Ileum	(50)	(50)	(50)	(50)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			1 (2%)
Liver	(50)	(50)	(50)	(50)
Hemangioma			1 (2%)	
Hemangiosarcoma	3 (6%)	5 (10%)	2 (4%)	2 (4%)
Hemangiosarcoma, Metastatic, Spleen				1 (2%)
Hepatoblastoma	4 (8%)	1 (2%)	3 (6%)	3 (6%)
Hepatoblastoma, Multiple			1 (2%)	
Hepatocellular Adenoma	10 (20%)	17 (34%)	16 (32%)	12 (24%)
Hepatocellular Adenoma, Multiple	29 (58%)	19 (38%)	22 (44%)	22 (44%)
Hepatocellular Carcinoma	13 (26%)	15 (30%)	17 (34%)	15 (30%)
Hepatocellular Carcinoma, Multiple	7 (14%)	3 (6%)	3 (6%)	6 (12%)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Mesentery	(8)	(6)	(8)	(10)
Hepatoblastoma, Metastatic, Liver				1 (10%)

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

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Species/Strain: MICE/B6C3F1

Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (17%)		
Sarcoma	1 (13%)			
Sarcoma, Metastatic, Skin		1 (17%)		
Oral Mucosa	(0)	(0)	(0)	(1)
Pharyngeal, Squamous Cell Carcinoma				1 (100%)
Pancreas	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Plasma Cell Tumor Malignant, Metastatic, Lymph Node, Mesenteric		1 (2%)		
Salivary Glands	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Skin	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma		1 (2%)		
Squamous Cell Papilloma, Multiple	1 (2%)			
Stomach, Glandular	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Tooth	(36)	(30)	(24)	(22)
Odontoma	1 (3%)	3 (10%)	3 (13%)	1 (5%)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skin		1 (2%)		
Subcapsular, Adenoma	8 (16%)	7 (14%)	6 (12%)	2 (4%)
Subcapsular, Adenoma, Multiple	1 (2%)	1 (2%)		1 (2%)
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign				1 (2%)

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

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Carcinoma	1 (2%)	1 (2%)		
Parathyroid Gland	(41)	(44)	(42)	(47)
Pituitary Gland	(50)	(50)	(50)	(50)
Thyroid Gland	(50)	(50)	(50)	(50)
C-cell, Carcinoma		1 (2%)		
<b>GENERAL BODY SYSTEM</b>				
Peritoneum	(0)	(1)	(1)	(1)
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(0)	(2)	(1)	(0)
Carcinoma			1 (100%)	
Sarcoma, Metastatic, Skin		1 (50%)		
Epididymis	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skin		1 (2%)		
Penis	(1)	(0)	(0)	(0)
Preputial Gland	(50)	(50)	(50)	(50)
Hemangioma	1 (2%)			
Hemangiosarcoma	1 (2%)			
Squamous Cell Carcinoma		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skin		1 (2%)		
Seminal Vesicle	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Skin		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Hemangioma		1 (2%)		
Hemangiosarcoma		1 (2%)		
Interstitial Cell, Adenoma			1 (2%)	2 (4%)

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Lab: BAT

B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma		2 (4%)		
Hemangiosarcoma, Metastatic, Spleen		1 (2%)		1 (2%)
Mast Cell Tumor Malignant		1 (2%)		
Lymph Node	(10)	(12)	(9)	(16)
Axillary, Hemangiosarcoma		1 (8%)		
Bronchial, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (11%)	
Lumbar, Sarcoma, Metastatic, Skin		1 (8%)		
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Skin	1 (2%)			
Lymph Node, Mesenteric	(50)	(49)	(50)	(49)
Plasma Cell Tumor Malignant		1 (2%)		
Sarcoma, Metastatic, Skin		1 (2%)		
Spleen	(50)	(49)	(50)	(50)
Hemangiosarcoma	1 (2%)	2 (4%)		1 (2%)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Thymus	(48)	(50)	(46)	(48)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Mast Cell Tumor Malignant, Metastatic, Skin	1 (2%)			
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(0)	(0)	(0)	(1)
Skin	(50)	(50)	(50)	(50)
Basal Cell Carcinoma		1 (2%)		
Fibrous Histiocytoma		3 (6%)	1 (2%)	
Trichoepithelioma		1 (2%)		
Control, Mast Cell Tumor Malignant	1 (2%)			
Site Of Application, Hamartoma		1 (2%)		
Site Of Application, Squamous Cell Papilloma				2 (4%)

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B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Site Of Application, Subcutaneous Tissue, Hemangiosarcoma	1 (2%)			
Site Of Application, Subcutaneous Tissue, Lipoma				1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma	1 (2%)			
Subcutaneous Tissue, Sarcoma		1 (2%)		
Subcutaneous Tissue, Schwannoma Malignant			1 (2%)	

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)		
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Skeletal Muscle	(0)	(0)	(1)	(2)

## NERVOUS SYSTEM

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

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	10 (20%)	6 (12%)	8 (16%)	6 (12%)
Alveolar/Bronchiolar Adenoma, Multiple	2 (4%)	1 (2%)		
Alveolar/Bronchiolar Carcinoma	4 (8%)	7 (14%)	5 (10%)	8 (16%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)		
Hepatocellular Carcinoma, Metastatic, Liver	8 (16%)	7 (14%)	10 (20%)	5 (10%)
Sarcoma, Metastatic, Skin		1 (2%)		
Nose	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Trachea	(50)	(50)	(50)	(50)

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B6C3F1 MICE MALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	6 (12%)	3 (6%)	7 (14%)	6 (12%)
Adenoma, Multiple				1 (2%)
Carcinoma	2 (4%)	2 (4%)	1 (2%)	1 (2%)

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Mast Cell Tumor Malignant, Metastatic, Bone Marrow		1 (2%)		
Renal Tubule, Adenoma			1 (2%)	
Urethra	(0)	(1)	(1)	(1)
Urinary Bladder	(50)	(50)	(50)	(50)

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma	1 (2%)		2 (4%)	2 (4%)
Lymphoma Malignant	2 (4%)	3 (6%)	3 (6%)	3 (6%)

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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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	47	47	46	45
Total Primary Neoplasms	114	116	105	100
Total Animals with Benign Neoplasms	42	43	42	40
Total Benign Neoplasms	70	61	65	57
Total Animals with Malignant Neoplasms	33	32	27	33
Total Malignant Neoplasms	44	55	40	43
Total Animals with Metastatic Neoplasms	9	11	11	7
Total Metastatic Neoplasms	11	27	11	8
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

Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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**Disposition Summary**

Animals Initially In Study	50	50	50	50
Early Deaths				
Moribund Sacrifice	9	15	7	29
Natural Death	8	5	7	4
Survivors				
Natural Death				1
Terminal Sacrifice	33	30	36	16
Animals Examined Microscopically	50	50	50	50

ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Gallbladder	(50)	(49)	(49)	(50)
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Leiomyoma				1 (2%)
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)	(50)	(50)	(50)
Hemangiosarcoma				1 (2%)
Intestine Small, Jejunum	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)		1 (2%)	
Liver	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)	4 (8%)	2 (4%)	1 (2%)
Hepatoblastoma	1 (2%)	1 (2%)	1 (2%)	
Hepatocellular Adenoma	9 (18%)	12 (24%)	9 (18%)	8 (16%)
Hepatocellular Adenoma, Multiple	21 (42%)	23 (46%)	25 (50%)	7 (14%)
Hepatocellular Carcinoma	12 (24%)	13 (26%)	14 (28%)	7 (14%)
Hepatocellular Carcinoma, Multiple	5 (10%)	13 (26%)	6 (12%)	1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Serosa, Sarcoma, Metastatic, Mesentery		1 (2%)		
Mesentery	(20)	(22)	(14)	(19)
Sarcoma		1 (5%)		

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Sarcoma Stromal, Metastatic, Uterus		1 (5%)		
Pancreas	(50)	(50)	(50)	(50)
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Squamous Cell Papilloma	1 (2%)	3 (6%)		1 (2%)
Stomach, Glandular	(50)	(50)	(50)	(50)
Tooth	(3)	(0)	(4)	(0)

## CARDIOVASCULAR SYSTEM

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

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	2 (4%)	2 (4%)	1 (2%)	
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	3 (6%)		
Parathyroid Gland	(45)	(47)	(39)	(38)
Pituitary Gland	(50)	(49)	(50)	(50)
Pars Distalis, Adenoma	4 (8%)	6 (12%)	10 (20%)	2 (4%)
Thyroid Gland	(50)	(50)	(50)	(50)
Follicular Cell, Adenoma		2 (4%)		

## GENERAL BODY SYSTEM

Peritoneum	(1)	(0)	(0)	(0)
Tissue NOS	(1)	(0)	(0)	(0)
Mediastinum, Hemangiosarcoma	1 (100%)			

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<b>GENITAL SYSTEM</b>				
Clitoral Gland	(49)	(50)	(50)	(49)
Ovary	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Cystadenoma	2 (4%)		1 (2%)	1 (2%)
Granulosa Cell Tumor Benign	1 (2%)			
Hemangioma	1 (2%)		1 (2%)	
Hemangiosarcoma	1 (2%)	4 (8%)	1 (2%)	
Luteoma		1 (2%)		
Oviduct	(1)	(0)	(0)	(0)
Uterus	(50)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Hemangiosarcoma			1 (2%)	
Polyp Stromal	3 (6%)	2 (4%)	2 (4%)	1 (2%)
Sarcoma Stromal		2 (4%)		

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(50)	(50)	(50)	(50)
Hemangiosarcoma	3 (6%)		2 (4%)	
Lymph Node	(19)	(13)	(18)	(29)
Mediastinal, Hemangiosarcoma, Metastatic, Skin				1 (3%)
Lymph Node, Mandibular	(50)	(50)	(50)	(50)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Hemangiosarcoma		1 (2%)	1 (2%)	
Spleen	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)		2 (4%)	2 (4%)
Thymus	(50)	(50)	(48)	(49)

**INTEGUMENTARY SYSTEM**

Mammary Gland	(50)	(50)	(50)	(50)
Carcinoma		1 (2%)		1 (2%)

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Skin	(50)	(50)	(50)	(50)
Sarcoma			1 (2%)	
Squamous Cell Carcinoma				1 (2%)
Site Of Application, Carcinoma, Metastatic, Uncertain Primary Site				1 (2%)
Site Of Application, Hemangioma				1 (2%)
Site Of Application, Squamous Cell Carcinoma				4 (8%)
Site Of Application, Subcutaneous Tissue, Lipoma		1 (2%)		
Subcutaneous Tissue, Fibrosarcoma	1 (2%)		2 (4%)	
Subcutaneous Tissue, Hemangiosarcoma	1 (2%)	1 (2%)		1 (2%)
Subcutaneous Tissue, Sarcoma		1 (2%)		
Subcutaneous Tissue, Schwannoma Benign	1 (2%)			

## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Hemangiosarcoma	3 (6%)		3 (6%)	
Osteosarcoma			1 (2%)	
Skeletal Muscle	(4)	(1)	(2)	(0)
Hemangiosarcoma	1 (25%)			
Sarcoma Stromal, Metastatic, Uterus		1 (100%)		

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Peripheral Nerve	(2)	(0)	(0)	(0)
Spinal Cord	(2)	(0)	(0)	(0)
Hemangiosarcoma	1 (50%)			

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Adenoma	1 (2%)			
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)	2 (4%)	2 (4%)

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

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Lab: BAT

B6C3F1 MICE FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
Alveolar/Bronchiolar Carcinoma	2 (4%)	6 (12%)	4 (8%)	3 (6%)
Alveolar/Bronchiolar Carcinoma, Multiple		1 (2%)		
Carcinoma, Metastatic, Harderian Gland				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	4 (8%)	7 (14%)	2 (4%)	2 (4%)
Osteosarcoma, Metastatic, Uncertain Primary Site			1 (2%)	
Nose	(50)	(50)	(50)	(50)
Olfactory Epithelium, Neuroblastoma				1 (2%)
Trachea	(50)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Eye	(50)	(50)	(50)	(50)
Harderian Gland	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	4 (8%)	4 (8%)	5 (10%)
Carcinoma	2 (4%)	4 (8%)	4 (8%)	2 (4%)
Lacrimal Gland	(0)	(0)	(1)	(0)

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)			
Renal Tubule, Carcinoma			1 (2%)	
Urinary Bladder	(50)	(50)	(50)	(50)
Sarcoma Stromal, Metastatic, Uterus		1 (2%)		

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Histiocytic Sarcoma		8 (16%)	2 (4%)	3 (6%)
Lymphoma Malignant	13 (26%)	14 (28%)	12 (24%)	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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B6C3F1 MICE FEMALE	0 MG/KG	5 MG/KG	20 MG/KG	75 MG/KG
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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	42	48	47	33
Total Primary Neoplasms	102	136	116	62
Total Animals with Benign Neoplasms	34	38	38	22
Total Benign Neoplasms	50	60	55	29
Total Animals with Malignant Neoplasms	34	45	38	24
Total Malignant Neoplasms	52	76	61	33
Total Animals with Metastatic Neoplasms	4	9	3	5
Total Metastatic Neoplasms	4	11	4	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