

**TDMs No.** 20116 - 04

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

**Date Report Requested:** 01/15/2010

**Test Type:** CHRONIC

Aloe vera whole leaf extract (native)

**Time Report Requested:** 14:39:08

**Route:** DOSED WATER

**CAS Number:** ALOEVLEAFEXT

**First Dose M/F:** 04/19/05 / 04/19/05

**Species/Strain:** MICE/B6C3F1/NCTR

**Lab:** NCTR

**C Number:** C20116B  
**Lock Date:** 09/08/2009  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.2.0

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE      CONTROL WATER      ALOEWHOLLEAF 1.0      ALOEWHOLLEAF 2.0      ALOEWHOLLEAF 3.0

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>48</b>	<b>48</b>	<b>48</b>	<b>48</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>16</b>	<b>16</b>	<b>23</b>	<b>15</b>
<b>Natural Death</b>		<b>2</b>	<b>4</b>	<b>4</b>
<b>Survivors</b>				
<b>Natural Death</b>	<b>1</b>	<b>1</b>		<b>1</b>
<b>Terminal Sacrifice</b>	<b>31</b>	<b>28</b>	<b>21</b>	<b>28</b>
<b>Animals Examined Microscopically</b>	<b>48</b>	<b>47</b>	<b>48</b>	<b>48</b>

ALIMENTARY SYSTEM

Esophagus	(48)	(46)	(47)	(47)
Hepatoblastoma, Metastatic, Liver		1 (2%)		
Gallbladder	(46)	(43)	(45)	(43)
Intestine Large, Ascending Colon	(47)	(44)	(45)	(42)
Intestine Large, Cecum	(47)	(44)	(44)	(43)
Intestine Large, Descending Colon	(47)	(44)	(45)	(43)
Intestine Large, Transverse Colon	(47)	(44)	(45)	(43)
Intestine Small, Duodenum	(47)	(44)	(44)	(44)
Fibrous Histiocytoma				1 (2%)
Intestine Small, Ileum	(47)	(44)	(45)	(43)
Intestine Small, Jejunum	(47)	(44)	(43)	(43)
Carcinoma		1 (2%)		
Liver	(47)	(46)	(47)	(46)
Cholangiocarcinoma			1 (2%)	1 (2%)
Fibrous Histiocytoma				1 (2%)
Hemangiosarcoma	3 (6%)			2 (4%)
Hepatoblastoma		1 (2%)		
Hepatocellular Adenoma	3 (6%)	6 (13%)	4 (9%)	2 (4%)
Hepatocellular Adenoma, Multiple	3 (6%)			
Hepatocellular Carcinoma	8 (17%)	13 (28%)	8 (17%)	9 (20%)
Hepatocellular Carcinoma, Multiple	1 (2%)			1 (2%)
Hepatoblastoma		1 (2%)	1 (2%)	
Mesentery	(0)	(4)	(2)	(4)

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

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE                      CONTROL WATER    ALOEWHOLLEAF 1.0    ALOEWHOLLEAF 2.0    ALOEWHOLLEAF 3.0

Fibrous Histiocytoma				1 (25%)
Pancreas	(47)	(46)	(47)	(45)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Fibrous Histiocytoma				1 (2%)
Hepatocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Salivary Glands	(48)	(45)	(46)	(45)
Stomach, Forestomach	(47)	(45)	(45)	(44)
Squamous Cell Carcinoma				1 (2%)
Squamous Cell Papilloma		1 (2%)		2 (5%)
Stomach, Glandular	(47)	(44)	(45)	(45)
Fibrous Histiocytoma				1 (2%)
Serosa, Hepatocarcinoma, Metastatic, Liver			1 (2%)	

CARDIOVASCULAR SYSTEM

Blood Vessel	(48)	(47)	(47)	(47)
Hepatocarcinoma, Metastatic, Liver		1 (2%)		
Heart	(48)	(47)	(47)	(47)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (2%)	
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Fibrosarcoma, Metastatic, Skin				1 (2%)
Hepatocarcinoma, Metastatic, Liver		1 (2%)		

ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(44)	(46)	(45)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Fibrous Histiocytoma				1 (2%)
Hepatocarcinoma, Metastatic, Liver		1 (2%)		
Subcapsular, Adenoma	1 (2%)	3 (7%)	2 (4%)	
Adrenal Medulla	(47)	(44)	(46)	(44)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Pheochromocytoma Benign			3 (7%)	1 (2%)

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Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
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Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(47)	(46)	(46)	(45)
Parathyroid Gland	(44)	(46)	(42)	(41)
Pituitary Gland	(48)	(45)	(45)	(45)
Thyroid Gland	(47)	(46)	(47)	(45)
Follicular Cell, Adenoma			1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	

## GENERAL BODY SYSTEM

Tissue NOS	(1)	(1)	(3)	(0)
Cholangiocarcinoma, Metastatic, Liver			1 (33%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (33%)	
Mediastinum, Fibrosarcoma, Metastatic, Skin	1 (100%)			
Mediastinum, Hepatocholangiocarcinoma, Metastatic, Liver		1 (100%)		

## GENITAL SYSTEM

Coagulating Gland	(1)	(1)	(0)	(0)
Epididymis	(48)	(44)	(46)	(45)
Fibrous Histiocytoma				1 (2%)
Hemangioma			1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Penis	(0)	(1)	(0)	(0)
Preputial Gland	(47)	(44)	(46)	(45)
Fibrosarcoma	1 (2%)			
Fibrous Histiocytoma	1 (2%)			
Prostate	(47)	(44)	(46)	(44)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Seminal Vesicle	(48)	(44)	(47)	(44)
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Testes	(47)	(44)	(45)	(44)
Hemangioma				1 (2%)

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Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
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## HEMATOPOIETIC SYSTEM

Bone Marrow	(47)	(45)	(47)	(45)
Lymph Node	(11)	(5)	(9)	(7)
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung	1 (9%)			
Mediastinal, Fibrous Histiocytoma				1 (14%)
Renal, Fibrosarcoma, Metastatic, Skin	1 (9%)			
Lymph Node, Mandibular	(47)	(44)	(45)	(44)
Lymph Node, Mesenteric	(48)	(45)	(45)	(43)
Hemangiosarcoma	1 (2%)		1 (2%)	
Spleen	(48)	(45)	(46)	(44)
Fibrous Histiocytoma				1 (2%)
Hemangiosarcoma		1 (2%)		
Thymus	(41)	(39)	(37)	(40)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (3%)	1 (3%)	

## INTEGUMENTARY SYSTEM

Skin	(48)	(47)	(46)	(48)
Carcinoma				1 (2%)
Fibroma	3 (6%)		2 (4%)	1 (2%)
Fibrosarcoma	11 (23%)	10 (21%)	13 (28%)	9 (19%)
Fibrous Histiocytoma	2 (4%)			1 (2%)
Hemangioma	1 (2%)			
Hemangiosarcoma		1 (2%)		
Melanoma Malignant			1 (2%)	
Neoplasm Nos			1 (2%)	
Sarcoma			1 (2%)	1 (2%)
Schwannoma Malignant	1 (2%)	2 (4%)	3 (7%)	1 (2%)
Squamous Cell Papilloma				2 (4%)

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
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## MUSCULOSKELETAL SYSTEM

Skeletal Muscle	(1)	(1)	(3)	(0)
Cholangiocarcinoma, Metastatic, Liver			1 (33%)	
Hepatocarcinoma, Metastatic, Liver		1 (100%)	1 (33%)	
Intercostal, Fibrosarcoma, Metastatic, Skin	1 (100%)			

## NERVOUS SYSTEM

Brain, Cerebrum	(47)	(46)	(46)	(43)
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## RESPIRATORY SYSTEM

Lung	(48)	(47)	(46)	(47)
Alveolar/Bronchiolar Adenoma	3 (6%)	1 (2%)	4 (9%)	3 (6%)
Alveolar/Bronchiolar Carcinoma	3 (6%)	1 (2%)	3 (7%)	1 (2%)
Carcinoma, Metastatic, Skin				1 (2%)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Fibrosarcoma, Metastatic, Skin	1 (2%)		1 (2%)	1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver		3 (6%)		
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	1 (2%)	
Nose	(48)	(47)	(47)	(47)
Trachea	(48)	(47)	(46)	(45)

## SPECIAL SENSES SYSTEM

Eye	(47)	(43)	(44)	(43)
Harderian Gland	(48)	(44)	(46)	(44)
Adenoma	3 (6%)	2 (5%)	2 (4%)	2 (5%)
Carcinoma	1 (2%)			

## URINARY SYSTEM

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Kidney	(48)	(45)	(46)	(45)
Cholangiocarcinoma, Metastatic, Liver			1 (2%)	
Fibrous Histiocytoma				1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		
Capsule, Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)	
Renal Tubule, Carcinoma				1 (2%)
Transitional Epithelium, Carcinoma				1 (2%)
Urethra	(1)	(0)	(0)	(1)
Urinary Bladder	(48)	(45)	(45)	(44)

SYSTEMIC LESIONS

Multiple Organ	*(48)	*(47)	*(48)	*(48)
Histiocytic Sarcoma			1 (2%)	1 (2%)
Lymphoma Malignant	4 (8%)	6 (13%)	5 (10%)	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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Lab: NCTR

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE                      CONTROL WATER    ALOEWHOLLEAF 1.0    ALOEWHOLLEAF 2.0    ALOEWHOLLEAF 3.0

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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	39	33	40	33
Total Primary Neoplasms	54	50	59	58
Total Animals with Benign Neoplasms	15	11	16	12
Total Benign Neoplasms	17	13	19	14
Total Animals with Malignant Neoplasms	30	28	32	27
Total Malignant Neoplasms	37	37	39	44
Total Animals with Metastatic Neoplasms	2	4	4	2
Total Metastatic Neoplasms	5	15	20	3
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant			1	
Total Uncertain Neoplasms			1	

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\*\*\* END OF MALE \*\*\*

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b - Primary tumors: all tumors except metastatic tumors



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Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE      CONTROL WATER      ALOEWHOLLEAF 1.0      ALOEWHOLLEAF 2.0      ALOEWHOLLEAF 3.0

**Disposition Summary**

<b>Animals Initially In Study</b>	<b>48</b>	<b>48</b>	<b>48</b>	<b>48</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>6</b>	<b>12</b>	<b>8</b>	<b>6</b>
<b>Natural Death</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>5</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>	<b>1</b>	<b>1</b>		<b>1</b>
<b>Natural Death</b>		<b>1</b>	<b>1</b>	<b>2</b>
<b>Terminal Sacrifice</b>	<b>35</b>	<b>30</b>	<b>36</b>	<b>34</b>
<b>Animals Examined Microscopically</b>	<b>47</b>	<b>48</b>	<b>48</b>	<b>48</b>

**ALIMENTARY SYSTEM**

Gallbladder	(42)	(43)	(44)	(41)
Intestine Large, Ascending Colon	(43)	(43)	(44)	(43)
Intestine Large, Cecum	(42)	(43)	(44)	(42)
Intestine Large, Descending Colon	(43)	(43)	(44)	(43)
Intestine Large, Rectum	(43)	(43)	(44)	(42)
Fibrosarcoma, Metastatic, Skin	1 (2%)			
Intestine Large, Transverse Colon	(42)	(42)	(44)	(43)
Intestine Small, Duodenum	(43)	(43)	(44)	(42)
Adenoma	2 (5%)	2 (5%)	1 (2%)	1 (2%)
Intestine Small, Ileum	(42)	(43)	(44)	(42)
Intestine Small, Jejunum	(42)	(43)	(44)	(42)
Liver	(45)	(44)	(46)	(46)
Hemangiosarcoma				1 (2%)
Hepatocellular Adenoma	2 (4%)	5 (11%)	1 (2%)	4 (9%)
Hepatocellular Carcinoma	3 (7%)	5 (11%)		2 (4%)
Hepatocholangiocarcinoma		1 (2%)		
Osteosarcoma, Metastatic, Bone, Femur			1 (2%)	1 (2%)
Mesentery	(6)	(8)	(9)	(3)
Osteosarcoma, Metastatic, Bone, Femur			1 (11%)	
Oral Mucosa	(1)	(0)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)			
Pancreas	(42)	(43)	(44)	(43)

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
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Salivary Glands	(43)	(43)	(44)	(43)
Stomach, Forestomach	(43)	(44)	(45)	(42)
Squamous Cell Papilloma		2 (5%)	2 (4%)	3 (7%)
Stomach, Glandular	(43)	(44)	(45)	(42)

## CARDIOVASCULAR SYSTEM

Heart	(45)	(46)	(46)	(44)
Osteosarcoma, Metastatic, Bone, Femur			1 (2%)	

## ENDOCRINE SYSTEM

Adrenal Cortex	(44)	(43)	(44)	(44)
Adrenal Medulla	(44)	(42)	(44)	(44)
Pheochromocytoma Benign				1 (2%)
Islets, Pancreatic	(42)	(43)	(44)	(43)
Parathyroid Gland	(42)	(37)	(42)	(40)
Pituitary Gland	(43)	(38)	(41)	(44)
Pars Distalis, Adenoma	14 (33%)	10 (26%)	6 (15%)	3 (7%)
Pars Intermedia, Adenoma	1 (2%)			
Thyroid Gland	(43)	(43)	(44)	(43)
Follicular Cell, Adenoma		1 (2%)		

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(44)	(44)	(44)	(42)
Ovary	(44)	(46)	(45)	(44)
Cystadenoma			1 (2%)	
Granulosa Cell Tumor Benign		1 (2%)	1 (2%)	1 (2%)

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
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Luteoma			1 (2%)	
Uterus	(46)	(45)	(44)	(45)
Hemangioma		1 (2%)	1 (2%)	
Hemangiosarcoma	1 (2%)			
Leiomyosarcoma			1 (2%)	
Polyp Stromal	1 (2%)	1 (2%)	5 (11%)	1 (2%)
Sarcoma	2 (4%)			

## HEMATOPOIETIC SYSTEM

Bone Marrow	(43)	(43)	(44)	(43)
Hemangiosarcoma				1 (2%)
Lymph Node	(14)	(15)	(12)	(13)
Inguinal, Osteosarcoma, Metastatic, Bone, Femur			1 (8%)	
Mediastinal, Fibrosarcoma, Metastatic, Skin		1 (7%)		
Mediastinal, Hepatocholangiocarcinoma, Metastatic, Liver		1 (7%)		
Lymph Node, Mandibular	(43)	(44)	(45)	(43)
Sarcoma, Metastatic, Skin	1 (2%)			
Lymph Node, Mesenteric	(43)	(45)	(43)	(42)
Fibrous Histiocytoma, Metastatic, Skin			1 (2%)	
Spleen	(44)	(46)	(45)	(44)
Hemangiosarcoma	3 (7%)	1 (2%)		1 (2%)
Thymus	(41)	(44)	(43)	(41)
Osteosarcoma, Metastatic, Bone, Femur			1 (2%)	

## INTEGUMENTARY SYSTEM

Mammary Gland	(44)	(43)	(44)	(44)
Adenocarcinoma	5 (11%)	3 (7%)	2 (5%)	4 (9%)
Carcinosarcoma				1 (2%)
Skin	(44)	(46)	(45)	(44)
Fibroma		1 (2%)		
Fibrosarcoma	2 (5%)	2 (4%)	2 (4%)	2 (5%)

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Fibrous Histiocytoma		1 (2%)	1 (2%)	
Hemangioma	1 (2%)			
Hemangiosarcoma				1 (2%)
Melanoma Benign	1 (2%)			1 (2%)
Sarcoma	3 (7%)			1 (2%)

## MUSCULOSKELETAL SYSTEM

Bone, Femur	(47)	(46)	(48)	(46)
Osteosarcoma			1 (2%)	1 (2%)
Skeletal Muscle	(0)	(2)	(2)	(0)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung			1 (50%)	
Hepatocholangiocarcinoma, Metastatic, Liver		1 (50%)		

## NERVOUS SYSTEM

Brain, Brain Stem	(43)	(44)	(44)	(43)
Brain, Cerebellum	(43)	(44)	(44)	(43)
Brain, Cerebrum	(43)	(44)	(44)	(43)

## RESPIRATORY SYSTEM

Lung	(45)	(45)	(46)	(44)
Adenocarcinoma, Metastatic, Mammary Gland	1 (2%)			
Alveolar/Bronchiolar Adenoma	3 (7%)	2 (4%)	1 (2%)	1 (2%)
Alveolar/Bronchiolar Adenoma, Multiple		1 (2%)		
Alveolar/Bronchiolar Carcinoma		3 (7%)	2 (4%)	3 (7%)
Fibrosarcoma, Metastatic, Skin		1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)		
Osteosarcoma, Metastatic, Bone, Femur			1 (2%)	1 (2%)
Sarcoma	1 (2%)			
Sarcoma, Metastatic, Skin	1 (2%)			
Nose	(45)	(44)	(45)	(45)

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## SPECIAL SENSES SYSTEM

Eye	(42)	(43)	(44)	(42)
Harderian Gland	(43)	(43)	(44)	(43)
Adenoma	3 (7%)	2 (5%)	2 (5%)	3 (7%)
Carcinoma	2 (5%)			
Bilateral, Adenoma		1 (2%)		
Lacrimal Gland	(1)	(0)	(0)	(0)

## URINARY SYSTEM

Kidney	(44)	(43)	(46)	(44)
Osteosarcoma, Metastatic, Bone, Femur			1 (2%)	
Urinary Bladder	(43)	(43)	(44)	(42)

## SYSTEMIC LESIONS

Multiple Organ	*(47)	*(48)	*(48)	*(48)
Histiocytic Sarcoma	3 (6%)	1 (2%)	1 (2%)	1 (2%)
Leukemia			1 (2%)	2 (4%)
Lymphoma Malignant	18 (38%)	20 (42%)	18 (38%)	8 (17%)

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

\* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

Aloe vera whole leaf extract (native)

Time Report Requested: 14:39:08

Route: DOSED WATER

CAS Number: ALOEVLEAFEXT

First Dose M/F: 04/19/05 / 04/19/05

Species/Strain: MICE/B6C3F1/NCTR

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE

CONTROL WATER

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 2.0

ALOEWHOLLEAF 3.0

**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	41	40	35	32
Total Primary Neoplasms	72	67	51	48
Total Animals with Benign Neoplasms	23	19	18	16
Total Benign Neoplasms	28	30	22	19
Total Animals with Malignant Neoplasms	37	33	28	23
Total Malignant Neoplasms	44	37	29	29
Total Animals with Metastatic Neoplasms	4	2	3	1
Total Metastatic Neoplasms	4	5	9	2
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