

**TDMS No.** 20116 - 03

**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:** 14:39:01

**Route:** DOSED WATER

**CAS Number:** ALOEVLEAFEXT

**First Dose M/F:** 04/17/05 / 04/17/05

**Species/Strain:** RATS/F 344/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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FISCHER 344 RATS-NCTR RATS MALE                      CONTROL WATER    ALOEWHOLLEAF 0.5    ALOEWHOLLEAF 1.0    ALOEWHOLLEAF 1.5

**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>28</b>	<b>26</b>	<b>23</b>	<b>26</b>
<b>Natural Death</b>	<b>2</b>	<b>5</b>	<b>2</b>	<b>4</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>	<b>3</b>		<b>4</b>	<b>3</b>
<b>Terminal Sacrifice</b>	<b>15</b>	<b>17</b>	<b>19</b>	<b>15</b>
<b>Animals Examined Microscopically</b>	<b>48</b>	<b>48</b>	<b>48</b>	<b>48</b>

ALIMENTARY SYSTEM

Esophagus	(48)	(48)	(48)	(48)
Intestine Large, Ascending Colon	(47)	(47)	(48)	(46)
Adenoma			19 (40%)	8 (17%)
Carcinoma			4 (8%)	8 (17%)
Leiomyoma			1 (2%)	
Intestine Large, Cecum	(46)	(45)	(48)	(48)
Adenoma			8 (17%)	7 (15%)
Adenoma, Multiple				1 (2%)
Carcinoma			1 (2%)	2 (4%)
Leiomyosarcoma				1 (2%)
Intestine Large, Colon	(0)	(1)	(3)	(5)
Adenoma			1 (33%)	2 (40%)
Carcinoma			1 (33%)	
Intestine Large, Descending Colon	(47)	(46)	(46)	(47)
Carcinoma			1 (2%)	
Intestine Large, Rectum	(47)	(47)	(48)	(48)
Intestine Large, Transverse Colon	(47)	(47)	(47)	(47)
Adenoma			6 (13%)	3 (6%)
Carcinoma			1 (2%)	1 (2%)
Intestine Small	(0)	(1)	(0)	(0)
Intestine Small, Duodenum	(48)	(46)	(48)	(48)
Intestine Small, Ileum	(45)	(45)	(48)	(48)
Intestine Small, Jejunum	(45)	(44)	(46)	(46)

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

Test Type: CHRONIC

Aloe vera whole leaf extract (native)

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First Dose M/F: 04/17/05 / 04/17/05

Species/Strain: RATS/F 344/NCTR

Lab: NCTR

FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Carcinoma		1 (2%)		
Liver	(48)	(48)	(48)	(48)
Cholangiocarcinoma		1 (2%)		
Hepatocellular Adenoma	5 (10%)	1 (2%)		
Hepatocellular Carcinoma	3 (6%)			1 (2%)
Mesentery	(10)	(10)	(4)	(5)
Oral Mucosa	(2)	(1)	(2)	(1)
Sarcoma			1 (50%)	
Squamous Cell Papilloma		1 (100%)	1 (50%)	1 (100%)
Pancreas	(48)	(48)	(48)	(48)
Mixed Tumor Benign		1 (2%)		
Acinar Cell, Adenoma		1 (2%)		1 (2%)
Proximal Colon	(44)	(44)	(46)	(41)
Adenoma			7 (15%)	10 (24%)
Carcinoma			4 (9%)	4 (10%)
Salivary Glands	(48)	(48)	(48)	(48)
Sublingual Gland, Adenoma		1 (2%)		
Stomach, Forestomach	(48)	(47)	(48)	(48)
Squamous Cell Papilloma		1 (2%)		
Stomach, Glandular	(48)	(47)	(48)	(48)

CARDIOVASCULAR SYSTEM

Blood Vessel	(48)	(48)	(48)	(48)
Heart	(48)	(48)	(48)	(48)
Schwannoma Malignant	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Pericardium, Osteosarcoma, Metastatic, Bone		1 (2%)		

ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(48)	(48)	(48)
Adenoma		1 (2%)	1 (2%)	
Adrenal Medulla	(48)	(47)	(48)	(48)
Pheochromocytoma Benign	1 (2%)		1 (2%)	4 (8%)
Pheochromocytoma Malignant	3 (6%)	10 (21%)	14 (29%)	7 (15%)

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

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Species/Strain: RATS/F 344/NCTR

Lab: NCTR

FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Bilateral, Pheochromocytoma Benign	2 (4%)		1 (2%)	
Bilateral, Pheochromocytoma Malignant	4 (8%)	2 (4%)	1 (2%)	1 (2%)
Islets, Pancreatic	(48)	(48)	(48)	(48)
Adenoma	3 (6%)	4 (8%)	5 (10%)	4 (8%)
Parathyroid Gland	(47)	(48)	(46)	(48)
Adenoma	1 (2%)	1 (2%)		1 (2%)
Pituitary Gland	(48)	(48)	(47)	(48)
Pars Distalis, Adenoma	30 (63%)	30 (63%)	27 (57%)	22 (46%)
Thyroid Gland	(48)	(47)	(48)	(48)
Bilateral, C-cell, Adenoma				1 (2%)
C-cell, Adenoma	2 (4%)	7 (15%)	3 (6%)	2 (4%)
C-cell, Carcinoma	1 (2%)	1 (2%)	3 (6%)	
Follicular Cell, Adenoma	2 (4%)	1 (2%)	1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	

## GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(1)	(2)
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## GENITAL SYSTEM

Epididymis	(48)	(48)	(48)	(48)
Preputial Gland	(48)	(48)	(48)	(48)
Adenoma	5 (10%)	4 (8%)	2 (4%)	1 (2%)
Carcinoma	2 (4%)		3 (6%)	1 (2%)
Squamous Cell Carcinoma	4 (8%)	2 (4%)		1 (2%)
Squamous Cell Papilloma		1 (2%)	3 (6%)	
Prostate	(48)	(48)	(48)	(48)
Seminal Vesicle	(48)	(48)	(48)	(48)
Testes	(48)	(48)	(48)	(48)
Bilateral, Interstitial Cell, Adenoma	27 (56%)	25 (52%)	28 (58%)	23 (48%)
Interstitial Cell, Adenoma	10 (21%)	14 (29%)	7 (15%)	11 (23%)

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Species/Strain: RATS/F 344/NCTR

Lab: NCTR

FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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## HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(48)	(48)	(48)
Lymph Node	(24)	(13)	(19)	(17)
Cervical, Carcinoma, Metastatic, Thyroid Gland			1 (5%)	
Lymph Node, Mandibular	(48)	(48)	(48)	(48)
Lymph Node, Mesenteric	(47)	(48)	(48)	(48)
Spleen	(48)	(48)	(48)	(48)
Hemangiosarcoma		1 (2%)		
Thymus	(46)	(47)	(44)	(44)

## INTEGUMENTARY SYSTEM

Mammary Gland	(44)	(46)	(48)	(41)
Adenocarcinoma		1 (2%)	1 (2%)	
Fibroadenoma	1 (2%)	4 (9%)	3 (6%)	1 (2%)
Skin	(48)	(48)	(48)	(48)
Basal Cell Carcinoma		1 (2%)		
Fibroma	4 (8%)	1 (2%)	3 (6%)	1 (2%)
Granular Cell Tumor Benign	1 (2%)			
Hemangiosarcoma			1 (2%)	
Keratoacanthoma	1 (2%)	1 (2%)	1 (2%)	2 (4%)
Lipoma	1 (2%)		1 (2%)	
Sarcoma				2 (4%)
Sebaceous Gland, Adenoma		1 (2%)		
Subcutaneous Tissue, Fibroma		1 (2%)		
Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Sarcoma			1 (2%)	

## MUSCULOSKELETAL SYSTEM

Bone	(0)	(2)	(2)	(1)
Chondrosarcoma			1 (50%)	
Osteoma		1 (50%)		

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Rib, Osteosarcoma		1 (50%)		
Bone, Femur	(48)	(48)	(48)	(48)
Skeletal Muscle	(2)	(2)	(0)	(2)

## NERVOUS SYSTEM

Brain	(0)	(0)	(1)	(0)
Meninges, Meningioma Malignant			1 (100%)	
Brain, Brain Stem	(48)	(48)	(48)	(48)
Brain, Cerebellum	(48)	(48)	(48)	(48)
Brain, Cerebrum	(48)	(48)	(48)	(48)
Granular Cell Tumor Benign	1 (2%)			
Spinal Cord	(1)	(1)	(0)	(3)
Astrocytoma Malignant				1 (33%)

## RESPIRATORY SYSTEM

Lung	(48)	(48)	(48)	(48)
Alveolar/Bronchiolar Adenoma		5 (10%)		1 (2%)
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Chondrosarcoma, Metastatic, Bone			1 (2%)	
Osteosarcoma, Metastatic, Bone		1 (2%)		
Sarcoma, Metastatic, Skin				1 (2%)
Nose	(48)	(48)	(47)	(48)
Sarcoma, Metastatic, Oral Mucosa			1 (2%)	
Trachea	(48)	(48)	(48)	(48)

## SPECIAL SENSES SYSTEM

Eye	(47)	(46)	(47)	(48)
Harderian Gland	(48)	(48)	(48)	(48)
Lacrimal Gland	(0)	(1)	(0)	(0)
Squamous Cell Carcinoma, Metastatic, Zymbal'S Gland		1 (100%)		

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Zymbal's Gland	(0)	(2)	(1)	(0)
Carcinoma			1 (100%)	
Squamous Cell Carcinoma		2 (100%)		

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URINARY SYSTEM

Kidney	(48)	(48)	(48)	(48)
Renal Tubule, Adenoma	1 (2%)			1 (2%)
Urinary Bladder	(48)	(48)	(48)	(48)
Transitional Epithelium, Papilloma	1 (2%)	1 (2%)		

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SYSTEMIC LESIONS

Multiple Organ	*(48)	*(48)	*(48)	*(48)
Histiocytic Sarcoma	1 (2%)	1 (2%)		
Leukemia Mononuclear	27 (56%)	21 (44%)	24 (50%)	24 (50%)
Mesothelioma Malignant		3 (6%)	1 (2%)	2 (4%)

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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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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	48	48	48	46
Total Primary Neoplasms	145	159	199	166
Total Animals with Benign Neoplasms	47	47	46	44
Total Benign Neoplasms	99	109	131	108
Total Animals with Malignant Neoplasms	35	35	39	35
Total Malignant Neoplasms	46	50	68	58
Total Animals with Metastatic Neoplasms		2	3	1
Total Metastatic Neoplasms		3	4	1
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant				
Total Uncertain Neoplasms				

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\*\*\* 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



Test Type: CHRONIC

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Species/Strain: RATS/F 344/NCTR

Lab: NCTR

FISCHER 344 RATS-NCTR RATS FEMALE

CONTROL WATER

ALOEWHOLLEAF 0.5

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 1.5

**Disposition Summary**

	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
<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>15</b>	<b>15</b>	<b>17</b>	<b>20</b>
<b>Natural Death</b>	<b>2</b>		<b>4</b>	<b>5</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>	<b>1</b>	<b>2</b>	<b>2</b>	<b>2</b>
<b>Natural Death</b>			<b>1</b>	<b>1</b>
<b>Terminal Sacrifice</b>	<b>30</b>	<b>31</b>	<b>24</b>	<b>20</b>
<b>Animals Examined Microscopically</b>	<b>48</b>	<b>48</b>	<b>48</b>	<b>48</b>

## ALIMENTARY SYSTEM

	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Esophagus	(48)	(47)	(48)	(48)
Intestine Large, Ascending Colon	(47)	(48)	(46)	(46)
Adenoma			1 (2%)	5 (11%)
Carcinoma			1 (2%)	1 (2%)
Intestine Large, Cecum	(47)	(48)	(47)	(48)
Adenoma			1 (2%)	5 (10%)
Adenoma, Multiple				1 (2%)
Lipoma		1 (2%)		
Intestine Large, Colon	(0)	(0)	(2)	(1)
Adenoma				1 (100%)
Intestine Large, Descending Colon	(47)	(48)	(46)	(47)
Intestine Large, Rectum	(48)	(48)	(47)	(47)
Intestine Large, Transverse Colon	(47)	(48)	(46)	(46)
Carcinoma				1 (2%)
Leiomyosarcoma				1 (2%)
Intestine Small, Duodenum	(48)	(48)	(48)	(48)
Leiomyoma			1 (2%)	
Intestine Small, Ileum	(47)	(48)	(43)	(44)
Leiomyosarcoma			1 (2%)	
Intestine Small, Jejunum	(47)	(48)	(45)	(43)
Liver	(48)	(48)	(48)	(48)
Hepatocellular Adenoma	1 (2%)			

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

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Species/Strain: RATS/F 344/NCTR

Lab: NCTR

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Mesentery	(6)	(9)	(10)	(4)
Oral Mucosa	(0)	(1)	(1)	(0)
Squamous Cell Carcinoma			1 (100%)	
Squamous Cell Papilloma		1 (100%)		
Pancreas	(48)	(48)	(48)	(48)
Proximal Colon	(43)	(45)	(42)	(39)
Adenoma			4 (10%)	5 (13%)
Carcinoma			2 (5%)	4 (10%)
Salivary Glands	(48)	(48)	(48)	(48)
Stomach, Forestomach	(48)	(48)	(48)	(48)
Squamous Cell Papilloma	1 (2%)			1 (2%)
Stomach, Glandular	(48)	(48)	(48)	(48)

## CARDIOVASCULAR SYSTEM

Heart	(48)	(48)	(48)	(48)
Schwannoma Malignant	1 (2%)			

## ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(48)	(48)	(48)
Adenoma		1 (2%)		1 (2%)
Adrenal Medulla	(47)	(46)	(48)	(47)
Pheochromocytoma Malignant			2 (4%)	
Bilateral, Pheochromocytoma Malignant				1 (2%)
Islets, Pancreatic	(48)	(48)	(47)	(48)
Parathyroid Gland	(47)	(45)	(46)	(47)
Adenoma			1 (2%)	1 (2%)
Pituitary Gland	(48)	(48)	(48)	(47)
Pars Distalis, Adenoma	32 (67%)	35 (73%)	30 (63%)	18 (38%)
Pars Distalis, Carcinoma	1 (2%)	1 (2%)		
Thyroid Gland	(48)	(48)	(48)	(47)
Bilateral, C-cell, Carcinoma			1 (2%)	
C-cell, Adenoma	5 (10%)	3 (6%)	1 (2%)	3 (6%)
C-cell, Carcinoma	1 (2%)	1 (2%)	3 (6%)	

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FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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## GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(2)	(0)
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## GENITAL SYSTEM

Clitoral Gland	(48)	(48)	(48)	(48)
Adenoma	5 (10%)	8 (17%)	3 (6%)	3 (6%)
Adenoma, Multiple		1 (2%)		
Carcinoma	3 (6%)	4 (8%)	1 (2%)	2 (4%)
Ovary	(48)	(48)	(48)	(48)
Uterus	(48)	(48)	(48)	(48)
Leiomyoma				1 (2%)
Leiomyosarcoma	1 (2%)			
Polyp Stromal	11 (23%)	13 (27%)	12 (25%)	8 (17%)
Endometrium, Adenocarcinoma			1 (2%)	1 (2%)
Vagina	(4)	(3)	(2)	(4)
Leiomyosarcoma, Metastatic, Uterus	1 (25%)			
Polyp		1 (33%)		

## HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(48)	(48)	(47)
Lymph Node	(9)	(7)	(8)	(9)
Lymph Node, Mandibular	(48)	(47)	(48)	(47)
Lymph Node, Mesenteric	(46)	(47)	(48)	(47)
Spleen	(48)	(48)	(48)	(48)
Hemangiosarcoma	1 (2%)			
Thymus	(46)	(45)	(45)	(44)

## INTEGUMENTARY SYSTEM

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FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Mammary Gland	(47)	(48)	(48)	(47)
Adenocarcinoma	1 (2%)	4 (8%)		
Fibroadenoma	12 (26%)	15 (31%)	9 (19%)	8 (17%)
Skin	(48)	(48)	(48)	(48)
Basal Cell Carcinoma	1 (2%)		1 (2%)	
Fibroma			1 (2%)	
Sarcoma	1 (2%)		2 (4%)	
Ear, Squamous Cell Papilloma	1 (2%)			
Head, Basal Cell Carcinoma				1 (2%)
Subcutaneous Tissue, Fibroma			1 (2%)	

## MUSCULOSKELETAL SYSTEM

Bone	(0)	(2)	(0)	(0)
Bone, Femur	(48)	(48)	(48)	(48)
Skeletal Muscle	(0)	(3)	(0)	(2)

## NERVOUS SYSTEM

Brain, Brain Stem	(48)	(48)	(48)	(48)
Brain, Cerebellum	(48)	(48)	(48)	(48)
Carcinoma, Metastatic, Pituitary Gland	1 (2%)			
Meningioma Malignant				1 (2%)
Brain, Cerebrum	(48)	(48)	(48)	(48)
Astrocytoma Malignant			1 (2%)	
Meningioma Malignant				1 (2%)

## RESPIRATORY SYSTEM

Lung	(48)	(48)	(48)	(48)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)		
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Nose	(48)	(48)	(48)	(48)

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Lab: NCTR

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FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(1)	(0)
Eye	(48)	(48)	(46)	(46)
Harderian Gland	(48)	(48)	(48)	(48)
Zymbal's Gland	(1)	(0)	(1)	(1)
Carcinoma			1 (100%)	
Squamous Cell Carcinoma	1 (100%)			1 (100%)

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URINARY SYSTEM

Kidney	(48)	(48)	(48)	(48)
Sarcoma				1 (2%)
Urinary Bladder	(48)	(48)	(48)	(48)
Transitional Epithelium, Papilloma	1 (2%)			

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SYSTEMIC LESIONS

Multiple Organ	*(48)	*(48)	*(48)	*(48)
Histiocytic Sarcoma			2 (4%)	
Leukemia Mononuclear	10 (21%)	12 (25%)	19 (40%)	18 (38%)

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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: 14:39:01

Route: DOSED WATER

CAS Number: ALOEVLEAFEXT

First Dose M/F: 04/17/05 / 04/17/05

Species/Strain: RATS/F 344/NCTR

Lab: NCTR

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FISCHER 344 RATS-NCTR RATS FEMALE                      CONTROL WATER    ALOEWHOLLEAF 0.5    ALOEWHOLLEAF 1.0    ALOEWHOLLEAF 1.5

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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	45	48	44	39
Total Primary Neoplasms	92	102	104	95
Total Animals with Benign Neoplasms	41	47	41	33
Total Benign Neoplasms	70	80	65	61
Total Animals with Malignant Neoplasms	22	21	32	25
Total Malignant Neoplasms	22	22	39	34
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				

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\*\*\* 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