

**TDMs No.** 20116 - 03

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
AVERAGE SEVERITY GRADES[b]**

**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)
Inflammation	1 [3.0]	1 [4.0]	1 [4.0]	
Ulcer	1 [3.0]	1 [4.0]	1 [4.0]	
Mucosa, Hyperplasia	1 [3.0]			
Intestine Large, Ascending Colon	(47)	(47)	(48)	(46)
Hyperplasia				2 [3.5]
Inflammation			1 [2.0]	2 [2.5]
Lymphoid Tissue, Hyperplasia				1 [3.0]
Mucosa, Hyperplasia		30 [1.9]	38 [2.8]	32 [3.2]
Intestine Large, Cecum	(46)	(45)	(48)	(48)
Dilatation	1		8	17
Hemorrhage				1 [3.0]
Hyperplasia	1 [1.0]			
Inflammation	1 [2.0]			2 [2.5]
Ulcer				1 [4.0]
Lymphoid Tissue, Hyperplasia		2 [2.5]	3 [2.0]	1 [2.0]
Mucosa, Hyperplasia		13 [1.5]	24 [1.9]	25 [2.4]
Intestine Large, Colon	(0)	(1)	(3)	(5)
Inflammation			1 [4.0]	
Ulcer			1 [4.0]	
Mucosa, Hyperplasia		1 [3.0]	1 [2.0]	4 [3.8]
Intestine Large, Descending Colon	(47)	(46)	(46)	(47)
Inflammation			2 [1.5]	

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Lymphoid Tissue, Hyperplasia		1 [2.0]		1 [2.0]
Mucosa, Hyperplasia		17 [1.5]	31 [1.6]	30 [1.7]
Intestine Large, Rectum	(47)	(47)	(48)	(48)
Mucosa, Hyperplasia		1 [1.0]	1 [2.0]	4 [2.0]
Intestine Large, Transverse Colon	(47)	(47)	(47)	(47)
Hyperplasia				1 [2.0]
Inflammation			1 [2.0]	
Lymphoid Tissue, Hyperplasia		1 [2.0]	2 [3.0]	
Mucosa, Hyperplasia		30 [1.8]	42 [2.2]	34 [2.4]
Intestine Small	(0)	(1)	(0)	(0)
Intestine Small, Duodenum	(48)	(46)	(48)	(48)
Mucosa, Hyperplasia	1 [2.0]	10 [2.3]	3 [2.7]	6 [2.2]
Intestine Small, Ileum	(45)	(45)	(48)	(48)
Hyperplasia	1 [1.0]			
Inflammation	1 [2.0]		1 [2.0]	
Lymphoid Tissue, Hyperplasia		1 [2.0]		2 [3.5]
Mucosa, Hyperplasia		3 [1.7]	3 [2.3]	2 [2.0]
Intestine Small, Jejunum	(45)	(44)	(46)	(46)
Inflammation				1 [2.0]
Lymphatic, Dilatation			1 [3.0]	
Lymphoid Tissue, Hyperplasia	1 [2.0]	1 [2.0]	1 [2.0]	1 [2.0]
Mucosa, Hyperplasia		1 [2.0]	2 [2.0]	3 [2.0]
Liver	(48)	(48)	(48)	(48)
Angiectasis			1 [2.0]	1 [3.0]
Basophilic Focus			2	
Basophilic Focus, Multiple		1	1	1
Cyst Multilocular	1			1
Degeneration, Cystic	9 [2.2]	6 [1.7]	2 [1.0]	
Eosinophilic Focus	4			1
Eosinophilic Focus, Multiple	1		1	
Granuloma	2 [2.0]	5 [1.2]	6 [1.7]	10 [1.7]
Hematopoietic Cell Proliferation		1 [1.0]	1 [2.0]	1 [1.0]
Hemorrhage			1 [2.0]	
Hepatodiaphragmatic Nodule	1	2	2	1
Infiltration Cellular, Lymphocyte		1 [2.0]	4 [1.3]	3 [1.3]
Infiltration Cellular, Polymorphonuclear				1 [2.0]

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Lab: NCTR

FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Necrosis, Coagulative	1 [3.0]	2 [2.0]		2 [1.5]
Regeneration				1 [3.0]
Tension Lipidosis				1 [3.0]
Vacuolization Cytoplasmic	12 [2.4]	14 [2.5]	6 [2.8]	1 [2.0]
Artery, Media, Hypertrophy		1 [2.0]		
Bile Duct, Hyperplasia	15 [2.1]	16 [1.8]	9 [1.4]	5 [1.6]
Caudate Lobe, Developmental Malformation			1	
Centrilobular, Degeneration		1 [4.0]	2 [2.5]	
Centrilobular, Necrosis	1 [2.0]	1 [3.0]	1 [3.0]	1 [3.0]
Hepatocyte, Periportal, Hypertrophy				1 [3.0]
Left Lateral Lobe, Developmental Malformation	1	2	2	1
Median Lobe, Developmental Malformation				1
Periductular, Fibrosis		1 [2.0]		
Right Lateral Lobe, Developmental Malformation				1
Mesentery	(10)	(10)	(4)	(5)
Accessory Spleen			1	
Ectopic Tissue				1
Hemorrhage	1 [4.0]			
Inflammation			1 [3.0]	1 [3.0]
Polyarteritis		1 [4.0]		1 [4.0]
Thrombosis	1			1
Fat, Necrosis	7 [3.1]	6 [2.7]	2 [3.0]	2 [2.5]
Oral Mucosa	(2)	(1)	(2)	(1)
Keratin Cyst			1	
Epithelium, Hyperplasia	1 [4.0]			
Pancreas	(48)	(48)	(48)	(48)
Infiltration Cellular, Lymphocyte				1 [1.0]
Polyarteritis	3 [3.7]		3 [2.3]	
Acinar Cell, Atrophy	12 [1.8]	17 [1.9]	19 [1.6]	24 [1.8]
Proximal Colon	(44)	(44)	(46)	(41)
Hemorrhage				1 [3.0]
Hyperplasia, Lymphoid				1 [3.0]
Inflammation	1 [2.0]	4 [2.3]	3 [2.0]	1 [2.0]
Ulcer		2 [2.5]		
Mucosa, Hyperplasia		29 [2.0]	36 [2.5]	32 [3.0]

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Salivary Glands	(48)	(48)	(48)	(48)
Acinar Cell, Atrophy		1 [3.0]		
Sublingual Gland, Infiltration Cellular		1 [2.0]		
Stomach, Forestomach	(48)	(47)	(48)	(48)
Edema	1 [4.0]	4 [3.8]	1 [2.0]	
Hyperplasia	10 [2.2]	13 [2.8]	9 [2.2]	2 [2.5]
Inflammation	11 [2.9]	9 [3.2]	5 [3.4]	3 [4.0]
Perforation		1 [4.0]		
Ulcer	3 [2.7]	3 [3.7]	3 [4.0]	1 [4.0]
Stomach, Glandular	(48)	(47)	(48)	(48)
Diverticulum		1		
Edema	1 [4.0]	1 [2.0]		1 [2.0]
Erosion	1 [2.0]			
Inflammation	1 [3.0]	3 [2.7]	3 [2.0]	
Mineralization	1 [2.0]			
Ulcer		1 [2.0]		
Mucosa, Hyperplasia	1 [2.0]	12 [2.3]	7 [2.4]	11 [2.4]
Mucosa, Necrosis, Focal	2 [1.5]		1 [2.0]	

## CARDIOVASCULAR SYSTEM

Blood Vessel	(48)	(48)	(48)	(48)
Heart	(48)	(48)	(48)	(48)
Cardiomyopathy	34 [2.0]	39 [2.0]	38 [2.0]	32 [2.0]
Dilatation			1	
Atrium, Dilatation			1 [4.0]	
Atrium, Thrombus	6	9	10	4
Atrium, Myocardium, Degeneration		1 [3.0]		

## ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(48)	(48)	(48)
Accessory Adrenal Cortical Nodule		1	1	
Angiectasis	2 [2.0]	2 [2.0]	2 [1.5]	2 [2.0]
Atrophy	1 [3.0]	2 [2.5]	1 [3.0]	

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Hyperplasia, Focal	2 [2.5]	1 [1.0]	2 [2.0]	3 [1.7]
Hypertrophy, Focal	3 [2.0]		8 [1.8]	2 [2.0]
Necrosis, Coagulative Thrombus		1 [3.0]		1 [2.0]
Vacuolization Cytoplasmic Adrenal Medulla	24 [2.5] (48)	22 [2.5] (47)	15 [2.3] (48)	14 [2.2] (48)
Angiectasis	3 [2.0]	2 [1.5]	2 [2.0]	3 [2.0]
Hyperplasia, Focal	10 [2.5]	4 [1.8]	3 [2.7]	6 [2.8]
Islets, Pancreatic	(48)	(48)	(48)	(48)
Hyperplasia		1 [2.0]	1 [3.0]	
Parathyroid Gland	(47)	(48)	(46)	(48)
Hyperplasia, Focal				1 [1.0]
Pituitary Gland	(48)	(48)	(47)	(48)
Angiectasis		2 [2.5]	2 [2.5]	5 [2.0]
Hemorrhage		1 [2.0]		1 [3.0]
Pars Distalis, Cyst	1	2	1	2
Pars Distalis, Hyperplasia	5 [2.2]		4 [2.5]	5 [2.0]
Pars Intermedia, Cyst	1	1		
Thyroid Gland	(48)	(47)	(48)	(48)
Ultimobranchial Cyst		1		
C-cell, Hyperplasia	8 [1.9]	7 [1.9]	6 [2.0]	6 [1.5]
Follicular Cell, Hyperplasia	1 [2.0]	1 [1.0]	1 [2.0]	1 [1.0]

## GENERAL BODY SYSTEM

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

Epididymis	(48)	(48)	(48)	(48)
Atrophy		1 [3.0]	1 [2.0]	
Exfoliated Germ Cell	37 [2.4]	27 [2.2]	36 [2.3]	23 [2.1]
Granuloma Sperm			2 [2.5]	
Hypospermia	28 [3.2]	25 [3.6]	27 [3.3]	26 [3.6]
Inflammation	1 [2.0]			1 [3.0]

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Preputial Gland	(48)	(48)	(48)	(48)
Atrophy		1 [2.0]		1 [2.0]
Inflammation	38 [2.6]	41 [2.5]	39 [2.4]	37 [2.3]
Duct, Ectasia	6 [2.7]	13 [2.5]	13 [2.3]	9 [2.3]
Duct, Hyperplasia		1 [2.0]	1 [2.0]	
Prostate	(48)	(48)	(48)	(48)
Atrophy		1 [3.0]		
Inflammation	34 [2.2]	32 [2.0]	36 [2.2]	27 [2.3]
Seminal Vesicle	(48)	(48)	(48)	(48)
Atrophy	4 [2.0]	11 [2.2]	8 [2.4]	6 [2.2]
Decreased Secretory Fluid	7 [2.7]	8 [2.9]	9 [3.3]	9 [3.2]
Testes	(48)	(48)	(48)	(48)
Granuloma Sperm	1 [2.0]			
Inflammation	1 [2.0]			
Polyarteritis	1 [2.0]		1 [3.0]	
Interstitial Cell, Hyperplasia	3 [2.3]	2 [2.0]	2 [2.5]	4 [2.0]
Seminiferous Tubule, Atrophy	17 [2.8]	11 [2.7]	17 [3.0]	8 [2.9]

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(48)	(48)	(48)	(48)
Atrophy	8 [2.1]	3 [2.7]	4 [2.8]	2 [3.0]
Hyperplasia	7 [2.6]	8 [2.6]	4 [2.5]	5 [2.8]
Myeloid Cell, Hyperplasia		1 [3.0]	1 [2.0]	1 [2.0]
Lymph Node	(24)	(13)	(19)	(17)
Lumbar, Degeneration, Cystic	4 [3.0]	4 [2.8]	2 [2.5]	1 [4.0]
Lumbar, Hyperplasia, Lymphoid		1 [3.0]		1 [2.0]
Lumbar, Infiltration Cellular, Plasma Cell		1 [3.0]		
Mediastinal, Degeneration, Cystic	1 [2.0]		1 [2.0]	
Mediastinal, Hemorrhage	1 [4.0]	2 [2.0]	1 [2.0]	1 [2.0]
Mediastinal, Pigmentation		1 [2.0]		
Mediastinal, Medulla, Sinus, Dilatation			1 [3.0]	
Medulla, Pancreatic, Sinus, Dilatation	1 [2.0]		2 [2.5]	
Medulla, Renal, Sinus, Dilatation		1 [3.0]		
Medulla, Sinus, Dilatation	1 [2.0]			

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Pancreatic, Degeneration, Cystic			1 [3.0]	1 [3.0]
Pancreatic, Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]	3 [2.3]	2 [2.0]
Pancreatic, Infiltration Cellular, Plasma Cell	1 [2.0]			
Pancreatic, Pigmentation			1 [2.0]	
Renal, Degeneration, Cystic	2 [1.5]	1 [2.0]	1 [3.0]	2 [2.5]
Renal, Hemorrhage			1 [2.0]	
Renal, Hyperplasia, Lymphoid		2 [2.5]		
Renal, Infiltration Cellular, Plasma Cell		1 [3.0]		
Renal, Pigmentation			1 [2.0]	
Lymph Node, Mandibular	(48)	(48)	(48)	(48)
Atrophy, Lymphocyte	1 [1.0]	1 [2.0]		
Degeneration, Cystic	11 [2.5]	9 [2.1]	5 [2.2]	5 [2.6]
Hematopoietic Cell Proliferation	1 [1.0]			
Hemorrhage		1 [3.0]		
Hyperplasia, Lymphoid	1 [2.0]	2 [2.0]	3 [2.0]	
Infiltration Cellular, Plasma Cell	9 [2.2]	14 [2.1]	10 [2.3]	11 [2.2]
Necrosis, Lymphoid	1 [2.0]			
Medulla, Sinus, Dilatation		1 [2.0]		1 [3.0]
Lymph Node, Mesenteric	(47)	(48)	(48)	(48)
Degeneration, Cystic	8 [2.5]	11 [2.8]	42 [3.8]	41 [3.6]
Fibrosis				1 [2.0]
Hemorrhage	2 [3.0]	2 [2.0]		1 [4.0]
Hyperplasia, Lymphoid			1 [2.0]	4 [2.8]
Infiltration Cellular, Plasma Cell	1 [2.0]			
Inflammation				1 [4.0]
Necrosis, Lymphoid	1 [2.0]		1 [3.0]	
Medulla, Sinus, Dilatation		4 [2.5]	1 [3.0]	
Spleen	(48)	(48)	(48)	(48)
Accessory Spleen	1		1	
Atrophy		2 [2.5]		
Congestion	1 [3.0]	3 [2.7]	2 [2.0]	
Fibrosis		1 [3.0]	1 [3.0]	
Hematopoietic Cell Proliferation	3 [2.3]	1 [2.0]	1 [2.0]	1 [2.0]
Hyperplasia, Lymphoid	1 [2.0]	1 [2.0]		
Hyperplasia, Focal	1 [3.0]			
Infarct	6	9	5	1

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Pigmentation	3 [2.7]	9 [2.3]	3 [2.3]	6 [2.2]
Thrombus	1		1	1
Capsule, Fibrosis			1 [2.0]	
Lymphoid Follicle, Necrosis	1 [4.0]			
Red Pulp, Hyperplasia			1 [2.0]	
Thymus	(46)	(47)	(44)	(44)
Atrophy	38 [2.4]	42 [2.4]	39 [2.4]	40 [2.3]
Cyst	1	2		
Ectopic Thyroid		1		
Hemorrhage				1 [1.0]
Epithelial Cell, Hyperplasia			1 [2.0]	

**INTEGUMENTARY SYSTEM**

Mammary Gland	(44)	(46)	(48)	(41)
Galactoceles	9	11	11	10
Lactation	23 [1.9]	19 [2.3]	24 [2.2]	10 [2.2]
Alveolus, Hyperplasia	12 [2.0]	14 [2.3]	12 [2.4]	6 [2.2]
Skin	(48)	(48)	(48)	(48)
Cyst Epithelial Inclusion	1	1		1
Inflammation	1 [3.0]	1 [2.0]	2 [2.5]	
Inflammation, Granulomatous		1 [4.0]		
Epidermis, Necrosis	1 [3.0]			
Fat, Subcutaneous Tissue, Necrosis			1 [3.0]	
Foot, Inflammation, Chronic				1 [2.0]
Subcutaneous Tissue, Inflammation, Focal		1 [3.0]		
Tail, Hyperkeratosis, Multifocal			1 [3.0]	

**MUSCULOSKELETAL SYSTEM**

Bone	(0)	(2)	(2)	(1)
Cartilage, Sternum, Degeneration				1 [4.0]
Cranium, Periosteum, Hemorrhage			1 [2.0]	
Bone, Femur	(48)	(48)	(48)	(48)
Osteopetrosis	1 [3.0]			

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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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Skeletal Muscle	(2)	(2)	(0)	(2)
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## NERVOUS SYSTEM

Brain	(0)	(0)	(1)	(0)
Brain, Brain Stem	(48)	(48)	(48)	(48)
Hemorrhage		1 [3.0]	1 [3.0]	
Hypothalamus, Compression	11 [2.1]	10 [3.0]	13 [2.6]	9 [3.0]
Brain, Cerebellum	(48)	(48)	(48)	(48)
Compression			1 [3.0]	
Hemorrhage			2 [1.5]	
Brain, Cerebrum	(48)	(48)	(48)	(48)
Hemorrhage				1 [2.0]
Hydrocephalus			1 [2.0]	1 [2.0]
Mineralization, Focal			1 [1.0]	
Spinal Cord	(1)	(1)	(0)	(3)
Hemorrhage				1 [3.0]

## RESPIRATORY SYSTEM

Lung	(48)	(48)	(48)	(48)
Granuloma			1 [1.0]	1 [2.0]
Hemorrhage	1 [2.0]			1 [1.0]
Infiltration Cellular, Lymphocyte		1 [1.0]		
Metaplasia, Osseous				1 [1.0]
Alveolar Epithelium, Hyperplasia	2 [2.0]	1 [2.0]	2 [3.0]	1 [1.0]
Alveolus, Infiltration Cellular, Histiocyte	3 [1.0]	3 [1.3]	10 [1.3]	6 [1.2]
Alveolus, Infiltration Cellular, Lymphocyte			1 [1.0]	
Alveolus, Inflammation	2 [2.5]		3 [2.0]	2 [2.5]
Mediastinum, Inflammation			1 [3.0]	
Nose	(48)	(48)	(47)	(48)
Foreign Body			1	
Fungus	1		1	
Inflammation	4 [1.8]	3 [2.0]	4 [2.0]	1 [2.0]
Goblet Cell, Hyperplasia	1 [3.0]	1 [2.0]	1 [2.0]	2 [1.5]

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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

FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Trachea	(48)	(48)	(48)	(48)
Mucosa, Cyst		1		

## SPECIAL SENSES SYSTEM

Eye	(47)	(46)	(47)	(48)
Cataract	2			2
Phthisis Bulbi				1
Retina, Degeneration	5 [2.8]	2 [1.5]		4 [2.5]
Sclera, Metaplasia, Osseous	2 [2.5]	1 [2.0]	1 [3.0]	1 [2.0]
Harderian Gland	(48)	(48)	(48)	(48)
Atrophy	1 [2.0]			
Infiltration Cellular, Lymphocyte	7 [1.3]	11 [1.1]	8 [1.3]	8 [1.5]
Inflammation			1 [2.0]	2 [2.0]
Lacrimal Gland	(0)	(1)	(0)	(0)
Zymbal's Gland	(0)	(2)	(1)	(0)

## URINARY SYSTEM

Kidney	(48)	(48)	(48)	(48)
Hydronephrosis		1 [2.0]	1 [2.0]	
Nephropathy	48 [3.0]	47 [3.2]	48 [2.7]	45 [2.3]
Cortex, Cyst	2			1
Renal Tubule, Necrosis		1 [3.0]		
Urinary Bladder	(48)	(48)	(48)	(48)
Dilatation	1	5	1	2
Hemorrhage				1 [3.0]
Hyperplasia			1 [2.0]	
Inflammation			1 [2.0]	

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

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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

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

**Disposition Summary**

Animals Initially In Study	48	48	48	48
Early Deaths				
Moribund Sacrifice	15	15	17	20
Natural Death	2		4	5
Survivors				
Moribund Sacrifice	1	2	2	2
Natural Death			1	1
Terminal Sacrifice	30	31	24	20
Animals Examined Microscopically	48	48	48	48

ALIMENTARY SYSTEM

Esophagus	(48)	(47)	(48)	(48)
Inflammation	1 [4.0]			
Intestine Large, Ascending Colon	(47)	(48)	(46)	(46)
Dilatation			1	1
Inflammation		1 [2.0]	1 [2.0]	2 [2.0]
Lymphoid Tissue, Hyperplasia			2 [2.5]	2 [3.5]
Mucosa, Hyperplasia		40 [2.0]	35 [2.3]	39 [2.6]
Intestine Large, Cecum	(47)	(48)	(47)	(48)
Dilatation			9	25
Inflammation		1 [2.0]	2 [2.0]	2 [2.5]
Perforation				1 [4.0]
Lymphoid Tissue, Hyperplasia		1 [2.0]		2 [2.5]
Mucosa, Hyperplasia		4 [1.8]	17 [2.2]	27 [2.2]
Intestine Large, Colon	(0)	(0)	(2)	(1)
Inflammation			1 [2.0]	
Necrosis			1 [4.0]	
Mucosa, Hyperplasia			1 [4.0]	
Intestine Large, Descending Colon	(47)	(48)	(46)	(47)
Inflammation			1 [2.0]	
Ulcer			1 [3.0]	
Mucosa, Hyperplasia		17 [1.4]	18 [1.4]	27 [1.5]
Intestine Large, Rectum	(48)	(48)	(47)	(47)

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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

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Polyarteritis		1 [2.0]		
Mucosa, Hyperplasia				5 [1.6]
Intestine Large, Transverse Colon	(47)	(48)	(46)	(46)
Dilatation			1	
Inflammation		1 [1.0]	1 [2.0]	
Lymphoid Tissue, Hyperplasia		1 [2.0]	1 [2.0]	
Mucosa, Hyperplasia		40 [1.7]	33 [1.8]	42 [2.1]
Intestine Small, Duodenum	(48)	(48)	(48)	(48)
Inflammation			1 [1.0]	1 [2.0]
Mucosa, Hyperplasia	1 [2.0]	4 [2.0]	5 [2.0]	2 [1.5]
Intestine Small, Ileum	(47)	(48)	(43)	(44)
Inflammation		1 [3.0]	1 [2.0]	
Lymphoid Tissue, Hyperplasia	1 [3.0]	1 [2.0]	1 [3.0]	
Mucosa, Hyperplasia		2 [2.5]	2 [1.5]	6 [2.5]
Intestine Small, Jejunum	(47)	(48)	(45)	(43)
Inflammation		2 [3.5]		
Ulcer		1 [4.0]		
Lymphatic, Dilatation		1 [4.0]		
Submucosa, Fibrosis		1 [4.0]		
Liver	(48)	(48)	(48)	(48)
Angiectasis			1 [3.0]	1 [4.0]
Basophilic Focus		1		1
Basophilic Focus, Multiple	22	27	12	13
Cyst Multilocular	1			
Eosinophilic Focus	5	7	2	1
Eosinophilic Focus, Multiple		1		1
Granuloma	21 [1.9]	19 [1.6]	20 [1.9]	15 [1.7]
Hematopoietic Cell Proliferation	1 [1.0]			
Hepatodiaphragmatic Nodule	4	2	4	2
Infiltration Cellular, Lymphocyte	1 [1.0]	3 [1.7]	1 [2.0]	3 [1.7]
Necrosis, Coagulative			2 [2.0]	
Regeneration				1 [3.0]
Tension Lipidosis			2 [2.5]	
Vacuolization Cytoplasmic	6 [2.5]	9 [2.6]	4 [2.5]	5 [1.8]
Bile Duct, Hyperplasia	9 [1.6]	5 [1.4]	6 [1.3]	2 [1.0]
Caudate Lobe, Developmental Malformation			4	1

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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

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Caudate Lobe, Infarct				1 [4.0]
Centrilobular, Necrosis				2 [2.0]
Left Lateral Lobe, Developmental Malformation	4	2	3	1
Left Lateral Lobe, Infarct				1 [4.0]
Median Lobe, Developmental Malformation				1
Periportal, Inflammation, Chronic			1 [2.0]	1 [2.0]
Right Lateral Lobe, Developmental Malformation			2	
Mesentery	(6)	(9)	(10)	(4)
Polyarteritis		1 [4.0]	1 [3.0]	
Thrombosis		1		
Fat, Necrosis	6 [2.8]	8 [2.6]	6 [2.7]	4 [3.0]
Oral Mucosa	(0)	(1)	(1)	(0)
Pancreas	(48)	(48)	(48)	(48)
Accessory Spleen			1	
Polyarteritis		1 [3.0]	1 [3.0]	
Acinar Cell, Atrophy	10 [2.1]	11 [1.6]	17 [1.7]	17 [2.0]
Proximal Colon	(43)	(45)	(42)	(39)
Dilatation			1	
Foreign Body				1
Inflammation		2 [1.5]	11 [2.4]	8 [2.3]
Ulcer		1 [2.0]	2 [2.5]	1 [3.0]
Mucosa, Hyperplasia		30 [2.1]	33 [2.5]	32 [2.5]
Salivary Glands	(48)	(48)	(48)	(48)
Acinar Cell, Atrophy	1 [2.0]			
Stomach, Forestomach	(48)	(48)	(48)	(48)
Edema		2 [3.0]	2 [2.5]	1 [3.0]
Hyperplasia	1 [3.0]	7 [2.6]	10 [2.4]	9 [2.3]
Inflammation			4 [3.3]	3 [3.3]
Stomach, Glandular	(48)	(48)	(48)	(48)
Edema		1 [3.0]		1 [3.0]
Inflammation			1 [2.0]	1 [2.0]
Ulcer				1 [2.0]
Mucosa, Hyperplasia		1 [2.0]	3 [2.3]	3 [2.0]
Mucosa, Necrosis, Focal		1 [2.0]		

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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

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

**CARDIOVASCULAR SYSTEM**

	(48)	(48)	(48)	(48)
Heart				
Cardiomyopathy	35 [1.8]	40 [1.8]	32 [1.5]	33 [1.7]
Atrium, Thrombus			1	1

**ENDOCRINE SYSTEM**

	(48)	(48)	(48)	(48)
Adrenal Cortex				
Accessory Adrenal Cortical Nodule			1	
Angiectasis	31 [2.1]	25 [2.2]	20 [2.4]	19 [2.1]
Atrophy				1 [2.0]
Fibrosis, Focal	1 [2.0]			
Hemorrhage				1 [3.0]
Hyperplasia, Focal		2 [2.0]		2 [1.5]
Hypertrophy	1 [2.0]			
Hypertrophy, Focal	2 [1.5]	2 [1.5]	6 [1.8]	1 [2.0]
Necrosis, Coagulative				1 [2.0]
Vacuolization Cytoplasmic	6 [1.8]	7 [2.4]	5 [2.4]	6 [2.2]
Adrenal Medulla	(47)	(46)	(48)	(47)
Angiectasis	2 [2.0]	6 [1.8]	1 [2.0]	6 [2.2]
Hyperplasia, Focal		1 [2.0]	1 [1.0]	1 [2.0]
Islets, Pancreatic	(48)	(48)	(47)	(48)
Parathyroid Gland	(47)	(45)	(46)	(47)
Hyperplasia, Focal	1 [2.0]			
Pituitary Gland	(48)	(48)	(48)	(47)
Angiectasis	2 [3.0]	1 [3.0]		1 [2.0]
Pigmentation				1 [3.0]
Pars Distalis, Cyst	1	5	4	6
Pars Distalis, Hyperplasia	3 [1.7]	3 [2.3]	2 [2.5]	4 [2.0]
Pars Intermedia, Cyst			1	1
Pars Nervosa, Cyst				1
Thyroid Gland	(48)	(48)	(48)	(47)
C-cell, Hyperplasia	15 [1.9]	13 [1.4]	8 [1.4]	3 [1.7]
Follicular Cell, Hyperplasia				1 [1.0]

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Aloe vera whole leaf extract (native)

Time Report Requested: 14:39:01

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Lab: NCTR

FISCHER 344 RATS-NCTR RATS FEMALE

CONTROL WATER

ALOEWHOLLEAF 0.5

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 1.5

## GENERAL BODY SYSTEM

Tissue NOS	(0)	(0)	(2)	(0)
Fat, Necrosis			1 [2.0]	

## GENITAL SYSTEM

	(48)	(48)	(48)	(48)
Clitoral Gland				
Atrophy				1 [2.0]
Hyperplasia			1 [2.0]	
Inflammation	33 [2.2]	26 [2.1]	30 [2.1]	30 [2.2]
Duct, Ectasia	12 [2.3]	15 [2.7]	8 [2.1]	8 [2.4]
Duct, Hyperplasia	2 [2.0]		2 [2.0]	5 [2.2]
Ovary	(48)	(48)	(48)	(48)
Atrophy	47 [2.3]	44 [2.5]	42 [2.6]	47 [2.4]
Cyst	2	4	6	4
Uterus	(48)	(48)	(48)	(48)
Hyperplasia, Focal	2 [3.5]	1 [2.0]	2 [2.0]	5 [2.0]
Hypoplasia	1			
Inflammation	1 [2.0]	2 [1.5]		2 [2.0]
Adventitia, Inflammation			1 [2.0]	
Bilateral, Horn, Dilatation				1 [3.0]
Cervix, Mucocyte, Metaplasia	1 [2.0]	1 [3.0]		
Cervix, Muscularis, Hyperplasia		1 [2.0]		
Cervix, Muscularis, Hypertrophy	1 [3.0]	1 [3.0]	1 [4.0]	
Endometrium, Hyperplasia, Cystic	10 [1.7]	16 [1.9]	8 [2.0]	12 [2.2]
Horn, Dilatation	1 [3.0]	2 [3.0]	1 [2.0]	
Vagina	(4)	(3)	(2)	(4)
Dilatation	1	1	1	
Inflammation, Suppurative	1 [2.0]			3 [2.7]
Mucocyte, Hyperplasia	3 [2.7]	1 [4.0]	2 [3.5]	4 [3.0]

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Test Type: CHRONIC

Aloe vera whole leaf extract (native)

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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
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## HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(48)	(48)	(47)
Atrophy		2 [2.0]	1 [3.0]	
Hyperplasia	1 [2.0]	4 [2.3]	3 [2.7]	1 [2.0]
Proliferation				1 [4.0]
Myeloid Cell, Hyperplasia			3 [2.0]	1 [2.0]
Lymph Node	(9)	(7)	(8)	(9)
Degeneration, Cystic			2 [2.0]	
Lumbar, Degeneration, Cystic	2 [2.5]			
Lumbar, Hyperplasia, Lymphoid	1 [2.0]			
Mediastinal, Hemorrhage		1 [3.0]	2 [2.5]	
Mediastinal, Hyperplasia, Lymphoid				1 [2.0]
Mediastinal, Polyarteritis		1 [4.0]		
Mediastinal, Medulla, Sinus, Dilatation		1 [2.0]		
Medulla, Pancreatic, Sinus, Dilatation				1 [3.0]
Pancreatic, Degeneration, Cystic				1 [3.0]
Pancreatic, Hemorrhage			1 [3.0]	
Pancreatic, Hyperplasia, Lymphoid		1 [2.0]		1 [3.0]
Lymph Node, Mandibular	(48)	(47)	(48)	(47)
Cyst	2 [2.5]	1 [2.0]		
Degeneration, Cystic	2 [1.5]	3 [2.0]	3 [2.3]	4 [1.8]
Hyperplasia, Lymphoid	1 [2.0]			1 [2.0]
Infiltration Cellular, Plasma Cell	7 [1.9]	9 [2.3]	9 [2.2]	4 [2.0]
Medulla, Sinus, Dilatation	2 [2.0]			2 [2.5]
Lymph Node, Mesenteric	(46)	(47)	(48)	(47)
Amyloid Deposition			1 [3.0]	1 [3.0]
Atrophy, Lymphocyte				4 [3.0]
Degeneration, Cystic		16 [3.2]	40 [3.8]	43 [3.5]
Fibrosis				1 [3.0]
Hemorrhage	3 [2.0]	3 [2.0]	1 [2.0]	
Hyperplasia, Lymphoid		2 [2.0]	2 [2.0]	3 [3.0]
Medulla, Sinus, Dilatation	1 [2.0]	3 [2.3]	1 [3.0]	1 [3.0]
Spleen	(48)	(48)	(48)	(48)
Accessory Spleen	2	1		
Atrophy	1 [4.0]	1 [2.0]	1 [3.0]	2 [2.0]

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b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Fibrosis	1 [4.0]			
Hematopoietic Cell Proliferation	4 [2.8]	1 [3.0]	1 [4.0]	1 [2.0]
Hyperplasia, Focal	1 [3.0]	5 [2.8]	1 [3.0]	1 [2.0]
Infarct	1	2		3
Pigmentation	7 [2.3]	6 [2.3]	5 [2.6]	6 [2.5]
Thrombus	2			
Red Pulp, Hyperplasia		3 [2.0]		
Thymus	(46)	(45)	(45)	(44)
Atrophy	43 [2.2]	44 [2.2]	40 [2.4]	42 [2.3]
Cyst		1		1
Hemorrhage	1 [2.0]			

## INTEGUMENTARY SYSTEM

Mammary Gland	(47)	(48)	(48)	(47)
Galactocele	3	1	3	5
Lactation	27 [1.9]	28 [2.1]	24 [2.1]	23 [2.1]
Alveolus, Hyperplasia	27 [2.0]	38 [2.2]	28 [2.1]	22 [2.1]
Alveolus, Hypertrophy	1 [2.0]			
Skin	(48)	(48)	(48)	(48)
Cyst Epithelial Inclusion			1	
Inflammation		1 [2.0]		
Epidermis, Hyperplasia	1 [2.0]			1 [3.0]
Epidermis, Necrosis	1 [2.0]	1 [3.0]		1 [2.0]
Foot, Hyperkeratosis	1 [2.0]			

## MUSCULOSKELETAL SYSTEM

Bone	(0)	(2)	(0)	(0)
Cervical, Vertebra, Fracture		2		
Bone, Femur	(48)	(48)	(48)	(48)
Fibrous Osteodystrophy		1 [2.0]		
Osteopetrosis	8 [3.0]	3 [3.0]	4 [3.0]	5 [3.2]
Skeletal Muscle	(0)	(3)	(0)	(2)
Polyarteritis		1 [4.0]		

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Test Type: CHRONIC

Aloe vera whole leaf extract (native)

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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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Diaphragm, Inflammation

1 [2.0]

## NERVOUS SYSTEM

Brain, Brain Stem	(48)	(48)	(48)	(48)
Hypothalamus, Compression	13 [2.2]	14 [2.4]	8 [2.4]	8 [2.3]
Brain, Cerebellum	(48)	(48)	(48)	(48)
Brain, Cerebrum	(48)	(48)	(48)	(48)
Hemorrhage			1 [2.0]	
Hydrocephalus	1 [2.0]	1 [2.0]		

## RESPIRATORY SYSTEM

Lung	(48)	(48)	(48)	(48)
Granuloma	6 [2.2]	4 [2.0]	4 [1.3]	3 [1.3]
Hemorrhage		2 [2.0]	1 [2.0]	
Alveolar Epithelium, Hyperplasia	4 [2.5]	2 [1.5]	1 [2.0]	
Alveolus, Infiltration Cellular, Histiocyte	13 [1.7]	8 [1.1]	9 [1.1]	11 [1.4]
Alveolus, Inflammation	3 [1.7]	4 [2.0]	2 [1.5]	
Artery, Mineralization			1 [1.0]	
Nose	(48)	(48)	(48)	(48)
Inflammation	1 [1.0]	6 [2.0]	8 [1.9]	2 [1.5]
Osteopetrosis	1 [3.0]	2 [2.5]	1 [3.0]	2 [2.0]
Goblet Cell, Hyperplasia		1 [2.0]	1 [2.0]	

## SPECIAL SENSES SYSTEM

Ear	(0)	(0)	(1)	(0)
Canal, External Ear, Inflammation			1 [3.0]	
Eye	(48)	(48)	(46)	(46)
Cataract		2	1	1
Hemorrhage		1 [4.0]		
Phthisis Bulbi		1		
Retina, Degeneration	4 [1.8]	8 [2.9]	3 [2.3]	3 [2.3]

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)

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

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
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Harderian Gland	(48)	(48)	(48)	(48)
Hyperplasia			1 [4.0]	
Infiltration Cellular, Lymphocyte	24 [1.5]	21 [1.3]	18 [1.6]	17 [1.2]
Inflammation	1 [2.0]	1 [2.0]		
Zymbal's Gland	(1)	(0)	(1)	(1)

## URINARY SYSTEM

Kidney	(48)	(48)	(48)	(48)
Hydronephrosis	1 [2.0]			
Infarct	2 [2.5]		2 [2.0]	
Mineralization	40 [2.2]	35 [1.9]	40 [2.1]	35 [1.9]
Nephropathy	47 [2.1]	45 [2.2]	40 [1.8]	40 [1.7]
Cortex, Cyst				1
Cortex, Inflammation, Chronic			1 [3.0]	
Epithelium, Pelvis, Hyperplasia			1 [3.0]	
Renal Tubule, Pigmentation				1 [2.0]
Urinary Bladder	(48)	(48)	(48)	(48)
Dilatation	1			
Inflammation				1 [2.0]

\*\*\* END OF REPORT \*\*\*

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

b-Average severity grade(1-minimal;2-mild;3-moderate;4-marked)