

**TDMS No.** 20116 - 03  
**Test Type:** CHRONIC  
**Route:** DOSED WATER  
**Species/Strain:** RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
Aloe vera whole leaf extract (native)  
**CAS Number:** ALOEVLEAFEXT

**Date Report Requested:** 01/15/2010  
**Time Report Requested:** 14:39:01  
**First Dose M/F:** 04/17/05 / 04/17/05  
**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**

	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>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**

	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Esophagus	(48)	(48)	(48)	(48)
Inflammation	1 (2%)	1 (2%)	1 (2%)	
Ulcer	1 (2%)	1 (2%)	1 (2%)	
Mucosa, Hyperplasia	1 (2%)			
Intestine Large, Ascending Colon	(47)	(47)	(48)	(46)
Hyperplasia				2 (4%)
Inflammation			1 (2%)	2 (4%)
Lymphoid Tissue, Hyperplasia				1 (2%)
Mucosa, Hyperplasia		30 (64%)	38 (79%)	32 (70%)
Intestine Large, Cecum	(46)	(45)	(48)	(48)
Dilatation	1 (2%)		8 (17%)	17 (35%)
Hemorrhage				1 (2%)
Hyperplasia	1 (2%)			
Inflammation	1 (2%)			2 (4%)
Ulcer				1 (2%)
Lymphoid Tissue, Hyperplasia		2 (4%)	3 (6%)	1 (2%)
Mucosa, Hyperplasia		13 (29%)	24 (50%)	25 (52%)
Intestine Large, Colon	(0)	(1)	(3)	(5)
Inflammation			1 (33%)	
Ulcer			1 (33%)	
Mucosa, Hyperplasia		1 (100%)	1 (33%)	4 (80%)
Intestine Large, Descending Colon	(47)	(46)	(46)	(47)
Inflammation			2 (4%)	

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

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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%)		1 (2%)
Mucosa, Hyperplasia		17 (37%)	31 (67%)	30 (64%)
Intestine Large, Rectum	(47)	(47)	(48)	(48)
Mucosa, Hyperplasia		1 (2%)	1 (2%)	4 (8%)
Intestine Large, Transverse Colon	(47)	(47)	(47)	(47)
Hyperplasia				1 (2%)
Inflammation			1 (2%)	
Lymphoid Tissue, Hyperplasia		1 (2%)	2 (4%)	
Mucosa, Hyperplasia		30 (64%)	42 (89%)	34 (72%)
Intestine Small	(0)	(1)	(0)	(0)
Intestine Small, Duodenum	(48)	(46)	(48)	(48)
Mucosa, Hyperplasia	1 (2%)	10 (22%)	3 (6%)	6 (13%)
Intestine Small, Ileum	(45)	(45)	(48)	(48)
Hyperplasia	1 (2%)			
Inflammation	1 (2%)		1 (2%)	
Lymphoid Tissue, Hyperplasia		1 (2%)		2 (4%)
Mucosa, Hyperplasia		3 (7%)	3 (6%)	2 (4%)
Intestine Small, Jejunum	(45)	(44)	(46)	(46)
Inflammation				1 (2%)
Lymphatic, Dilatation			1 (2%)	
Lymphoid Tissue, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Mucosa, Hyperplasia		1 (2%)	2 (4%)	3 (7%)
Liver	(48)	(48)	(48)	(48)
Angiectasis			1 (2%)	1 (2%)
Basophilic Focus			2 (4%)	
Basophilic Focus, Multiple		1 (2%)	1 (2%)	1 (2%)
Cyst Multilocular	1 (2%)			1 (2%)
Degeneration, Cystic	9 (19%)	6 (13%)	2 (4%)	
Eosinophilic Focus	4 (8%)			1 (2%)
Eosinophilic Focus, Multiple	1 (2%)		1 (2%)	
Granuloma	2 (4%)	5 (10%)	6 (13%)	10 (21%)
Hematopoietic Cell Proliferation		1 (2%)	1 (2%)	1 (2%)
Hemorrhage			1 (2%)	
Hepatodiaphragmatic Nodule	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Infiltration Cellular, Lymphocyte		1 (2%)	4 (8%)	3 (6%)
Infiltration Cellular, Polymorphonuclear				1 (2%)

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Aloe vera whole leaf extract (native)

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Necrosis, Coagulative	1 (2%)	2 (4%)		2 (4%)
Regeneration				1 (2%)
Tension Lipidosis				1 (2%)
Vacuolization Cytoplasmic	12 (25%)	14 (29%)	6 (13%)	1 (2%)
Artery, Media, Hypertrophy		1 (2%)		
Bile Duct, Hyperplasia	15 (31%)	16 (33%)	9 (19%)	5 (10%)
Caudate Lobe, Developmental Malformation			1 (2%)	
Centrilobular, Degeneration		1 (2%)	2 (4%)	
Centrilobular, Necrosis	1 (2%)	1 (2%)	1 (2%)	1 (2%)
Hepatocyte, Periportal, Hypertrophy				1 (2%)
Left Lateral Lobe, Developmental Malformation	1 (2%)	2 (4%)	2 (4%)	1 (2%)
Median Lobe, Developmental Malformation				1 (2%)
Periductular, Fibrosis		1 (2%)		
Right Lateral Lobe, Developmental Malformation				1 (2%)
Mesentery	(10)	(10)	(4)	(5)
Accessory Spleen			1 (25%)	
Ectopic Tissue				1 (20%)
Hemorrhage	1 (10%)			
Inflammation			1 (25%)	1 (20%)
Polyarteritis		1 (10%)		1 (20%)
Thrombosis	1 (10%)			1 (20%)
Fat, Necrosis	7 (70%)	6 (60%)	2 (50%)	2 (40%)
Oral Mucosa	(2)	(1)	(2)	(1)
Keratin Cyst			1 (50%)	
Epithelium, Hyperplasia	1 (50%)			
Pancreas	(48)	(48)	(48)	(48)
Infiltration Cellular, Lymphocyte				1 (2%)
Polyarteritis	3 (6%)		3 (6%)	
Acinar Cell, Atrophy	12 (25%)	17 (35%)	19 (40%)	24 (50%)
Proximal Colon	(44)	(44)	(46)	(41)
Hemorrhage				1 (2%)
Hyperplasia, Lymphoid				1 (2%)
Inflammation	1 (2%)	4 (9%)	3 (7%)	1 (2%)
Ulcer		2 (5%)		
Mucosa, Hyperplasia		29 (66%)	36 (78%)	32 (78%)

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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 (2%)		
Sublingual Gland, Infiltration Cellular		1 (2%)		
Stomach, Forestomach	(48)	(47)	(48)	(48)
Edema	1 (2%)	4 (9%)	1 (2%)	
Hyperplasia	10 (21%)	13 (28%)	9 (19%)	2 (4%)
Inflammation	11 (23%)	9 (19%)	5 (10%)	3 (6%)
Perforation		1 (2%)		
Ulcer	3 (6%)	3 (6%)	3 (6%)	1 (2%)
Stomach, Glandular	(48)	(47)	(48)	(48)
Diverticulum		1 (2%)		
Edema	1 (2%)	1 (2%)		1 (2%)
Erosion	1 (2%)			
Inflammation	1 (2%)	3 (6%)	3 (6%)	
Mineralization	1 (2%)			
Ulcer		1 (2%)		
Mucosa, Hyperplasia	1 (2%)	12 (26%)	7 (15%)	11 (23%)
Mucosa, Necrosis, Focal	2 (4%)		1 (2%)	

## CARDIOVASCULAR SYSTEM

Blood Vessel	(48)	(48)	(48)	(48)
Heart	(48)	(48)	(48)	(48)
Cardiomyopathy	34 (71%)	39 (81%)	38 (79%)	32 (67%)
Dilatation			1 (2%)	
Atrium, Dilatation			1 (2%)	
Atrium, Thrombus	6 (13%)	9 (19%)	10 (21%)	4 (8%)
Atrium, Myocardium, Degeneration		1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(48)	(48)	(48)
Accessory Adrenal Cortical Nodule		1 (2%)	1 (2%)	
Angiectasis	2 (4%)	2 (4%)	2 (4%)	2 (4%)
Atrophy	1 (2%)	2 (4%)	1 (2%)	

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FISCHER 344 RATS-NCTR RATS MALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Hyperplasia, Focal	2 (4%)	1 (2%)	2 (4%)	3 (6%)
Hypertrophy, Focal	3 (6%)		8 (17%)	2 (4%)
Necrosis, Coagulative		1 (2%)		
Thrombus				1 (2%)
Vacuolization Cytoplasmic	24 (50%)	22 (46%)	15 (31%)	14 (29%)
Adrenal Medulla	(48)	(47)	(48)	(48)
Angiectasis	3 (6%)	2 (4%)	2 (4%)	3 (6%)
Hyperplasia, Focal	10 (21%)	4 (9%)	3 (6%)	6 (13%)
Islets, Pancreatic	(48)	(48)	(48)	(48)
Hyperplasia		1 (2%)	1 (2%)	
Parathyroid Gland	(47)	(48)	(46)	(48)
Hyperplasia, Focal				1 (2%)
Pituitary Gland	(48)	(48)	(47)	(48)
Angiectasis		2 (4%)	2 (4%)	5 (10%)
Hemorrhage		1 (2%)		1 (2%)
Pars Distalis, Cyst	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Pars Distalis, Hyperplasia	5 (10%)		4 (9%)	5 (10%)
Pars Intermedia, Cyst	1 (2%)	1 (2%)		
Thyroid Gland	(48)	(47)	(48)	(48)
Ultimobranchial Cyst		1 (2%)		
C-cell, Hyperplasia	8 (17%)	7 (15%)	6 (13%)	6 (13%)
Follicular Cell, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	1 (2%)

**GENERAL BODY SYSTEM**

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

Epididymis	(48)	(48)	(48)	(48)
Atrophy		1 (2%)	1 (2%)	
Exfoliated Germ Cell	37 (77%)	27 (56%)	36 (75%)	23 (48%)
Granuloma Sperm			2 (4%)	
Hypospermia	28 (58%)	25 (52%)	27 (56%)	26 (54%)
Inflammation	1 (2%)			1 (2%)

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Preputial Gland	(48)	(48)	(48)	(48)
Atrophy		1 (2%)		1 (2%)
Inflammation	38 (79%)	41 (85%)	39 (81%)	37 (77%)
Duct, Ectasia	6 (13%)	13 (27%)	13 (27%)	9 (19%)
Duct, Hyperplasia		1 (2%)	1 (2%)	
Prostate	(48)	(48)	(48)	(48)
Atrophy		1 (2%)		
Inflammation	34 (71%)	32 (67%)	36 (75%)	27 (56%)
Seminal Vesicle	(48)	(48)	(48)	(48)
Atrophy	4 (8%)	11 (23%)	8 (17%)	6 (13%)
Decreased Secretory Fluid	7 (15%)	8 (17%)	9 (19%)	9 (19%)
Testes	(48)	(48)	(48)	(48)
Granuloma Sperm	1 (2%)			
Inflammation	1 (2%)			
Polyarteritis	1 (2%)		1 (2%)	
Interstitial Cell, Hyperplasia	3 (6%)	2 (4%)	2 (4%)	4 (8%)
Seminiferous Tubule, Atrophy	17 (35%)	11 (23%)	17 (35%)	8 (17%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(48)	(48)	(48)
Atrophy	8 (17%)	3 (6%)	4 (8%)	2 (4%)
Hyperplasia	7 (15%)	8 (17%)	4 (8%)	5 (10%)
Myeloid Cell, Hyperplasia		1 (2%)	1 (2%)	1 (2%)
Lymph Node	(24)	(13)	(19)	(17)
Lumbar, Degeneration, Cystic	4 (17%)	4 (31%)	2 (11%)	1 (6%)
Lumbar, Hyperplasia, Lymphoid		1 (8%)		1 (6%)
Lumbar, Infiltration Cellular, Plasma Cell		1 (8%)		
Mediastinal, Degeneration, Cystic	1 (4%)		1 (5%)	
Mediastinal, Hemorrhage	1 (4%)	2 (15%)	1 (5%)	1 (6%)
Mediastinal, Pigmentation		1 (8%)		
Mediastinal, Medulla, Sinus, Dilatation			1 (5%)	
Medulla, Pancreatic, Sinus, Dilatation	1 (4%)		2 (11%)	
Medulla, Renal, Sinus, Dilatation		1 (8%)		
Medulla, Sinus, Dilatation	1 (4%)			

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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 (5%)	1 (6%)
Pancreatic, Hyperplasia, Lymphoid	1 (4%)	1 (8%)	3 (16%)	2 (12%)
Pancreatic, Infiltration Cellular, Plasma Cell	1 (4%)			
Pancreatic, Pigmentation			1 (5%)	
Renal, Degeneration, Cystic	2 (8%)	1 (8%)	1 (5%)	2 (12%)
Renal, Hemorrhage			1 (5%)	
Renal, Hyperplasia, Lymphoid		2 (15%)		
Renal, Infiltration Cellular, Plasma Cell		1 (8%)		
Renal, Pigmentation			1 (5%)	
Lymph Node, Mandibular	(48)	(48)	(48)	(48)
Atrophy, Lymphocyte	1 (2%)	1 (2%)		
Degeneration, Cystic	11 (23%)	9 (19%)	5 (10%)	5 (10%)
Hematopoietic Cell Proliferation	1 (2%)			
Hemorrhage		1 (2%)		
Hyperplasia, Lymphoid	1 (2%)	2 (4%)	3 (6%)	
Infiltration Cellular, Plasma Cell	9 (19%)	14 (29%)	10 (21%)	11 (23%)
Necrosis, Lymphoid	1 (2%)			
Medulla, Sinus, Dilatation		1 (2%)		1 (2%)
Lymph Node, Mesenteric	(47)	(48)	(48)	(48)
Degeneration, Cystic	8 (17%)	11 (23%)	42 (88%)	41 (85%)
Fibrosis				1 (2%)
Hemorrhage	2 (4%)	2 (4%)		1 (2%)
Hyperplasia, Lymphoid			1 (2%)	4 (8%)
Infiltration Cellular, Plasma Cell	1 (2%)			
Inflammation				1 (2%)
Necrosis, Lymphoid	1 (2%)		1 (2%)	
Medulla, Sinus, Dilatation		4 (8%)	1 (2%)	
Spleen	(48)	(48)	(48)	(48)
Accessory Spleen	1 (2%)		1 (2%)	
Atrophy		2 (4%)		
Congestion	1 (2%)	3 (6%)	2 (4%)	
Fibrosis		1 (2%)	1 (2%)	
Hematopoietic Cell Proliferation	3 (6%)	1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Lymphoid	1 (2%)	1 (2%)		
Hyperplasia, Focal	1 (2%)			
Infarct	6 (13%)	9 (19%)	5 (10%)	1 (2%)

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

Pigmentation	3 (6%)	9 (19%)	3 (6%)	6 (13%)
Thrombus	1 (2%)		1 (2%)	1 (2%)
Capsule, Fibrosis			1 (2%)	
Lymphoid Follicle, Necrosis	1 (2%)			
Red Pulp, Hyperplasia			1 (2%)	
Thymus	(46)	(47)	(44)	(44)
Atrophy	38 (83%)	42 (89%)	39 (89%)	40 (91%)
Cyst	1 (2%)	2 (4%)		
Ectopic Thyroid		1 (2%)		
Hemorrhage				1 (2%)
Epithelial Cell, Hyperplasia			1 (2%)	

INTEGUMENTARY SYSTEM

Mammary Gland	(44)	(46)	(48)	(41)
Galactocoele	9 (20%)	11 (24%)	11 (23%)	10 (24%)
Lactation	23 (52%)	19 (41%)	24 (50%)	10 (24%)
Alveolus, Hyperplasia	12 (27%)	14 (30%)	12 (25%)	6 (15%)
Skin	(48)	(48)	(48)	(48)
Cyst Epithelial Inclusion	1 (2%)	1 (2%)		1 (2%)
Inflammation	1 (2%)	1 (2%)	2 (4%)	
Inflammation, Granulomatous		1 (2%)		
Epidermis, Necrosis	1 (2%)			
Fat, Subcutaneous Tissue, Necrosis			1 (2%)	
Foot, Inflammation, Chronic				1 (2%)
Subcutaneous Tissue, Inflammation, Focal		1 (2%)		
Tail, Hyperkeratosis, Multifocal			1 (2%)	

MUSCULOSKELETAL SYSTEM

Bone	(0)	(2)	(2)	(1)
Cartilage, Sternum, Degeneration				1 (100%)
Cranium, Periosteum, Hemorrhage			1 (50%)	
Bone, Femur	(48)	(48)	(48)	(48)
Osteopetrosis	1 (2%)			

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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 (2%)	1 (2%)	
Hypothalamus, Compression	11 (23%)	10 (21%)	13 (27%)	9 (19%)
Brain, Cerebellum	(48)	(48)	(48)	(48)
Compression			1 (2%)	
Hemorrhage			2 (4%)	
Brain, Cerebrum	(48)	(48)	(48)	(48)
Hemorrhage				1 (2%)
Hydrocephalus			1 (2%)	1 (2%)
Mineralization, Focal			1 (2%)	
Spinal Cord	(1)	(1)	(0)	(3)
Hemorrhage				1 (33%)

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**RESPIRATORY SYSTEM**

Lung	(48)	(48)	(48)	(48)
Granuloma			1 (2%)	1 (2%)
Hemorrhage	1 (2%)			1 (2%)
Infiltration Cellular, Lymphocyte		1 (2%)		
Metaplasia, Osseous				1 (2%)
Alveolar Epithelium, Hyperplasia	2 (4%)	1 (2%)	2 (4%)	1 (2%)
Alveolus, Infiltration Cellular, Histiocyte	3 (6%)	3 (6%)	10 (21%)	6 (13%)
Alveolus, Infiltration Cellular, Lymphocyte			1 (2%)	
Alveolus, Inflammation	2 (4%)		3 (6%)	2 (4%)
Mediastinum, Inflammation			1 (2%)	
Nose	(48)	(48)	(47)	(48)
Foreign Body			1 (2%)	
Fungus	1 (2%)		1 (2%)	
Inflammation	4 (8%)	3 (6%)	4 (9%)	1 (2%)
Goblet Cell, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	2 (4%)

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Trachea	(48)	(48)	(48)	(48)
Mucosa, Cyst		1 (2%)		

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**SPECIAL SENSES SYSTEM**

Eye	(47)	(46)	(47)	(48)
Cataract	2 (4%)			2 (4%)
Phthisis Bulbi				1 (2%)
Retina, Degeneration	5 (11%)	2 (4%)		4 (8%)
Sclera, Metaplasia, Osseous	2 (4%)	1 (2%)	1 (2%)	1 (2%)
Harderian Gland	(48)	(48)	(48)	(48)
Atrophy	1 (2%)			
Infiltration Cellular, Lymphocyte	7 (15%)	11 (23%)	8 (17%)	8 (17%)
Inflammation			1 (2%)	2 (4%)
Lacrimal Gland	(0)	(1)	(0)	(0)
Zymbal's Gland	(0)	(2)	(1)	(0)

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**URINARY SYSTEM**

Kidney	(48)	(48)	(48)	(48)
Hydronephrosis		1 (2%)	1 (2%)	
Nephropathy	48 (100%)	47 (98%)	48 (100%)	45 (94%)
Cortex, Cyst	2 (4%)			1 (2%)
Renal Tubule, Necrosis		1 (2%)		
Urinary Bladder	(48)	(48)	(48)	(48)
Dilatation	1 (2%)	5 (10%)	1 (2%)	2 (4%)
Hemorrhage				1 (2%)
Hyperplasia			1 (2%)	
Inflammation			1 (2%)	

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

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

Lab: NCTR

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

**Disposition Summary**

	CONTROL WATER	ALOEWOLLEAF 0.5	ALOEWOLLEAF 1.0	ALOEWOLLEAF 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	ALOEWOLLEAF 0.5	ALOEWOLLEAF 1.0	ALOEWOLLEAF 1.5
Esophagus	(48)	(47)	(48)	(48)
Inflammation	1 (2%)			
Intestine Large, Ascending Colon	(47)	(48)	(46)	(46)
Dilatation			1 (2%)	1 (2%)
Inflammation		1 (2%)	1 (2%)	2 (4%)
Lymphoid Tissue, Hyperplasia			2 (4%)	2 (4%)
Mucosa, Hyperplasia		40 (83%)	35 (76%)	39 (85%)
Intestine Large, Cecum	(47)	(48)	(47)	(48)
Dilatation			9 (19%)	25 (52%)
Inflammation		1 (2%)	2 (4%)	2 (4%)
Perforation				1 (2%)
Lymphoid Tissue, Hyperplasia		1 (2%)		2 (4%)
Mucosa, Hyperplasia		4 (8%)	17 (36%)	27 (56%)
Intestine Large, Colon	(0)	(0)	(2)	(1)
Inflammation			1 (50%)	
Necrosis			1 (50%)	
Mucosa, Hyperplasia			1 (50%)	
Intestine Large, Descending Colon	(47)	(48)	(46)	(47)
Inflammation			1 (2%)	
Ulcer			1 (2%)	
Mucosa, Hyperplasia		17 (35%)	18 (39%)	27 (57%)
Intestine Large, Rectum	(48)	(48)	(47)	(47)

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010  
 Time Report Requested: 14:39:01  
 First Dose M/F: 04/17/05 / 04/17/05  
 Lab: NCTR

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Polyarteritis		1 (2%)		
Mucosa, Hyperplasia				5 (11%)
Intestine Large, Transverse Colon	(47)	(48)	(46)	(46)
Dilatation			1 (2%)	
Inflammation		1 (2%)	1 (2%)	
Lymphoid Tissue, Hyperplasia		1 (2%)	1 (2%)	
Mucosa, Hyperplasia		40 (83%)	33 (72%)	42 (91%)
Intestine Small, Duodenum	(48)	(48)	(48)	(48)
Inflammation			1 (2%)	1 (2%)
Mucosa, Hyperplasia	1 (2%)	4 (8%)	5 (10%)	2 (4%)
Intestine Small, Ileum	(47)	(48)	(43)	(44)
Inflammation		1 (2%)	1 (2%)	
Lymphoid Tissue, Hyperplasia	1 (2%)	1 (2%)	1 (2%)	
Mucosa, Hyperplasia		2 (4%)	2 (5%)	6 (14%)
Intestine Small, Jejunum	(47)	(48)	(45)	(43)
Inflammation		2 (4%)		
Ulcer		1 (2%)		
Lymphatic, Dilatation		1 (2%)		
Submucosa, Fibrosis		1 (2%)		
Liver	(48)	(48)	(48)	(48)
Angiectasis			1 (2%)	1 (2%)
Basophilic Focus		1 (2%)		1 (2%)
Basophilic Focus, Multiple	22 (46%)	27 (56%)	12 (25%)	13 (27%)
Cyst Multilocular	1 (2%)			
Eosinophilic Focus	5 (10%)	7 (15%)	2 (4%)	1 (2%)
Eosinophilic Focus, Multiple		1 (2%)		1 (2%)
Granuloma	21 (44%)	19 (40%)	20 (42%)	15 (31%)
Hematopoietic Cell Proliferation	1 (2%)			
Hepatodiaphragmatic Nodule	4 (8%)	2 (4%)	4 (8%)	2 (4%)
Infiltration Cellular, Lymphocyte	1 (2%)	3 (6%)	1 (2%)	3 (6%)
Necrosis, Coagulative			2 (4%)	
Regeneration				1 (2%)
Tension Lipidosis			2 (4%)	
Vacuolization Cytoplasmic	6 (13%)	9 (19%)	4 (8%)	5 (10%)
Bile Duct, Hyperplasia	9 (19%)	5 (10%)	6 (13%)	2 (4%)
Caudate Lobe, Developmental Malformation			4 (8%)	1 (2%)

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

Lab: NCTR

FISCHER 344 RATS-NCTR RATS FEMALE	CONTROL WATER	ALOEWHOLLEAF 0.5	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 1.5
Caudate Lobe, Infarct				1 (2%)
Centrilobular, Necrosis				2 (4%)
Left Lateral Lobe, Developmental Malformation	4 (8%)	2 (4%)	3 (6%)	1 (2%)
Left Lateral Lobe, Infarct				1 (2%)
Median Lobe, Developmental Malformation				1 (2%)
Periportal, Inflammation, Chronic			1 (2%)	1 (2%)
Right Lateral Lobe, Developmental Malformation			2 (4%)	
Mesentery	(6)	(9)	(10)	(4)
Polyarteritis		1 (11%)	1 (10%)	
Thrombosis		1 (11%)		
Fat, Necrosis	6 (100%)	8 (89%)	6 (60%)	4 (100%)
Oral Mucosa	(0)	(1)	(1)	(0)
Pancreas	(48)	(48)	(48)	(48)
Accessory Spleen			1 (2%)	
Polyarteritis		1 (2%)	1 (2%)	
Acinar Cell, Atrophy	10 (21%)	11 (23%)	17 (35%)	17 (35%)
Proximal Colon	(43)	(45)	(42)	(39)
Dilatation			1 (2%)	
Foreign Body				1 (3%)
Inflammation		2 (4%)	11 (26%)	8 (21%)
Ulcer		1 (2%)	2 (5%)	1 (3%)
Mucosa, Hyperplasia		30 (67%)	33 (79%)	32 (82%)
Salivary Glands	(48)	(48)	(48)	(48)
Acinar Cell, Atrophy	1 (2%)			
Stomach, Forestomach	(48)	(48)	(48)	(48)
Edema		2 (4%)	2 (4%)	1 (2%)
Hyperplasia	1 (2%)	7 (15%)	10 (21%)	9 (19%)
Inflammation			4 (8%)	3 (6%)
Stomach, Glandular	(48)	(48)	(48)	(48)
Edema		1 (2%)		1 (2%)
Inflammation			1 (2%)	1 (2%)
Ulcer				1 (2%)
Mucosa, Hyperplasia		1 (2%)	3 (6%)	3 (6%)
Mucosa, Necrosis, Focal		1 (2%)		

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

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 (73%)	40 (83%)	32 (67%)	33 (69%)
Atrium, Thrombus			1 (2%)	1 (2%)

ENDOCRINE SYSTEM

	(48)	(48)	(48)	(48)
Adrenal Cortex				
Accessory Adrenal Cortical Nodule			1 (2%)	
Angiectasis	31 (65%)	25 (52%)	20 (42%)	19 (40%)
Atrophy				1 (2%)
Fibrosis, Focal	1 (2%)			
Hemorrhage				1 (2%)
Hyperplasia, Focal		2 (4%)		2 (4%)
Hypertrophy	1 (2%)			
Hypertrophy, Focal	2 (4%)	2 (4%)	6 (13%)	1 (2%)
Necrosis, Coagulative				1 (2%)
Vacuolization Cytoplasmic	6 (13%)	7 (15%)	5 (10%)	6 (13%)
Adrenal Medulla	(47)	(46)	(48)	(47)
Angiectasis	2 (4%)	6 (13%)	1 (2%)	6 (13%)
Hyperplasia, Focal		1 (2%)	1 (2%)	1 (2%)
Islets, Pancreatic	(48)	(48)	(47)	(48)
Parathyroid Gland	(47)	(45)	(46)	(47)
Hyperplasia, Focal	1 (2%)			
Pituitary Gland	(48)	(48)	(48)	(47)
Angiectasis	2 (4%)	1 (2%)		1 (2%)
Pigmentation				1 (2%)
Pars Distalis, Cyst	1 (2%)	5 (10%)	4 (8%)	6 (13%)
Pars Distalis, Hyperplasia	3 (6%)	3 (6%)	2 (4%)	4 (9%)
Pars Intermedia, Cyst			1 (2%)	1 (2%)
Pars Nervosa, Cyst				1 (2%)
Thyroid Gland	(48)	(48)	(48)	(47)
C-cell, Hyperplasia	15 (31%)	13 (27%)	8 (17%)	3 (6%)
Follicular Cell, Hyperplasia				1 (2%)

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

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 (50%)	

GENITAL SYSTEM

Clitoral Gland	(48)	(48)	(48)	(48)
Atrophy				1 (2%)
Hyperplasia			1 (2%)	
Inflammation	33 (69%)	26 (54%)	30 (63%)	30 (63%)
Duct, Ectasia	12 (25%)	15 (31%)	8 (17%)	8 (17%)
Duct, Hyperplasia	2 (4%)		2 (4%)	5 (10%)
Ovary	(48)	(48)	(48)	(48)
Atrophy	47 (98%)	44 (92%)	42 (88%)	47 (98%)
Cyst	2 (4%)	4 (8%)	6 (13%)	4 (8%)
Uterus	(48)	(48)	(48)	(48)
Hyperplasia, Focal	2 (4%)	1 (2%)	2 (4%)	5 (10%)
Hypoplasia	1 (2%)			
Inflammation	1 (2%)	2 (4%)		2 (4%)
Adventitia, Inflammation			1 (2%)	
Bilateral, Horn, Dilatation				1 (2%)
Cervix, Mucocyte, Metaplasia	1 (2%)	1 (2%)		
Cervix, Muscularis, Hyperplasia		1 (2%)		
Cervix, Muscularis, Hypertrophy	1 (2%)	1 (2%)	1 (2%)	
Endometrium, Hyperplasia, Cystic	10 (21%)	16 (33%)	8 (17%)	12 (25%)
Horn, Dilatation	1 (2%)	2 (4%)	1 (2%)	
Vagina	(4)	(3)	(2)	(4)
Dilatation	1 (25%)	1 (33%)	1 (50%)	
Inflammation, Suppurative	1 (25%)			3 (75%)
Mucocyte, Hyperplasia	3 (75%)	1 (33%)	2 (100%)	4 (100%)

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TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

Lab: NCTR

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

HEMATOPOIETIC SYSTEM

Bone Marrow	(48)	(48)	(48)	(47)
Atrophy		2 (4%)	1 (2%)	
Hyperplasia	1 (2%)	4 (8%)	3 (6%)	1 (2%)
Proliferation				1 (2%)
Myeloid Cell, Hyperplasia			3 (6%)	1 (2%)
Lymph Node	(9)	(7)	(8)	(9)
Degeneration, Cystic			2 (25%)	
Lumbar, Degeneration, Cystic	2 (22%)			
Lumbar, Hyperplasia, Lymphoid	1 (11%)			
Mediastinal, Hemorrhage		1 (14%)	2 (25%)	
Mediastinal, Hyperplasia, Lymphoid				1 (11%)
Mediastinal, Polyarteritis		1 (14%)		
Mediastinal, Medulla, Sinus, Dilatation		1 (14%)		
Medulla, Pancreatic, Sinus, Dilatation				1 (11%)
Pancreatic, Degeneration, Cystic				1 (11%)
Pancreatic, Hemorrhage			1 (13%)	
Pancreatic, Hyperplasia, Lymphoid		1 (14%)		1 (11%)
Lymph Node, Mandibular	(48)	(47)	(48)	(47)
Cyst	2 (4%)	1 (2%)		
Degeneration, Cystic	2 (4%)	3 (6%)	3 (6%)	4 (9%)
Hyperplasia, Lymphoid	1 (2%)			1 (2%)
Infiltration Cellular, Plasma Cell	7 (15%)	9 (19%)	9 (19%)	4 (9%)
Medulla, Sinus, Dilatation	2 (4%)			2 (4%)
Lymph Node, Mesenteric	(46)	(47)	(48)	(47)
Amyloid Deposition			1 (2%)	1 (2%)
Atrophy, Lymphocyte				4 (9%)
Degeneration, Cystic		16 (34%)	40 (83%)	43 (91%)
Fibrosis				1 (2%)
Hemorrhage	3 (7%)	3 (6%)	1 (2%)	
Hyperplasia, Lymphoid		2 (4%)	2 (4%)	3 (6%)
Medulla, Sinus, Dilatation	1 (2%)	3 (6%)	1 (2%)	1 (2%)
Spleen	(48)	(48)	(48)	(48)
Accessory Spleen	2 (4%)	1 (2%)		
Atrophy	1 (2%)	1 (2%)	1 (2%)	2 (4%)

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

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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Fibrosis	1 (2%)			
Hematopoietic Cell Proliferation	4 (8%)	1 (2%)	1 (2%)	1 (2%)
Hyperplasia, Focal	1 (2%)	5 (10%)	1 (2%)	1 (2%)
Infarct	1 (2%)	2 (4%)		3 (6%)
Pigmentation	7 (15%)	6 (13%)	5 (10%)	6 (13%)
Thrombus	2 (4%)			
Red Pulp, Hyperplasia		3 (6%)		
Thymus	(46)	(45)	(45)	(44)
Atrophy	43 (93%)	44 (98%)	40 (89%)	42 (95%)
Cyst		1 (2%)		1 (2%)
Hemorrhage	1 (2%)			

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**INTEGUMENTARY SYSTEM**

Mammary Gland	(47)	(48)	(48)	(47)
Galactocele	3 (6%)	1 (2%)	3 (6%)	5 (11%)
Lactation	27 (57%)	28 (58%)	24 (50%)	23 (49%)
Alveolus, Hyperplasia	27 (57%)	38 (79%)	28 (58%)	22 (47%)
Alveolus, Hypertrophy	1 (2%)			
Skin	(48)	(48)	(48)	(48)
Cyst Epithelial Inclusion			1 (2%)	
Inflammation		1 (2%)		
Epidermis, Hyperplasia	1 (2%)			1 (2%)
Epidermis, Necrosis	1 (2%)	1 (2%)		1 (2%)
Foot, Hyperkeratosis	1 (2%)			

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**MUSCULOSKELETAL SYSTEM**

Bone	(0)	(2)	(0)	(0)
Cervical, Vertebra, Fracture		2 (100%)		
Bone, Femur	(48)	(48)	(48)	(48)
Fibrous Osteodystrophy		1 (2%)		
Osteopetrosis	8 (17%)	3 (6%)	4 (8%)	5 (10%)
Skeletal Muscle	(0)	(3)	(0)	(2)
Polyarteritis		1 (33%)		

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
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 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

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Lab: NCTR

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<b>FISCHER 344 RATS-NCTR RATS FEMALE</b>	<b>CONTROL WATER</b>	<b>ALOEWHOLLEAF 0.5</b>	<b>ALOEWHOLLEAF 1.0</b>	<b>ALOEWHOLLEAF 1.5</b>
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Diaphragm, Inflammation		1 (33%)		
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**NERVOUS SYSTEM**

Brain, Brain Stem	(48)	(48)	(48)	(48)
Hypothalamus, Compression	13 (27%)	14 (29%)	8 (17%)	8 (17%)
Brain, Cerebellum	(48)	(48)	(48)	(48)
Brain, Cerebrum	(48)	(48)	(48)	(48)
Hemorrhage			1 (2%)	
Hydrocephalus	1 (2%)	1 (2%)		

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**RESPIRATORY SYSTEM**

Lung	(48)	(48)	(48)	(48)
Granuloma	6 (13%)	4 (8%)	4 (8%)	3 (6%)
Hemorrhage		2 (4%)	1 (2%)	
Alveolar Epithelium, Hyperplasia	4 (8%)	2 (4%)	1 (2%)	
Alveolus, Infiltration Cellular, Histiocyte	13 (27%)	8 (17%)	9 (19%)	11 (23%)
Alveolus, Inflammation	3 (6%)	4 (8%)	2 (4%)	
Artery, Mineralization			1 (2%)	
Nose	(48)	(48)	(48)	(48)
Inflammation	1 (2%)	6 (13%)	8 (17%)	2 (4%)
Osteopetrosis	1 (2%)	2 (4%)	1 (2%)	2 (4%)
Goblet Cell, Hyperplasia		1 (2%)	1 (2%)	

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**SPECIAL SENSES SYSTEM**

Ear	(0)	(0)	(1)	(0)
Canal, External Ear, Inflammation			1 (100%)	
Eye	(48)	(48)	(46)	(46)
Cataract		2 (4%)	1 (2%)	1 (2%)
Hemorrhage		1 (2%)		
Phthisis Bulbi		1 (2%)		
Retina, Degeneration	4 (8%)	8 (17%)	3 (7%)	3 (7%)

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

TDMS No. 20116 - 03  
 Test Type: CHRONIC  
 Route: DOSED WATER  
 Species/Strain: RATS/F 344/NCTR

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 01/15/2010

Time Report Requested: 14:39:01

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

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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Harderian Gland	(48)	(48)	(48)	(48)
Hyperplasia			1 (2%)	
Infiltration Cellular, Lymphocyte	24 (50%)	21 (44%)	18 (38%)	17 (35%)
Inflammation	1 (2%)	1 (2%)		
Zymbal's Gland	(1)	(0)	(1)	(1)

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URINARY SYSTEM

Kidney	(48)	(48)	(48)	(48)
Hydronephrosis	1 (2%)			
Infarct	2 (4%)		2 (4%)	
Mineralization	40 (83%)	35 (73%)	40 (83%)	35 (73%)
Nephropathy	47 (98%)	45 (94%)	40 (83%)	40 (83%)
Cortex, Cyst				1 (2%)
Cortex, Inflammation, Chronic			1 (2%)	
Epithelium, Pelvis, Hyperplasia			1 (2%)	
Renal Tubule, Pigmentation				1 (2%)
Urinary Bladder	(48)	(48)	(48)	(48)
Dilatation	1 (2%)			
Inflammation				1 (2%)

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

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