

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	ALOEWOLLEAF 0.5	ALOEWOLLEAF 1.0	ALOEWOLLEAF 1.5
Animals Initially In Study	48	48	48	48
Early Deaths				
Moribund Sacrifice	28	26	23	26
Natural Death	2	5	2	4
Survivors				
Moribund Sacrifice	3		4	3
Terminal Sacrifice	15	17	19	15
Animals Examined Microscopically	48	48	48	48

ALIMENTARY SYSTEM

	CONTROL WATER	ALOEWOLLEAF 0.5	ALOEWOLLEAF 1.0	ALOEWOLLEAF 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%)	

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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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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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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)
Galactocele	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%)

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%)		

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)

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%)	

*** 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
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

	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)

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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%)

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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
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%)		

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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)

CAS Number: ALOEVLEAFEXT

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Lab: NCTR

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

Heart	(48)	(48)	(48)	(48)
Cardiomyopathy	35 (73%)	40 (83%)	32 (67%)	33 (69%)
Atrium, Thrombus			1 (2%)	1 (2%)

ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(48)	(48)	(48)
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%)

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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)
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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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%)

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

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%)			

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%)		

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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 (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%)		

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%)	

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%)

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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)

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%)

*** END OF REPORT ***

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