

TDMS No. 20116 - 04
Test Type: CHRONIC
Route: DOSED WATER
Species/Strain: MICE/B6C3F1/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: 14:39:08
First Dose M/F: 04/19/05 / 04/19/05
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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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE CONTROL WATER ALOEWHOLLEAF 1.0 ALOEWHOLLEAF 2.0 ALOEWHOLLEAF 3.0

Disposition Summary

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
Animals Initially In Study	48	48	48	48
Early Deaths				
Moribund Sacrifice	16	16	23	15
Natural Death		2	4	4
Survivors				
Natural Death	1	1		1
Terminal Sacrifice	31	28	21	28
Animals Examined Microscopically	48	47	48	48

ALIMENTARY SYSTEM

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
Esophagus	(48)	(46)	(47)	(47)
Gallbladder	(46)	(43)	(45)	(43)
Intestine Large, Ascending Colon	(47)	(44)	(45)	(42)
Goblet Cell, Hyperplasia	2 (4%)	16 (36%)	20 (44%)	19 (45%)
Intestine Large, Cecum	(47)	(44)	(44)	(43)
Hyperplasia, Lymphoid	2 (4%)			
Goblet Cell, Hyperplasia				1 (2%)
Intestine Large, Descending Colon	(47)	(44)	(45)	(43)
Goblet Cell, Hyperplasia		7 (16%)	12 (27%)	17 (40%)
Intestine Large, Transverse Colon	(47)	(44)	(45)	(43)
Goblet Cell, Hyperplasia	4 (9%)	14 (32%)	21 (47%)	22 (51%)
Intestine Small, Duodenum	(47)	(44)	(44)	(44)
Intestine Small, Ileum	(47)	(44)	(45)	(43)
Hyperplasia, Lymphoid	1 (2%)			
Intestine Small, Jejunum	(47)	(44)	(43)	(43)
Hyperplasia, Lymphoid			1 (2%)	1 (2%)
Liver	(47)	(46)	(47)	(46)
Angiectasis				1 (2%)
Basophilic Focus	8 (17%)	6 (13%)	5 (11%)	5 (11%)
Basophilic Focus, Multiple				1 (2%)
Congestion	1 (2%)			
Cyst	1 (2%)			1 (2%)
Deformity	1 (2%)			

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

C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Degeneration, Cystic	1 (2%)			
Eosinophilic Focus	1 (2%)			
Fatty Change	1 (2%)			
Infiltration Cellular, Lymphocyte	1 (2%)	1 (2%)	2 (4%)	4 (9%)
Infiltration Cellular, Polymorphonuclear				1 (2%)
Inflammation, Chronic Active	1 (2%)	1 (2%)	1 (2%)	3 (7%)
Karyomegaly				1 (2%)
Mixed Cell Focus	3 (6%)			
Necrosis		1 (2%)	1 (2%)	1 (2%)
Tension Lipidosis		7 (15%)	4 (9%)	2 (4%)
Thrombus		1 (2%)		
Vacuolization Cytoplasmic	3 (6%)	2 (4%)	2 (4%)	2 (4%)
Mesentery	(0)	(4)	(2)	(4)
Fat, Necrosis		4 (100%)	2 (100%)	3 (75%)
Pancreas	(47)	(46)	(47)	(45)
Infiltration Cellular, Lymphocyte	2 (4%)	3 (7%)	1 (2%)	4 (9%)
Vacuolization Cytoplasmic	1 (2%)	2 (4%)	3 (6%)	1 (2%)
Acinus, Degeneration	3 (6%)	2 (4%)		
Duct, Dilatation			1 (2%)	
Salivary Glands	(48)	(45)	(46)	(45)
Infiltration Cellular, Lymphocyte	39 (81%)	31 (69%)	23 (50%)	29 (64%)
Stomach, Forestomach	(47)	(45)	(45)	(44)
Epithelium, Hyperplasia	1 (2%)			
Stomach, Glandular	(47)	(44)	(45)	(45)
Inflammation, Chronic Active			1 (2%)	1 (2%)
Epithelium, Hyperplasia	1 (2%)	2 (5%)	3 (7%)	2 (4%)

CARDIOVASCULAR SYSTEM

Blood Vessel	(48)	(47)	(47)	(47)
Heart	(48)	(47)	(47)	(47)
Cardiomyopathy	2 (4%)		2 (4%)	1 (2%)
Inflammation, Chronic Active	1 (2%)			

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

ENDOCRINE SYSTEM

Adrenal Cortex	(48)	(44)	(46)	(45)
Accessory Adrenal Cortical Nodule	3 (6%)			1 (2%)
Cyst				1 (2%)
Hematopoietic Cell Proliferation			1 (2%)	
Hypertrophy		1 (2%)		1 (2%)
Mineralization	1 (2%)			
Subcapsular, Hyperplasia	43 (90%)	34 (77%)	32 (70%)	35 (78%)
Adrenal Medulla	(47)	(44)	(46)	(44)
Hyperplasia	4 (9%)	2 (5%)	5 (11%)	4 (9%)
Islets, Pancreatic	(47)	(46)	(46)	(45)
Hyperplasia	9 (19%)	3 (7%)	1 (2%)	2 (4%)
Parathyroid Gland	(44)	(46)	(42)	(41)
Cyst	1 (2%)			
Infiltration Cellular, Lymphocyte			1 (2%)	
Pituitary Gland	(48)	(45)	(45)	(45)
Pars Distalis, Cyst		1 (2%)	4 (9%)	3 (7%)
Pars Intermedia, Hyperplasia	1 (2%)			
Thyroid Gland	(47)	(46)	(47)	(45)
Cyst		1 (2%)		
Ectopic Thymus	1 (2%)			
Infiltration Cellular, Lymphocyte	1 (2%)	3 (7%)	1 (2%)	3 (7%)
Inflammation, Chronic Active			2 (4%)	
Follicle, Degeneration	6 (13%)	6 (13%)	3 (6%)	4 (9%)
Follicular Cell, Hyperplasia		1 (2%)		

GENERAL BODY SYSTEM

Tissue NOS	(1)	(1)	(3)	(0)
Cyst			1 (33%)	

GENITAL SYSTEM

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C57BL/6N XC3H/HEN MTV-NCTR MICE MALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Coagulating Gland	(1)	(1)	(0)	(0)
Lumen, Dilatation	1 (100%)			
Epididymis	(48)	(44)	(46)	(45)
Atrophy			1 (2%)	
Degeneration	1 (2%)			
Fibrosis			1 (2%)	
Hypospermia	1 (2%)	2 (5%)	2 (4%)	
Infiltration Cellular, Lymphocyte		2 (5%)		
Inflammation, Chronic Active				1 (2%)
Spermatocoele		1 (2%)	1 (2%)	
Serosa, Hyperplasia				1 (2%)
Penis	(0)	(1)	(0)	(0)
Inflammation, Chronic Active		1 (100%)		
Necrosis		1 (100%)		
Ulcer		1 (100%)		
Preputial Gland	(47)	(44)	(46)	(45)
Cyst	4 (9%)	6 (14%)	5 (11%)	4 (9%)
Degeneration	15 (32%)	11 (25%)	10 (22%)	17 (38%)
Infiltration Cellular, Lymphocyte	3 (6%)	4 (9%)	4 (9%)	5 (11%)
Inflammation, Suppurative	2 (4%)	6 (14%)	6 (13%)	1 (2%)
Inflammation, Chronic Active	1 (2%)	4 (9%)	4 (9%)	
Bilateral, Cyst			1 (2%)	
Duct, Ectasia	3 (6%)	6 (14%)	3 (7%)	
Fat, Necrosis	1 (2%)		1 (2%)	1 (2%)
Prostate	(47)	(44)	(46)	(44)
Infiltration Cellular, Lymphocyte	7 (15%)	7 (16%)	6 (13%)	6 (14%)
Inflammation, Suppurative			1 (2%)	
Inflammation, Chronic Active				1 (2%)
Seminal Vesicle	(48)	(44)	(47)	(44)
Atrophy			1 (2%)	
Infiltration Cellular, Lymphocyte		1 (2%)		
Inflammation, Suppurative			1 (2%)	
Inflammation, Chronic Active	1 (2%)			
Lumen, Dilatation	5 (10%)	4 (9%)	4 (9%)	5 (11%)
Testes	(47)	(44)	(45)	(44)
Interstitial Cell, Hyperplasia		1 (2%)		1 (2%)

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Seminiferous Tubule, Degeneration 4 (9%) 4 (9%) 11 (24%) 3 (7%)

HEMATOPOIETIC SYSTEM

Bone Marrow	(47)	(45)	(47)	(45)
Hyperplasia	8 (17%)	9 (20%)	13 (28%)	7 (16%)
Lymph Node	(11)	(5)	(9)	(7)
Axillary, Hyperplasia, Lymphoid	3 (27%)		2 (22%)	1 (14%)
Axillary, Infiltration Cellular, Plasma Cell			1 (11%)	
Inguinal, Hyperplasia, Lymphoid	2 (18%)		3 (33%)	1 (14%)
Inguinal, Infiltration Cellular, Plasma Cell		1 (20%)	2 (22%)	1 (14%)
Lumbar, Erythrophagocytosis				1 (14%)
Lumbar, Hyperplasia, Lymphoid		1 (20%)		1 (14%)
Lumbar, Infiltration Cellular, Plasma Cell				1 (14%)
Mediastinal, Hyperplasia, Lymphoid	2 (18%)			
Mediastinal, Infiltration Cellular, Plasma Cell	1 (9%)			
Pancreatic, Erythrophagocytosis				1 (14%)
Pancreatic, Infiltration Cellular, Plasma Cell				1 (14%)
Renal, Erythrophagocytosis				1 (14%)
Renal, Hyperplasia, Lymphoid	1 (9%)		1 (11%)	
Renal, Infiltration Cellular, Plasma Cell			1 (11%)	1 (14%)
Lymph Node, Mandibular	(47)	(44)	(45)	(44)
Hyperplasia, Lymphoid	9 (19%)	5 (11%)	4 (9%)	2 (5%)
Infiltration Cellular, Plasma Cell		1 (2%)	1 (2%)	1 (2%)
Pigmentation		1 (2%)		
Lymph Node, Mesenteric	(48)	(45)	(45)	(43)
Angiectasis	5 (10%)	1 (2%)	2 (4%)	1 (2%)
Hematopoietic Cell Proliferation	1 (2%)			1 (2%)
Hemorrhage	10 (21%)	13 (29%)	10 (22%)	11 (26%)
Hyperplasia, Lymphoid	28 (58%)	17 (38%)	17 (38%)	23 (53%)
Infiltration Cellular, Histiocyte			2 (4%)	4 (9%)
Infiltration Cellular, Plasma Cell				2 (5%)
Infiltration Cellular, Polymorphonuclear		1 (2%)	2 (4%)	1 (2%)
Thrombus		1 (2%)		1 (2%)
Sinus, Dilatation	6 (13%)	2 (4%)	4 (9%)	2 (5%)

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Spleen	(48)	(45)	(46)	(44)
Angiectasis	1 (2%)		1 (2%)	
Depletion Lymphoid			1 (2%)	
Hematopoietic Cell Proliferation	20 (42%)	15 (33%)	18 (39%)	14 (32%)
Hyperplasia, Lymphoid	24 (50%)	21 (47%)	20 (43%)	22 (50%)
Pigmentation			1 (2%)	
Thymus	(41)	(39)	(37)	(40)
Atrophy	22 (54%)	19 (49%)	17 (46%)	23 (58%)
Hyperplasia, Lymphoid	2 (5%)	1 (3%)		1 (3%)
Mineralization			1 (3%)	

INTEGUMENTARY SYSTEM

Skin	(48)	(47)	(46)	(48)
Fibrosis		1 (2%)	4 (9%)	
Hemorrhage				1 (2%)
Hyperplasia, Basal Cell			1 (2%)	
Inflammation, Suppurative	1 (2%)	2 (4%)	3 (7%)	1 (2%)
Inflammation, Chronic			1 (2%)	
Inflammation, Chronic Active	1 (2%)	3 (6%)	4 (9%)	2 (4%)
Metaplasia, Osseous			1 (2%)	
Mineralization	1 (2%)	1 (2%)	1 (2%)	
Necrosis				1 (2%)
Ulcer	1 (2%)		4 (9%)	3 (6%)
Epithelium, Hyperplasia	1 (2%)	6 (13%)	4 (9%)	4 (8%)

MUSCULOSKELETAL SYSTEM

Skeletal Muscle	(1)	(1)	(3)	(0)
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NERVOUS SYSTEM

Brain, Cerebrum	(47)	(46)	(46)	(43)
Mineralization	29 (62%)	24 (52%)	24 (52%)	24 (56%)

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

CONTROL WATER

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 2.0

ALOEWHOLLEAF 3.0

RESPIRATORY SYSTEM

Lung	(48)	(47)	(46)	(47)
Congestion		1 (2%)		
Infiltration Cellular, Histiocyte	5 (10%)		2 (4%)	
Infiltration Cellular, Lymphocyte				1 (2%)
Inflammation, Chronic Active	1 (2%)			
Thrombus		1 (2%)		
Alveolar Epithelium, Hyperplasia		5 (11%)	4 (9%)	2 (4%)
Nose	(48)	(47)	(47)	(47)
Hyaline Droplet	6 (13%)	31 (66%)	39 (83%)	13 (28%)
Posterior To Upper Incisor, Dysplasia	1 (2%)		1 (2%)	
Trachea	(48)	(47)	(46)	(45)

SPECIAL SENSES SYSTEM

Eye	(47)	(43)	(44)	(43)
Cataract			1 (2%)	1 (2%)
Cornea, Hyperplasia		1 (2%)		
Cornea, Inflammation, Chronic Active		1 (2%)		
Harderian Gland	(48)	(44)	(46)	(44)
Infiltration Cellular, Lymphocyte	1 (2%)	2 (5%)	3 (7%)	2 (5%)
Inflammation, Chronic Active				1 (2%)
Acinus, Degeneration		1 (2%)		1 (2%)
Acinus, Dilatation				1 (2%)
Epithelium, Hyperplasia			1 (2%)	

URINARY SYSTEM

Kidney	(48)	(45)	(46)	(45)
Cyst		3 (7%)	2 (4%)	
Cyst Multilocular				1 (2%)
Fibrosis			1 (2%)	

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Hyaline Droplet			3 (7%)	
Infiltration Cellular, Lymphocyte	10 (21%)	8 (18%)	10 (22%)	12 (27%)
Inflammation, Chronic Active				1 (2%)
Metaplasia, Osseous	2 (4%)		2 (4%)	
Nephropathy	26 (54%)	18 (40%)	17 (37%)	20 (44%)
Pigmentation			1 (2%)	
Pelvis, Dilatation		1 (2%)	1 (2%)	
Urethra	(1)	(0)	(0)	(1)
Bulbourethral Gland, Dilatation	1 (100%)			
Bulbourethral Gland, Infiltration Cellular, Lymphocyte	1 (100%)			
Urinary Bladder	(48)	(45)	(45)	(44)
Infiltration Cellular, Lymphocyte	3 (6%)	2 (4%)	2 (4%)	2 (5%)
Inflammation, Chronic Active				1 (2%)
Lumen, Dilatation	3 (6%)	1 (2%)	1 (2%)	1 (2%)

*** END OF MALE ***

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Disposition Summary

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
Animals Initially In Study	48	48	48	48
Early Deaths				
Moribund Sacrifice	6	12	8	6
Natural Death	5	4	3	5
Survivors				
Moribund Sacrifice	1	1		1
Natural Death		1	1	2
Terminal Sacrifice	35	30	36	34
Animals Examined Microscopically	47	48	48	48

ALIMENTARY SYSTEM

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
Gallbladder	(42)	(43)	(44)	(41)
Intestine Large, Ascending Colon	(43)	(43)	(44)	(43)
Goblet Cell, Hyperplasia	1 (2%)	15 (35%)	20 (45%)	25 (58%)
Intestine Large, Cecum	(42)	(43)	(44)	(42)
Hyperplasia, Lymphoid	1 (2%)			
Goblet Cell, Hyperplasia	1 (2%)		2 (5%)	2 (5%)
Intestine Large, Descending Colon	(43)	(43)	(44)	(43)
Goblet Cell, Hyperplasia		4 (9%)	7 (16%)	17 (40%)
Intestine Large, Rectum	(43)	(43)	(44)	(42)
Intestine Large, Transverse Colon	(42)	(42)	(44)	(43)
Goblet Cell, Hyperplasia	2 (5%)	18 (43%)	23 (52%)	26 (60%)
Intestine Small, Duodenum	(43)	(43)	(44)	(42)
Intestine Small, Ileum	(42)	(43)	(44)	(42)
Hyperplasia, Lymphoid			1 (2%)	1 (2%)
Intestine Small, Jejunum	(42)	(43)	(44)	(42)
Liver	(45)	(44)	(46)	(46)
Autolysis				1 (2%)
Basophilic Focus	1 (2%)		1 (2%)	4 (9%)
Clear Cell Focus		1 (2%)		
Cyst, Multiple				1 (2%)
Cytomegaly		1 (2%)		
Eosinophilic Focus	1 (2%)			1 (2%)

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)		2 (4%)
Infiltration Cellular, Lymphocyte	10 (22%)	6 (14%)	6 (13%)	9 (20%)
Inflammation, Chronic Active	6 (13%)	5 (11%)	4 (9%)	5 (11%)
Mixed Cell Focus	1 (2%)		1 (2%)	1 (2%)
Necrosis	3 (7%)	2 (5%)	2 (4%)	3 (7%)
Pigmentation	1 (2%)		1 (2%)	
Tension Lipidosis	7 (16%)	5 (11%)	2 (4%)	5 (11%)
Vacuolization Cytoplasmic	12 (27%)	14 (32%)	12 (26%)	16 (35%)
Bile Duct, Hyperplasia		1 (2%)		
Oval Cell, Hyperplasia	1 (2%)			
Parenchyma, Degeneration			1 (2%)	
Mesentery	(6)	(8)	(9)	(3)
Angiectasis			1 (11%)	
Infiltration Cellular, Lymphocyte			1 (11%)	
Inflammation, Chronic Active			1 (11%)	
Fat, Hemorrhage	1 (17%)			1 (33%)
Fat, Infiltration Cellular, Histiocyte				1 (33%)
Fat, Necrosis	6 (100%)	8 (100%)	8 (89%)	2 (67%)
Oral Mucosa	(1)	(0)	(0)	(0)
Pancreas	(42)	(43)	(44)	(43)
Cyst				1 (2%)
Hemorrhage				1 (2%)
Infiltration Cellular, Lymphocyte	11 (26%)	4 (9%)	13 (30%)	15 (35%)
Vacuolization Cytoplasmic	1 (2%)	2 (5%)		
Acinus, Degeneration	1 (2%)	1 (2%)	1 (2%)	
Duct, Dilatation			1 (2%)	1 (2%)
Salivary Glands	(43)	(43)	(44)	(43)
Infiltration Cellular, Lymphocyte	29 (67%)	31 (72%)	31 (70%)	26 (60%)
Stomach, Forestomach	(43)	(44)	(45)	(42)
Keratin Cyst	1 (2%)	1 (2%)		
Epithelium, Hyperplasia		2 (5%)	1 (2%)	1 (2%)
Stomach, Glandular	(43)	(44)	(45)	(42)
Cyst	1 (2%)			
Erosion				1 (2%)
Inflammation, Chronic Active		1 (2%)		
Epithelium, Hyperplasia		1 (2%)	3 (7%)	4 (10%)

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

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

CONTROL WATER

ALOEWHOLLEAF 1.0

ALOEWHOLLEAF 2.0

ALOEWHOLLEAF 3.0

CARDIOVASCULAR SYSTEM

Heart	(45)	(46)	(46)	(44)
Cardiomyopathy	4 (9%)	2 (4%)	3 (7%)	
Inflammation, Chronic Active			1 (2%)	
Mineralization	1 (2%)			

ENDOCRINE SYSTEM

Adrenal Cortex	(44)	(43)	(44)	(44)
Vacuolization Cytoplasmic	4 (9%)	4 (9%)	1 (2%)	1 (2%)
Subcapsular, Hyperplasia	43 (98%)	43 (100%)	43 (98%)	44 (100%)
Adrenal Medulla	(44)	(42)	(44)	(44)
Hyperplasia	1 (2%)		1 (2%)	
Pigmentation				1 (2%)
Islets, Pancreatic	(42)	(43)	(44)	(43)
Hyperplasia	1 (2%)	5 (12%)	1 (2%)	2 (5%)
Parathyroid Gland	(42)	(37)	(42)	(40)
Cyst		1 (3%)	1 (2%)	
Infiltration Cellular, Lymphocyte				1 (3%)
Pituitary Gland	(43)	(38)	(41)	(44)
Thrombus			1 (2%)	
Pars Distalis, Angiectasis			1 (2%)	1 (2%)
Pars Distalis, Cyst			1 (2%)	2 (5%)
Pars Distalis, Hyperplasia	7 (16%)	8 (21%)	10 (24%)	11 (25%)
Pars Intermedia, Angiectasis			1 (2%)	
Thyroid Gland	(43)	(43)	(44)	(43)
Cyst		1 (2%)	1 (2%)	
Ectopic Thymus	2 (5%)	1 (2%)		
Infiltration Cellular, Lymphocyte	3 (7%)	1 (2%)	2 (5%)	6 (14%)
Inflammation, Suppurative				1 (2%)
Inflammation, Chronic Active			1 (2%)	
Follicle, Degeneration	6 (14%)	10 (23%)	9 (20%)	6 (14%)
Follicular Cell, Hyperplasia	3 (7%)	1 (2%)	1 (2%)	

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

TDMS No. 20116 - 04
 Test Type: CHRONIC
 Route: DOSED WATER
 Species/Strain: MICE/B6C3F1/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: 14:39:08

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

Lab: NCTR

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

Follicular Cell, Hypertrophy 1 (2%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland	(44)	(44)	(44)	(42)
Degeneration	43 (98%)	44 (100%)	43 (98%)	40 (95%)
Ovary	(44)	(46)	(45)	(44)
Atrophy	40 (91%)	39 (85%)	40 (89%)	39 (89%)
Autolysis		1 (2%)		
Cyst	14 (32%)	18 (39%)	12 (27%)	9 (20%)
Cyst, Multiple	1 (2%)		2 (4%)	2 (5%)
Hemorrhage			1 (2%)	
Uterus	(46)	(45)	(44)	(45)
Angiectasis			1 (2%)	
Autolysis	1 (2%)			1 (2%)
Edema	1 (2%)			
Hydrometra		1 (2%)		1 (2%)
Thrombus		1 (2%)	1 (2%)	1 (2%)
Endometrium, Hyperplasia, Cystic	43 (93%)	44 (98%)	43 (98%)	43 (96%)
Lumen, Dilatation	1 (2%)			

HEMATOPOIETIC SYSTEM

Bone Marrow	(43)	(43)	(44)	(43)
Fibrosis	1 (2%)			
Hyperplasia	7 (16%)	5 (12%)	5 (11%)	3 (7%)
Lymph Node	(14)	(15)	(12)	(13)
Axillary, Infiltration Cellular, Polymorphonuclear		1 (7%)		
Iliac, Hyperplasia, Lymphoid				1 (8%)
Iliac, Infiltration Cellular, Plasma Cell				1 (8%)

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TDMS No. 20116 - 04
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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: 14:39:08

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

Lab: NCTR

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Iliac, Infiltration Cellular, Polymorphonuclear				1 (8%)
Lumbar, Hemorrhage				2 (15%)
Lumbar, Hyperplasia, Lymphoid	3 (21%)		1 (8%)	5 (38%)
Lumbar, Infiltration Cellular, Plasma Cell	1 (7%)		1 (8%)	
Lumbar, Infiltration Cellular, Polymorphonuclear	2 (14%)	1 (7%)		
Lumbar, Sinus, Dilatation				1 (8%)
Renal, Hemorrhage				1 (8%)
Renal, Hyperplasia, Lymphoid	2 (14%)			1 (8%)
Renal, Infiltration Cellular, Polymorphonuclear	2 (14%)			
Lymph Node, Mandibular	(43)	(44)	(45)	(43)
Amyloid Deposition		1 (2%)		
Hyperplasia, Lymphoid	11 (26%)	13 (30%)	12 (27%)	14 (33%)
Infiltration Cellular, Lymphocyte		1 (2%)		
Infiltration Cellular, Plasma Cell	1 (2%)	2 (5%)		
Infiltration Cellular, Polymorphonuclear	1 (2%)		1 (2%)	
Lymph Node, Mesenteric	(43)	(45)	(43)	(42)
Amyloid Deposition		1 (2%)		
Angiectasis	1 (2%)		1 (2%)	
Hemorrhage		1 (2%)		2 (5%)
Hyperplasia, Lymphoid	10 (23%)	12 (27%)	14 (33%)	16 (38%)
Infiltration Cellular, Plasma Cell	1 (2%)	2 (4%)		
Sinus, Dilatation				1 (2%)
Spleen	(44)	(46)	(45)	(44)
Amyloid Deposition		1 (2%)		
Depletion Lymphoid				1 (2%)
Fibrosis, Stromal	1 (2%)			
Hematopoietic Cell Proliferation	16 (36%)	13 (28%)	9 (20%)	12 (27%)
Hyperplasia, Lymphoid	20 (45%)	23 (50%)	21 (47%)	24 (55%)
Necrosis			1 (2%)	
Pigmentation	3 (7%)	4 (9%)	4 (9%)	5 (11%)
Thrombus	1 (2%)			
Thymus	(41)	(44)	(43)	(41)
Amyloid Deposition		1 (2%)		
Atrophy	10 (24%)	14 (32%)	17 (40%)	10 (24%)
Cyst				1 (2%)

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TDMS No. 20116 - 04
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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: 14:39:08

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

Lab: NCTR

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

Hyperplasia, Lymphoid	8 (20%)	7 (16%)	8 (19%)	12 (29%)
Necrosis	1 (2%)			
Epithelial Cell, Hyperplasia				1 (2%)

INTEGUMENTARY SYSTEM

Mammary Gland	(44)	(43)	(44)	(44)
Galactocele	1 (2%)		1 (2%)	
Infiltration Cellular, Lymphocyte			1 (2%)	1 (2%)
Lactation	2 (5%)		2 (5%)	
Alveolus, Hyperplasia	4 (9%)	3 (7%)	3 (7%)	3 (7%)
Skin	(44)	(46)	(45)	(44)
Fat, Necrosis			1 (2%)	

MUSCULOSKELETAL SYSTEM

Bone, Femur	(47)	(46)	(48)	(46)
Fibro-Osseous Lesion	1 (2%)	1 (2%)	2 (4%)	1 (2%)
Skeletal Muscle	(0)	(2)	(2)	(0)
Diaphragm, Inflammation, Chronic Active			1 (50%)	

NERVOUS SYSTEM

Brain, Brain Stem	(43)	(44)	(44)	(43)
Compression	2 (5%)	1 (2%)	2 (5%)	1 (2%)
Brain, Cerebellum	(43)	(44)	(44)	(43)
Infiltration Cellular, Lymphocyte				1 (2%)
Brain, Cerebrum	(43)	(44)	(44)	(43)
Infiltration Cellular, Lymphocyte				1 (2%)
Mineralization	24 (56%)	30 (68%)	24 (55%)	27 (63%)

RESPIRATORY SYSTEM

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

C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
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Lung	(45)	(45)	(46)	(44)
Autolysis	1 (2%)		1 (2%)	
Congestion				1 (2%)
Hemorrhage	2 (4%)	1 (2%)		
Infiltration Cellular, Histiocyte	5 (11%)	4 (9%)	3 (7%)	1 (2%)
Infiltration Cellular, Lymphocyte	4 (9%)	2 (4%)	2 (4%)	3 (7%)
Inflammation, Chronic		1 (2%)		
Inflammation, Chronic Active	2 (4%)	1 (2%)		1 (2%)
Metaplasia, Osseous		1 (2%)		
Mineralization			1 (2%)	
Alveolar Epithelium, Hyperplasia			2 (4%)	1 (2%)
Nose	(45)	(44)	(45)	(45)
Hyaline Droplet	12 (27%)	12 (27%)	17 (38%)	9 (20%)
Inflammation, Chronic Active	1 (2%)			

SPECIAL SENSES SYSTEM

Eye	(42)	(43)	(44)	(42)
Cataract	2 (5%)		2 (5%)	
Phthisis Bulbi		1 (2%)		
Cornea, Inflammation, Chronic Active	1 (2%)			
Cornea, Ulcer	1 (2%)			
Harderian Gland	(43)	(43)	(44)	(43)
Hyperplasia				1 (2%)
Infiltration Cellular, Lymphocyte	6 (14%)	5 (12%)	5 (11%)	5 (12%)
Epithelium, Hyperplasia		2 (5%)		
Lacrimal Gland	(1)	(0)	(0)	(0)
Infiltration Cellular, Lymphocyte	1 (100%)			

URINARY SYSTEM

Kidney	(44)	(43)	(46)	(44)
Amyloid Deposition	1 (2%)	1 (2%)		2 (5%)
Autolysis	1 (2%)			1 (2%)
Cyst, Multiple		1 (2%)		

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TDMS No. 20116 - 04
Test Type: CHRONIC
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Aloe vera whole leaf extract (native)

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C57BL/6N XC3H/HEN MTV-NCTR MICE FEMALE	CONTROL WATER	ALOEWHOLLEAF 1.0	ALOEWHOLLEAF 2.0	ALOEWHOLLEAF 3.0
Hyaline Droplet	3 (7%)	1 (2%)	1 (2%)	1 (2%)
Infiltration Cellular, Histiocyte	1 (2%)			
Infiltration Cellular, Lymphocyte	22 (50%)	23 (53%)	22 (48%)	27 (61%)
Metaplasia, Osseous			3 (7%)	2 (5%)
Nephropathy	5 (11%)	6 (14%)	7 (15%)	6 (14%)
Polyarteritis				1 (2%)
Pelvis, Dilatation		1 (2%)	2 (4%)	
Pelvis, Mineralization		1 (2%)		
Transitional Epithelium, Hyperplasia		1 (2%)		
Urinary Bladder	(43)	(43)	(44)	(42)
Infiltration Cellular, Lymphocyte	22 (51%)	22 (51%)	22 (50%)	25 (60%)
Lumen, Dilatation			1 (2%)	

*** END OF REPORT ***

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