

**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
<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>16</b>	<b>16</b>	<b>23</b>	<b>15</b>
<b>Natural Death</b>		<b>2</b>	<b>4</b>	<b>4</b>
<b>Survivors</b>				
<b>Natural Death</b>	<b>1</b>	<b>1</b>		<b>1</b>
<b>Terminal Sacrifice</b>	<b>31</b>	<b>28</b>	<b>21</b>	<b>28</b>
<b>Animals Examined Microscopically</b>	<b>48</b>	<b>47</b>	<b>48</b>	<b>48</b>

**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%)
<b>CARDIOVASCULAR SYSTEM</b>				
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

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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%)		

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GENERAL BODY SYSTEM

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

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

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
<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>6</b>	<b>12</b>	<b>8</b>	<b>6</b>
<b>Natural Death</b>	<b>5</b>	<b>4</b>	<b>3</b>	<b>5</b>
<b>Survivors</b>				
<b>Moribund Sacrifice</b>	<b>1</b>	<b>1</b>		<b>1</b>
<b>Natural Death</b>		<b>1</b>	<b>1</b>	<b>2</b>
<b>Terminal Sacrifice</b>	<b>35</b>	<b>30</b>	<b>36</b>	<b>34</b>
<b>Animals Examined Microscopically</b>	<b>47</b>	<b>48</b>	<b>48</b>	<b>48</b>

**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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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%)

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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

CARDIOVASCULAR SYSTEM

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
Heart	(45)	(46)	(46)	(44)
Cardiomyopathy	4 (9%)	2 (4%)	3 (7%)	
Inflammation, Chronic Active			1 (2%)	
Mineralization	1 (2%)			

ENDOCRINE SYSTEM

	CONTROL WATER	ALOEWOLLEAF 1.0	ALOEWOLLEAF 2.0	ALOEWOLLEAF 3.0
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%)	

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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

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

Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

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

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

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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%)	

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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%)	

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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%)

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RESPIRATORY SYSTEM

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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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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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