

**Experiment Number:** 20116-01  
**Test Type:** 90-DAY  
**Route:** DOSED WATER  
**Species/Strain:** Rat/F 344/N

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

**Test Compound:** Aloe vera whole leaf extract (native)

**CAS Number:** ALOEVLEAFEXT

**Date Report Requested:** 10/23/2014

**Time Report Requested:** 13:04:13

**First Dose M/F:** NA / NA

**Lab:** NCTR

<b>C Number:</b>	C20116B
<b>Lock Date:</b>	Not Entered.
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Both
<b>PWG Approval Date</b>	NONE

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
<b>Disposition Summary</b>				
Animals Initially In Study	12	11	12	12
Early Deaths				
Moribund Sacrifice			2	5
Survivors				
Terminal Sacrifice	12	11	10	7
Animals Examined Microscopically	12	11	12	12
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(12)	(0)	(12)	(12)
Intestine Large, Cecum	(12)	(11)	(12)	(12)
Goblet Cell, Hyperplasia		6 (55%)	11 (92%)	8 (67%)
Infiltration Cellular, Polymorphnuclr		1 (9%)	4 (33%)	3 (25%)
Intestine Large, Colon	(12)	(11)	(12)	(12)
Goblet Cell, Hyperplasia		10 (91%)	11 (92%)	8 (67%)
Infiltration Cellular, Polymorphnuclr		4 (36%)	4 (33%)	3 (25%)
Intestine Large, Rectum	(10)	(0)	(11)	(11)
Anus, Epithelium, Hyperplasia, Squamous			1 (9%)	
Anus, Hyperplasia, Squamous			2 (18%)	3 (27%)
Anus, Inflammation, Chronic Active			4 (36%)	3 (27%)
Goblet Cell, Hyperplasia			9 (82%)	5 (45%)
Intestine Small, Duodenum	(12)	(0)	(12)	(12)
Intestine Small, Ileum	(12)	(0)	(12)	(12)
Goblet Cell, Hyperplasia			1 (8%)	1 (8%)
Intestine Small, Jejunum	(12)	(0)	(12)	(12)
Liver	(12)	(11)	(12)	(12)
Hepatodiaphragmatic Nodule		1 (9%)		
Inflammation, Chronic Active	2 (17%)			1 (8%)
Vacuolization Cytoplasmic	3 (25%)			
Pancreas	(12)	(0)	(12)	(12)

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

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
Acinus, Degeneration	1 (8%)		1 (8%)	
Salivary Glands	(12)	(0)	(12)	(12)
Stomach, Forestomach	(12)	(0)	(12)	(12)
Hyperkeratosis				2 (17%)
Stomach, Glandular	(12)	(0)	(12)	(12)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(12)	(0)	(12)	(12)
Heart	(12)	(0)	(12)	(12)
Cardiomyopathy	4 (33%)			
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(12)	(0)	(11)	(12)
Adrenal Medulla	(11)	(0)	(10)	(11)
Islets, Pancreatic	(12)	(0)	(12)	(12)
Parathyroid Gland	(12)	(0)	(12)	(12)
Pituitary Gland	(9)	(0)	(12)	(10)
Thyroid Gland	(12)	(0)	(12)	(12)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Coagulating Gland	(0)	(0)	(0)	(3)
Hypoplasia				3 (100%)
Epididymis	(12)	(0)	(12)	(12)
Hypospermia				3 (25%)
Preputial Gland	(12)	(0)	(12)	(12)
Inflammation, Suppurative	7 (58%)		9 (75%)	9 (75%)
Prostate	(12)	(0)	(12)	(12)
Inflammation, Suppurative				1 (8%)
Seminal Vesicle	(12)	(0)	(12)	(12)

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
Hypoplasia			2 (17%)	3 (25%)
Testes	(12)	(0)	(12)	(12)
Hypoplasia				3 (25%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(12)	(0)	(12)	(12)
Hypocellularity			2 (17%)	4 (33%)
Lymph Node	(0)	(0)	(0)	(1)
Inguinal, Hyperplasia, Lymphoid				1 (100%)
Lymph Node, Mandibular	(12)	(0)	(12)	(12)
Lymph Node, Mesenteric	(12)	(3)	(11)	(12)
Degeneration, Cystic			1 (9%)	1 (8%)
Hyperplasia, Lymphoid	9 (75%)	3 (100%)	9 (82%)	8 (67%)
Spleen	(12)	(11)	(12)	(12)
Hematopoietic Cell Proliferation		1 (9%)	1 (8%)	1 (8%)
Hyperplasia, Lymphoid	1 (8%)	1 (9%)		1 (8%)
Thymus	(12)	(0)	(11)	(12)
Atrophy			1 (9%)	4 (33%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(12)	(0)	(8)	(11)
Skin	(12)	(0)	(12)	(12)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone, Femur	(12)	(0)	(12)	(12)
<b>NERVOUS SYSTEM</b>				
Brain, Brain Stem	(12)	(0)	(12)	(12)
Brain, Cerebellum	(12)	(0)	(12)	(12)
Brain, Cerebrum	(12)	(0)	(12)	(12)
<b>RESPIRATORY SYSTEM</b>				
Lung	(12)	(0)	(12)	(12)

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

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<b>F 344/N Rat MALE</b>	<b>CONTROL</b>	<b>1% WLN</b>	<b>2% WLN</b>	<b>3% WLN</b>
Infiltration Cellular, Histiocyte			1 (8%)	
Nose	(12)	(0)	(12)	(12)
Trachea	(12)	(0)	(12)	(12)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(12)	(0)	(12)	(12)
Harderian Gland	(12)	(0)	(12)	(12)
Infiltration Cellular, Lymphoid			1 (8%)	
<b>URINARY SYSTEM</b>				
Kidney	(12)	(11)	(12)	(12)
Nephropathy, Chronic	12 (100%)	11 (100%)	12 (100%)	7 (58%)
Urinary Bladder	(12)	(0)	(12)	(12)
Dilatation	1 (8%)			2 (17%)
Hemorrhage				1 (8%)

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

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F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
<b>Disposition Summary</b>				
<b>Animals Initially In Study</b>	12	12	12	12
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>			4	7
<b>Natural Death</b>				1
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	12	12	8	4
<b>Animals Examined Microscopically</b>	12	12	12	11
<b>ALIMENTARY SYSTEM</b>				
Esophagus	(12)	(0)	(11)	(11)
Intestine Large, Cecum	(12)	(12)	(12)	(11)
Goblet Cell, Hyperplasia	1 (8%)	6 (50%)	8 (67%)	4 (36%)
Infiltration Cellular, Polymorphnuclr		1 (8%)		2 (18%)
Intestine Large, Colon	(12)	(12)	(12)	(11)
Goblet Cell, Hyperplasia		8 (67%)	9 (75%)	4 (36%)
Infiltration Cellular, Lymphoid			1 (8%)	
Infiltration Cellular, Polymorphnuclr		2 (17%)	4 (33%)	1 (9%)
Intestine Large, Rectum	(11)	(0)	(12)	(11)
Anus, Epithelium, Hyperplasia, Squamous				1 (9%)
Anus, Hyperplasia, Squamous			2 (17%)	
Anus, Inflammation, Chronic Active			2 (17%)	1 (9%)
Goblet Cell, Hyperplasia			7 (58%)	3 (27%)
Intestine Small, Duodenum	(12)	(0)	(12)	(11)
Intestine Small, Ileum	(12)	(0)	(12)	(11)
Goblet Cell, Hyperplasia				1 (9%)
Intestine Small, Jejunum	(12)	(0)	(12)	(11)
Liver	(12)	(12)	(12)	(11)
Deformity		1 (8%)		
Hepatodiaphragmatic Nodule				1 (9%)

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F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Inflammation, Chronic Active	1 (8%)			1 (9%)
Vacuolization Cytoplasmic		1 (8%)		
Pancreas	(12)	(0)	(12)	(11)
Salivary Glands	(12)	(0)	(12)	(11)
Stomach, Forestomach	(12)	(0)	(12)	(11)
Hyperkeratosis			2 (17%)	2 (18%)
Stomach, Glandular	(12)	(0)	(12)	(11)
<b>CARDIOVASCULAR SYSTEM</b>				
Blood Vessel	(12)	(0)	(12)	(11)
Heart	(12)	(0)	(12)	(11)
Inflammation, Chronic Active			1 (8%)	
Polyarteritis			1 (8%)	
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(12)	(0)	(12)	(11)
Adrenal Medulla	(12)	(0)	(12)	(10)
Islets, Pancreatic	(12)	(0)	(12)	(11)
Parathyroid Gland	(11)	(0)	(10)	(11)
Pituitary Gland	(12)	(0)	(11)	(10)
Thyroid Gland	(12)	(0)	(11)	(11)
<b>GENERAL BODY SYSTEM</b>				
None				
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(12)	(0)	(12)	(11)
Duct, Dilatation			2 (17%)	
Infiltration Cellular, Lymphoid	4 (33%)			1 (9%)
Inflammation, Chronic Active			1 (8%)	
Inflammation, Suppurative	4 (33%)		6 (50%)	9 (82%)
Ovary	(12)	(0)	(12)	(11)

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F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Hypoplasia			2 (17%)	5 (45%)
Interstit Cell, Hyperplasia			2 (17%)	1 (9%)
Uterus	(12)	(2)	(12)	(11)
Hypoplasia			2 (17%)	5 (45%)
Lumen, Dilatation	3 (25%)	2 (100%)	1 (8%)	
Vagina	(0)	(0)	(0)	(1)
Lumen, Dilatation				1 (100%)
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(12)	(0)	(12)	(11)
Hypocellularity			4 (33%)	7 (64%)
Lymph Node	(0)	(0)	(1)	(0)
Lumbar, Hyperplasia, Lymphoid			1 (100%)	
Lymph Node, Mandibular	(12)	(0)	(12)	(11)
Hyperplasia, Lymphoid	1 (8%)			
Lymph Node, Mesenteric	(12)	(4)	(12)	(10)
Degeneration, Cystic			1 (8%)	
Hyperplasia, Lymphoid	9 (75%)	4 (100%)	8 (67%)	4 (40%)
Spleen	(12)	(12)	(12)	(11)
Inflammation, Chronic Active		1 (8%)		
Thymus	(12)	(0)	(12)	(10)
Atrophy			4 (33%)	6 (60%)
<b>INTEGUMENTARY SYSTEM</b>				
Mammary Gland	(12)	(0)	(12)	(8)
Skin	(12)	(0)	(12)	(11)
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone, Femur	(12)	(0)	(12)	(11)
<b>NERVOUS SYSTEM</b>				
Brain, Brain Stem	(12)	(0)	(12)	(11)

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



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<b>F 344/N Rat FEMALE</b>	<b>CONTROL</b>	<b>1% WLN</b>	<b>2% WLN</b>	<b>3% WLN</b>
Brain, Cerebellum	(12)	(0)	(12)	(11)
Brain, Cerebrum	(12)	(0)	(12)	(11)
<b>RESPIRATORY SYSTEM</b>				
Lung	(12)	(0)	(12)	(11)
Nose	(12)	(0)	(12)	(11)
Trachea	(12)	(0)	(11)	(11)
<b>SPECIAL SENSES SYSTEM</b>				
Eye	(12)	(0)	(12)	(11)
Harderian Gland	(12)	(0)	(12)	(11)
Infiltration Cellular, Lymphoid	3 (25%)		2 (17%)	
<b>URINARY SYSTEM</b>				
Kidney	(12)	(12)	(12)	(11)
Nephropathy, Chronic		7 (58%)	3 (25%)	1 (9%)
Renal Tubule, Mineralization	12 (100%)	12 (100%)	9 (75%)	7 (64%)
Urinary Bladder	(12)	(0)	(12)	(11)

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