

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

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**

Test Compound: Aloe vera whole leaf extract (native)

CAS Number: ALOEVLEAFEXT

Date Report Requested: 10/23/2014

Time Report Requested: 13:03:41

First Dose M/F: NA / NA

Lab: NCTR

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

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
Disposition Summary				
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
ALIMENTARY SYSTEM				
Esophagus	(12)	(0)	(12)	(12)
Intestine Large, Cecum	(12)	(11)	(12)	(12)
Goblet Cell, Hyperplasia		6 [2.2]	11 [2.2]	8 [2.9]
Infiltration Cellular, Polymorphnuclr		1 [1.0]	4 [1.5]	3 [2.0]
Intestine Large, Colon	(12)	(11)	(12)	(12)
Goblet Cell, Hyperplasia		10 [2.0]	11 [2.3]	8 [2.8]
Infiltration Cellular, Polymorphnuclr		4 [2.5]	4 [2.0]	3 [2.7]
Intestine Large, Rectum	(10)	(0)	(11)	(11)
Anus, Epithelium, Hyperplasia, Squamous			1 [3.0]	
Anus, Hyperplasia, Squamous			2 [2.5]	3 [3.0]
Anus, Inflammation, Chronic Active			4 [1.8]	3 [2.7]
Goblet Cell, Hyperplasia			9 [2.0]	5 [2.4]
Intestine Small, Duodenum	(12)	(0)	(12)	(12)
Intestine Small, Ileum	(12)	(0)	(12)	(12)
Goblet Cell, Hyperplasia			1 [1.0]	1 [2.0]
Intestine Small, Jejunum	(12)	(0)	(12)	(12)
Liver	(12)	(11)	(12)	(12)
Hepatodiaphragmatic Nodule		1		
Inflammation, Chronic Active	2 [1.5]			1 [1.0]
Vacuolization Cytoplasmic	3 [1.0]			

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
Pancreas	(12)	(0)	(12)	(12)
Acinus, Degeneration	1 [1.0]		1 [1.0]	
Salivary Glands	(12)	(0)	(12)	(12)
Stomach, Forestomach	(12)	(0)	(12)	(12)
Hyperkeratosis				2 [2.0]
Stomach, Glandular	(12)	(0)	(12)	(12)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(12)	(0)	(12)	(12)
Heart	(12)	(0)	(12)	(12)
Cardiomyopathy	4 [1.3]			
ENDOCRINE SYSTEM				
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)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Coagulating Gland	(0)	(0)	(0)	(3)
Hypoplasia				3 [4.0]
Epididymis	(12)	(0)	(12)	(12)
Hypospermia				3 [4.0]
Preputial Gland	(12)	(0)	(12)	(12)
Inflammation, Suppurative	7 [2.1]		9 [1.9]	9 [2.2]
Prostate	(12)	(0)	(12)	(12)

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
Inflammation, Suppurative				1 [1.0]
Seminal Vesicle	(12)	(0)	(12)	(12)
Hypoplasia			2 [4.0]	3 [4.0]
Testes	(12)	(0)	(12)	(12)
Hypoplasia				3 [3.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(12)	(0)	(12)	(12)
Hypocellularity			2 [2.0]	4 [2.5]
Lymph Node	(0)	(0)	(0)	(1)
Inguinal, Hyperplasia, Lymphoid				1 [2.0]
Lymph Node, Mandibular	(12)	(0)	(12)	(12)
Lymph Node, Mesenteric	(12)	(3)	(11)	(12)
Degeneration, Cystic			1 [3.0]	1 [2.0]
Hyperplasia, Lymphoid	9 [2.1]	3 [4.0]	9 [3.6]	8 [3.9]
Spleen	(12)	(11)	(12)	(12)
Hematopoietic Cell Proliferation		1 [1.0]	1 [1.0]	1 [1.0]
Hyperplasia, Lymphoid	1 [1.0]	1 [1.0]		1 [1.0]
Thymus	(12)	(0)	(11)	(12)
Atrophy			1 [3.0]	4 [2.3]
INTEGUMENTARY SYSTEM				
Mammary Gland	(12)	(0)	(8)	(11)
Skin	(12)	(0)	(12)	(12)
MUSCULOSKELETAL SYSTEM				
Bone, Femur	(12)	(0)	(12)	(12)
NERVOUS SYSTEM				
Brain, Brain Stem	(12)	(0)	(12)	(12)
Brain, Cerebellum	(12)	(0)	(12)	(12)

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F 344/N Rat MALE	CONTROL	1% WLN	2% WLN	3% WLN
Brain, Cerebrum	(12)	(0)	(12)	(12)
RESPIRATORY SYSTEM				
Lung	(12)	(0)	(12)	(12)
Infiltration Cellular, Histiocyte			1 [1.0]	
Nose	(12)	(0)	(12)	(12)
Trachea	(12)	(0)	(12)	(12)
SPECIAL SENSES SYSTEM				
Eye	(12)	(0)	(12)	(12)
Harderian Gland	(12)	(0)	(12)	(12)
Infiltration Cellular, Lymphoid			1 [2.0]	
URINARY SYSTEM				
Kidney	(12)	(11)	(12)	(12)
Nephropathy, Chronic	12 [1.0]	11 [1.0]	12 [1.1]	7 [1.1]
Urinary Bladder	(12)	(0)	(12)	(12)
Dilatation	1 [4.0]			2 [4.0]
Hemorrhage				1 [2.0]

END OF MALE DATA

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Lab: NCTR

F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Disposition Summary				
Animals Initially In Study	12	12	12	12
Early Deaths				
Moribund Sacrifice			4	7
Natural Death				1
Survivors				
Terminal Sacrifice	12	12	8	4
Animals Examined Microscopically	12	12	12	11

ALIMENTARY SYSTEM

Esophagus	(12)	(0)	(11)	(11)
Intestine Large, Cecum	(12)	(12)	(12)	(11)
Goblet Cell, Hyperplasia	1 [1.0]	6 [1.5]	8 [2.3]	4 [2.3]
Infiltration Cellular, Polymorphnuclr		1 [1.0]		2 [1.5]
Intestine Large, Colon	(12)	(12)	(12)	(11)
Goblet Cell, Hyperplasia		8 [1.5]	9 [2.4]	4 [3.0]
Infiltration Cellular, Lymphoid			1 [2.0]	
Infiltration Cellular, Polymorphnuclr		2 [1.5]	4 [1.5]	1 [3.0]
Intestine Large, Rectum	(11)	(0)	(12)	(11)
Anus, Epithelium, Hyperplasia, Squamous				1 [3.0]
Anus, Hyperplasia, Squamous			2 [2.5]	
Anus, Inflammation, Chronic Active			2 [2.5]	1 [2.0]
Goblet Cell, Hyperplasia			7 [1.6]	3 [1.7]
Intestine Small, Duodenum	(12)	(0)	(12)	(11)
Intestine Small, Ileum	(12)	(0)	(12)	(11)
Goblet Cell, Hyperplasia				1 [2.0]
Intestine Small, Jejunum	(12)	(0)	(12)	(11)
Liver	(12)	(12)	(12)	(11)
Deformity		1		

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F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Hepatodiaphragmatic Nodule Inflammation, Chronic Active Vacuolization Cytoplasmic	1 [1.0]	1 [1.0]		1 1 [1.0]
Pancreas	(12)	(0)	(12)	(11)
Salivary Glands	(12)	(0)	(12)	(11)
Stomach, Forestomach Hyperkeratosis	(12)	(0)	(12) 2 [1.5]	(11) 2 [1.0]
Stomach, Glandular	(12)	(0)	(12)	(11)
CARDIOVASCULAR SYSTEM				
Blood Vessel	(12)	(0)	(12)	(11)
Heart Inflammation, Chronic Active Polyarteritis	(12)	(0)	(12) 1 [4.0] 1 [4.0]	(11) (11)
ENDOCRINE SYSTEM				
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)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
Clitoral Gland Duct, Dilatation	(12)	(0)	(12) 2 [3.0]	(11)
Infiltration Cellular, Lymphoid Inflammation, Chronic Active	4 [2.0]		1 [2.0]	1 [1.0]

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Inflammation, Suppurative Ovary	4 [2.0] (12)	(0)	6 [2.3] (12)	9 [2.3] (11)
Hypoplasia Interstit Cell, Hyperplasia			2 [2.5] 2 [1.0]	5 [2.6] 1 [2.0]
Uterus	(12)	(2)	(12)	(11)
Hypoplasia Lumen, Dilatation			2 [2.0]	5 [2.6]
Vagina	3 [2.7] (0)	2 [4.0] (0)	1 [3.0] (0)	(1)
Lumen, Dilatation				1 [3.0]
HEMATOPOIETIC SYSTEM				
Bone Marrow	(12)	(0)	(12)	(11)
Hypocellularity			4 [3.3]	7 [3.0]
Lymph Node	(0)	(0)	(1)	(0)
Lumbar, Hyperplasia, Lymphoid			1 [1.0]	
Lymph Node, Mandibular	(12)	(0)	(12)	(11)
Hyperplasia, Lymphoid	1 [2.0]			
Lymph Node, Mesenteric	(12)	(4)	(12)	(10)
Degeneration, Cystic			1 [4.0]	
Hyperplasia, Lymphoid	9 [2.1]	4 [4.0]	8 [3.6]	4 [3.5]
Spleen	(12)	(12)	(12)	(11)
Inflammation, Chronic Active		1 [4.0]		
Thymus	(12)	(0)	(12)	(10)
Atrophy			4 [2.8]	6 [2.8]
INTEGUMENTARY SYSTEM				
Mammary Gland	(12)	(0)	(12)	(8)
Skin	(12)	(0)	(12)	(11)
MUSCULOSKELETAL SYSTEM				
Bone, Femur	(12)	(0)	(12)	(11)

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F 344/N Rat FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
NERVOUS SYSTEM				
Brain, Brain Stem	(12)	(0)	(12)	(11)
Brain, Cerebellum	(12)	(0)	(12)	(11)
Brain, Cerebrum	(12)	(0)	(12)	(11)
RESPIRATORY SYSTEM				
Lung	(12)	(0)	(12)	(11)
Nose	(12)	(0)	(12)	(11)
Trachea	(12)	(0)	(11)	(11)
SPECIAL SENSES SYSTEM				
Eye	(12)	(0)	(12)	(11)
Harderian Gland	(12)	(0)	(12)	(11)
Infiltration Cellular, Lymphoid	3 [1.0]		2 [1.5]	
URINARY SYSTEM				
Kidney	(12)	(12)	(12)	(11)
Nephropathy, Chronic		7 [1.0]	3 [1.0]	1 [1.0]
Renal Tubule, Mineralization	12 [2.3]	12 [2.3]	9 [2.3]	7 [2.0]
Urinary Bladder	(12)	(0)	(12)	(11)

**** END OF REPORT ****

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

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)