

Experiment Number: 20116 - 01

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

Date Report Requested: 09/06/2016

Test Type: 90-DAY

Aloe vera whole leaf extract (native)

Time Report Requested: 10:34:59

Route: DOSED WATER

CAS Number: ALOEVLEAFEXT

First Dose M/F: 11/16/03 / 11/16/03

Species/Strain: RATS/F 344/N

Lab: NCTR

NTP Study Number: C20116B
Lock Date: Not Entered.
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

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FISCHER 344 RATS MALE	CONTROL	1% WLN	2% WLN	3% WLN
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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)
Infiltration Cellular, Polymorphonuclear		1 [1.0]	4 [1.5]	3 [2.0]
Goblet Cell, Hyperplasia		6 [2.2]	11 [2.2]	8 [2.9]
Intestine Large, Colon	(12)	(11)	(12)	(12)
Infiltration Cellular, Polymorphonuclear		4 [2.5]	4 [2.0]	3 [2.7]
Goblet Cell, Hyperplasia		10 [2.0]	11 [2.3]	8 [2.8]
Intestine Large, Rectum	(10)	(0)	(11)	(11)
Anus, Hyperplasia, Squamous			2 [2.5]	3 [3.0]
Anus, Inflammation, Chronic Active			4 [1.8]	3 [2.7]
Anus, Epithelium, Hyperplasia, Squamous			1 [3.0]	
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]			
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]

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)

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FISCHER 344 RATS MALE	CONTROL	1% WLN	2% WLN	3% WLN
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)
Inflammation, Suppurative				1 [1.0]
Seminal Vesicle	(12)	(0)	(12)	(12)
Hypoplasia			2 [4.0]	3 [4.0]

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FISCHER 344 RATS MALE	CONTROL	1% WLN	2% WLN	3% WLN
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)
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NERVOUS SYSTEM

Brain, Brain Stem	(12)	(0)	(12)	(12)
Brain, Cerebellum	(12)	(0)	(12)	(12)
Brain, Cerebrum	(12)	(0)	(12)	(12)

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)

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Lab: NCTR

FISCHER 344 RATS MALE	CONTROL	1% WLN	2% WLN	3% WLN
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RESPIRATORY SYSTEM				
Lung	(12)	(0)	(12)	(12)
Infiltration Cellular, Histiocyte			1 [1.0]	
Nose	(12)	(0)	(12)	(12)
Trachea	(12)	(0)	(12)	(12)
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SPECIAL SENSES SYSTEM				
Eye	(12)	(0)	(12)	(12)
Harderian Gland	(12)	(0)	(12)	(12)
Infiltration Cellular, Lymphoid			1 [2.0]	
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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 ***

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FISCHER 344 RATS FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
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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)
Infiltration Cellular, Polymorphonuclear		1 [1.0]		2 [1.5]
Goblet Cell, Hyperplasia	1 [1.0]	6 [1.5]	8 [2.3]	4 [2.3]
Intestine Large, Colon	(12)	(12)	(12)	(11)
Infiltration Cellular, Lymphoid			1 [2.0]	
Infiltration Cellular, Polymorphonuclear		2 [1.5]	4 [1.5]	1 [3.0]
Goblet Cell, Hyperplasia		8 [1.5]	9 [2.4]	4 [3.0]
Intestine Large, Rectum	(11)	(0)	(12)	(11)
Anus, Hyperplasia, Squamous			2 [2.5]	
Anus, Inflammation, Chronic Active			2 [2.5]	1 [2.0]
Anus, Epithelium, Hyperplasia, Squamous				1 [3.0]
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		
Hepatodiaphragmatic Nodule				1
Inflammation, Chronic Active	1 [1.0]			1 [1.0]
Vacuolization Cytoplasmic		1 [1.0]		
Pancreas	(12)	(0)	(12)	(11)
Salivary Glands	(12)	(0)	(12)	(11)

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FISCHER 344 RATS FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Stomach, Forestomach	(12)	(0)	(12)	(11)
Hyperkeratosis			2 [1.5]	2 [1.0]
Stomach, Glandular	(12)	(0)	(12)	(11)

CARDIOVASCULAR SYSTEM

Blood Vessel	(12)	(0)	(12)	(11)
Heart	(12)	(0)	(12)	(11)
Inflammation, Chronic Active			1 [4.0]	
Polyarteritis			1 [4.0]	

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	(12)	(0)	(12)	(11)
Infiltration Cellular, Lymphoid	4 [2.0]			1 [1.0]
Inflammation, Suppurative	4 [2.0]		6 [2.3]	9 [2.3]
Inflammation, Chronic Active			1 [2.0]	
Duct, Dilatation			2 [3.0]	
Ovary	(12)	(0)	(12)	(11)
Hypoplasia			2 [2.5]	5 [2.6]

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FISCHER 344 RATS FEMALE	CONTROL	1% WLN	2% WLN	3% WLN
Interstitial Cell, Hyperplasia			2 [1.0]	1 [2.0]
Uterus	(12)	(2)	(12)	(11)
Hypoplasia			2 [2.0]	5 [2.6]
Lumen, Dilatation	3 [2.7]	2 [4.0]	1 [3.0]	
Vagina	(0)	(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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NERVOUS SYSTEM				
Brain, Brain Stem	(12)	(0)	(12)	(11)
Brain, Cerebellum	(12)	(0)	(12)	(11)
Brain, Cerebrum	(12)	(0)	(12)	(11)
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RESPIRATORY SYSTEM				
Lung	(12)	(0)	(12)	(11)
Nose	(12)	(0)	(12)	(11)
Trachea	(12)	(0)	(11)	(11)
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SPECIAL SENSES SYSTEM				
Eye	(12)	(0)	(12)	(11)
Harderian Gland	(12)	(0)	(12)	(11)
Infiltration Cellular, Lymphoid	3 [1.0]		2 [1.5]	
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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)