

Experiment Number: 20316 - 01
Test Type: 90-DAY
Route: SKIN APPLICATION
Species/Strain: RATS/F 344/N

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

Cedarwood oil
CAS Number: 8000-27-9

Date Report Requested: 02/03/2014
Time Report Requested: 08:13:55
First Dose M/F: 06/15/05 / 06/16/05
Lab: BAT

F1_Rev.1_R2

NTP Study Number: C20316
Lock Date: 03/06/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.0_001
PWG Approval Date: 11/26/2007

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FISCHER 344 RATS MALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
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Disposition Summary

Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Moribund Sacrifice						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10

ALIMENTARY SYSTEM

Esophagus	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Cecum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Colon	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Rectum	(10)	(10)	(0)	(0)	(0)	(0)
Parasite Metazoan	1 (10%)					
Intestine Small, Duodenum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Ileum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Jejunum	(10)	(10)	(0)	(0)	(0)	(0)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation		1 (10%)		1 (10%)		1 (10%)
Hepatodiaphragmatic Nodule	1 (10%)	1 (10%)				
Inflammation	8 (80%)	8 (80%)	10 (100%)	10 (100%)	7 (70%)	7 (70%)
Necrosis, Focal						
Pancreas	(10)	(10)	(0)	(0)	(0)	(0)
Atrophy		1 (10%)				
Infiltration Cellular, Mononuclear Cell	4 (40%)	5 (50%)				
Salivary Glands	(10)	(10)	(0)	(0)	(0)	(0)
Submandibular Gland, Vacuolization	5 (50%)	2 (20%)				
Cytoplasmic						
Stomach, Forestomach	(10)	(10)	(0)	(0)	(0)	(0)
Stomach, Glandular	(10)	(10)	(0)	(0)	(0)	(0)
Glands, Ectasia		2 (20%)				

CARDIOVASCULAR SYSTEM

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

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FISCHER 344 RATS MALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
Blood Vessel	(10)	(10)	(0)	(0)	(0)	(0)
Heart	(10)	(10)	(0)	(0)	(0)	(0)
Cardiomyopathy	10 (100%)	10 (100%)				
Epicardium, Hyperplasia						
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(10)	(10)	(10)	(10)	(10)
Angiectasis	4 (40%)	2 (20%)				
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)
Islets, Pancreatic	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	1 (10%)	1 (10%)				
Parathyroid Gland	(9)	(9)	(0)	(0)	(0)	(0)
Pituitary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Cyst		1 (10%)				
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Ultimobranchial Cyst			2 (20%)			
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Epididymis	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell		1 (10%)				
Inflammation	1 (10%)	2 (20%)				
Preputial Gland	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Focal, Chronic		1 (10%)				
Prostate	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation	2 (20%)					
Seminal Vesicle	(10)	(10)	(0)	(0)	(0)	(0)
Testes	(10)	(10)	(0)	(1)	(0)	(0)
Germinal Epithelium, Right, Atrophy				1 (100%)		

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FISCHER 344 RATS MALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
HEMATOPOIETIC SYSTEM						
Bone Marrow	(10)	(10)	(10)	(10)	(10)	(10)
Hyperplasia						1 (10%)
Lymph Node, Mesenteric	(10)	(10)	(0)	(0)	(0)	(0)
Spleen	(10)	(10)	(0)	(0)	(0)	(0)
Hematopoietic Cell Proliferation		1 (10%)				
Thymus	(10)	(10)	(0)	(0)	(0)	(0)
INTEGUMENTARY SYSTEM						
Mammary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hair Follicle, Site Of Application, Hyperplasia					9 (90%)	10 (100%)
Sebaceous Gland, Site Of Application, Hyperplasia					9 (90%)	10 (100%)
Site Of Application, Inflammation, Chronic Active			1 (10%)	4 (40%)	9 (90%)	10 (100%)
Site Of Application - Dermis, Fibrosis					7 (70%)	10 (100%)
Site Of Application - Epidermis, Hyperkeratosis				1 (10%)	7 (70%)	10 (100%)
Site Of Application - Epidermis, Hyperplasia			2 (20%)	4 (40%)	10 (100%)	10 (100%)
Site Of Application - Epidermis, Ulcer				1 (10%)	1 (10%)	7 (70%)
MUSCULOSKELETAL SYSTEM						
Bone	(10)	(10)	(0)	(0)	(0)	(0)
NERVOUS SYSTEM						
Brain	(10)	(10)	(0)	(0)	(0)	(0)

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FISCHER 344 RATS MALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
RESPIRATORY SYSTEM						
Lung	(10)	(10)	(0)	(0)	(0)	(0)
Hemorrhage						
Infiltration Cellular, Histiocyte	2 (20%)	1 (10%)				
Inflammation	2 (20%)	5 (50%)				
Metaplasia, Osseous	5 (50%)	5 (50%)				
Pigmentation, Hemosiderin						
Serosa, Inflammation, Granulomatous						
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic Active						
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)
URINARY SYSTEM						
Kidney	(10)	(10)	(10)	(10)	(10)	(10)
Accumulation, Hyaline Droplet					10 (100%)	10 (100%)
Infiltration Cellular, Mononuclear Cell	1 (10%)	1 (10%)			1 (10%)	
Mineralization	9 (90%)	4 (40%)	7 (70%)	9 (90%)	8 (80%)	8 (80%)
Nephropathy	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Renal Tubule, Casts Granular					5 (50%)	10 (100%)
Renal Tubule, Degeneration	2 (20%)	4 (40%)	5 (50%)	6 (60%)	7 (70%)	10 (100%)
Urinary Bladder	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	1 (10%)	1 (10%)				
Serosa, Mineralization, Focal						

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FISCHER 344 RATS MALE

100 %

Disposition Summary

Animals Initially In Study	10
Early Deaths	
Moribund Sacrifice	2
Survivors	
Terminal Sacrifice	8
Animals Examined Microscopically	10

ALIMENTARY SYSTEM

Esophagus	(10)
Intestine Large, Cecum	(10)
Intestine Large, Colon	(10)
Intestine Large, Rectum	(10)
Parasite Metazoan	1 (10%)
Intestine Small, Duodenum	(10)
Intestine Small, Ileum	(10)
Intestine Small, Jejunum	(10)
Liver	(10)
Hematopoietic Cell Proliferation	
Hepatodiaphragmatic Nodule	
Inflammation	9 (90%)
Necrosis, Focal	1 (10%)
Pancreas	(10)
Atrophy	1 (10%)
Infiltration Cellular, Mononuclear Cell	3 (30%)
Salivary Glands	(10)
Submandibular Gland, Vacuolization	4 (40%)
Cytoplasmic	
Stomach, Forestomach	(10)
Stomach, Glandular	(10)
Glands, Ectasia	

CARDIOVASCULAR SYSTEM

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FISCHER 344 RATS MALE

100 %

Blood Vessel	(10)
Heart	(10)
Cardiomyopathy	10 (100%)
Epicardium, Hyperplasia	1 (10%)

ENDOCRINE SYSTEM

Adrenal Cortex	(10)
Angiectasis	
Adrenal Medulla	(10)
Islets, Pancreatic	(10)
Infiltration Cellular, Mononuclear Cell	
Parathyroid Gland	(10)
Pituitary Gland	(10)
Cyst	
Thyroid Gland	(10)
Ultimobranchial Cyst	

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Epididymis	(10)
Infiltration Cellular, Mononuclear Cell	
Inflammation	2 (20%)
Preputial Gland	(10)
Inflammation, Focal, Chronic	3 (30%)
Prostate	(10)
Inflammation	
Seminal Vesicle	(10)
Testes	(10)
Germinal Epithelium, Right, Atrophy	

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FISCHER 344 RATS MALE

100 %

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)
Hyperplasia	7 (70%)
Lymph Node, Mesenteric	(10)
Spleen	(10)
Hematopoietic Cell Proliferation	
Thymus	(10)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)
Skin	(10)
Hair Follicle, Site Of Application, Hyperplasia	9 (90%)
Sebaceous Gland, Site Of Application, Hyperplasia	10 (100%)
Site Of Application, Inflammation, Chronic Active	10 (100%)
Site Of Application - Dermis, Fibrosis	10 (100%)
Site Of Application - Epidermis, Hyperkeratosis	10 (100%)
Site Of Application - Epidermis, Hyperplasia	9 (90%)
Site Of Application - Epidermis, Ulcer	8 (80%)

MUSCULOSKELETAL SYSTEM

Bone	(10)
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NERVOUS SYSTEM

Brain	(10)
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FISCHER 344 RATS MALE

100 %

RESPIRATORY SYSTEM

Lung	(10)
Hemorrhage	1 (10%)
Infiltration Cellular, Histiocyte	2 (20%)
Inflammation	4 (40%)
Metaplasia, Osseous	4 (40%)
Pigmentation, Hemosiderin	1 (10%)
Serosa, Inflammation, Granulomatous	1 (10%)
Nose	(10)
Inflammation, Chronic Active	2 (20%)
Trachea	(10)

SPECIAL SENSES SYSTEM

Eye	(10)
Harderian Gland	(10)

URINARY SYSTEM

Kidney	(10)
Accumulation, Hyaline Droplet	10 (100%)
Infiltration Cellular, Mononuclear Cell	1 (10%)
Mineralization	8 (80%)
Nephropathy	10 (100%)
Renal Tubule, Casts Granular	10 (100%)
Renal Tubule, Degeneration	10 (100%)
Urinary Bladder	(10)
Infiltration Cellular, Mononuclear Cell	1 (10%)
Serosa, Mineralization, Focal	1 (10%)

*** END OF MALE ***

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Lab: BAT

FISCHER 344 RATS FEMALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
Disposition Summary						
Animals Initially In Study	10	10	10	10	10	10
Early Deaths						
Survivors						
Terminal Sacrifice	10	10	10	10	10	10
Animals Examined Microscopically	10	10	10	10	10	10
ALIMENTARY SYSTEM						
Esophagus	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Cecum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Colon	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Large, Rectum	(10)	(10)	(0)	(0)	(0)	(0)
Parasite Metazoan		1 (10%)				
Intestine Small, Duodenum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Ileum	(10)	(10)	(0)	(0)	(0)	(0)
Intestine Small, Jejunum	(10)	(10)	(0)	(0)	(0)	(0)
Liver	(10)	(10)	(10)	(10)	(10)	(10)
Hematopoietic Cell Proliferation	2 (20%)					
Hepatodiaphragmatic Nodule	2 (20%)	1 (10%)				
Inflammation	10 (100%)	9 (90%)	10 (100%)	9 (90%)	8 (80%)	5 (50%)
Mesentery	(0)	(0)	(1)	(0)	(0)	(0)
Mineralization			1 (100%)			
Necrosis			1 (100%)			
Fat, Inflammation, Granulomatous, Chronic Active			1 (100%)			
Pancreas	(10)	(10)	(0)	(0)	(0)	(0)
Atrophy						
Infiltration Cellular, Mononuclear Cell	7 (70%)	4 (40%)				
Salivary Glands	(10)	(10)	(0)	(0)	(10)	(10)
Sublingual Gland, Ectopic Tissue						
Submandibular Gland, Ectopic Tissue						
Submandibular Gland, Vacuolization Cytoplasmic	3 (30%)	4 (40%)				
Stomach, Forestomach	(10)	(10)	(0)	(0)	(0)	(0)

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FISCHER 344 RATS FEMALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
Stomach, Glandular	(10)	(10)	(0)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM						
Blood Vessel	(10)	(10)	(0)	(0)	(0)	(0)
Heart	(10)	(10)	(0)	(0)	(0)	(0)
Cardiomyopathy	10 (100%)	9 (90%)				
Inflammation, Chronic Active	1 (10%)					
ENDOCRINE SYSTEM						
Adrenal Cortex	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular	1 (10%)					
Infiltration Cellular, Mononuclear Cell		1 (10%)				
Mineralization		1 (10%)				
Adrenal Medulla	(10)	(10)	(0)	(0)	(0)	(0)
Islets, Pancreatic	(10)	(10)	(0)	(0)	(0)	(0)
Parathyroid Gland	(9)	(9)	(0)	(0)	(0)	(0)
Pituitary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Cyst	2 (20%)	2 (20%)				
Thyroid Gland	(10)	(10)	(10)	(10)	(10)	(10)
Infiltration Cellular, Mononuclear Cell		2 (20%)				
Ultimobranchial Cyst		3 (30%)	2 (20%)		3 (30%)	3 (30%)
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
Clitoral Gland	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	1 (10%)					
Inflammation, Focal, Chronic Active	1 (10%)					

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FISCHER 344 RATS FEMALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
Inflammation, Chronic Active	1 (10%)					
Ovary	(10)	(10)	(0)	(0)	(0)	(0)
Left, Cyst	1 (10%)					
Uterus	(10)	(10)	(0)	(0)	(0)	(0)

HEMATOPOIETIC SYSTEM

Bone Marrow	(10)	(10)	(9)	(10)	(10)	(10)
Hyperplasia					2 (20%)	2 (20%)
Lymph Node, Mesenteric	(10)	(10)	(0)	(0)	(0)	(0)
Spleen	(10)	(10)	(0)	(0)	(0)	(0)
Thymus	(10)	(10)	(0)	(0)	(0)	(0)

INTEGUMENTARY SYSTEM

Mammary Gland	(10)	(10)	(0)	(0)	(0)	(0)
Skin	(10)	(10)	(10)	(10)	(10)	(10)
Hair Follicle, Site Of Application, Hyperplasia				1 (10%)	9 (90%)	10 (100%)
Sebaceous Gland, Site Of Application, Hyperplasia				4 (40%)	9 (90%)	10 (100%)
Site Of Application, Inflammation, Chronic Active				7 (70%)	10 (100%)	10 (100%)
Site Of Application - Dermis, Fibrosis				1 (10%)	7 (70%)	8 (80%)
Site Of Application - Epidermis, Hyperkeratosis			1 (10%)	5 (50%)	10 (100%)	10 (100%)
Site Of Application - Epidermis, Hyperplasia			4 (40%)	7 (70%)	10 (100%)	10 (100%)
Site Of Application - Epidermis, Ulcer				1 (10%)	1 (10%)	4 (40%)

MUSCULOSKELETAL SYSTEM

Bone	(10)	(10)	(0)	(0)	(0)	(0)
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NERVOUS SYSTEM

Brain	(10)	(10)	(0)	(0)	(0)	(0)
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FISCHER 344 RATS FEMALE	UNTREATED	0 %	6.25 %	12.5 %	25 %	50 %
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RESPIRATORY SYSTEM						
Lung	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Histiocyte		1 (10%)				
Inflammation	3 (30%)	2 (20%)				
Metaplasia, Osseous	1 (10%)	1 (10%)				
Nose	(10)	(10)	(0)	(0)	(0)	(0)
Inflammation, Chronic Active						
Vacuolization Cytoplasmic		1 (10%)				
Trachea	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	1 (10%)					

SPECIAL SENSES SYSTEM						
Eye	(10)	(10)	(0)	(0)	(0)	(0)
Harderian Gland	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular						

URINARY SYSTEM						
Kidney	(10)	(10)	(0)	(0)	(0)	(0)
Infarct, Focal, Chronic	1 (10%)					
Mineralization	5 (50%)	5 (50%)				
Nephropathy		1 (10%)				
Urinary Bladder	(10)	(10)	(0)	(0)	(0)	(0)
Infiltration Cellular, Mononuclear Cell	5 (50%)	2 (20%)				

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

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Date Report Requested: 02/03/2014

Time Report Requested: 08:13:55

First Dose M/F: 06/15/05 / 06/16/05

Lab: BAT

FISCHER 344 RATS FEMALE

100 %

Disposition Summary

Animals Initially In Study	10
Early Deaths	
Survivors	
Terminal Sacrifice	10
Animals Examined Microscopically	10

ALIMENTARY SYSTEM

Esophagus	(10)
Intestine Large, Cecum	(10)
Intestine Large, Colon	(10)
Intestine Large, Rectum	(10)
Parasite Metazoan	
Intestine Small, Duodenum	(10)
Intestine Small, Ileum	(10)
Intestine Small, Jejunum	(10)
Liver	(10)
Hematopoietic Cell Proliferation	
Hepatodiaphragmatic Nodule	
Inflammation	7 (70%)
Mesentery	(0)
Mineralization	
Necrosis	
Fat, Inflammation, Granulomatous, Chronic Active	
Pancreas	(10)
Atrophy	1 (10%)
Infiltration Cellular, Mononuclear Cell	3 (30%)
Salivary Glands	(10)
Sublingual Gland, Ectopic Tissue	1 (10%)
Submandibular Gland, Ectopic Tissue	1 (10%)
Submandibular Gland, Vacuolization Cytoplasmic	1 (10%)
Stomach, Forestomach	(10)

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

Experiment Number: 20316 - 01

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: RATS/F 344/N

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

Cedarwood oil

CAS Number: 8000-27-9

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Lab: BAT

FISCHER 344 RATS FEMALE

100 %

Stomach, Glandular

(10)

CARDIOVASCULAR SYSTEM

Blood Vessel

(10)

Heart

(10)

 Cardiomyopathy

10 (100%)

 Inflammation, Chronic Active

ENDOCRINE SYSTEM

Adrenal Cortex

(10)

 Infiltration Cellular

 Infiltration Cellular, Mononuclear Cell

 Mineralization

Adrenal Medulla

(10)

Islets, Pancreatic

(10)

Parathyroid Gland

(10)

Pituitary Gland

(10)

 Cyst

1 (10%)

Thyroid Gland

(10)

 Infiltration Cellular, Mononuclear Cell

1 (10%)

 Ultimobranchial Cyst

2 (20%)

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

Clitoral Gland

(10)

 Infiltration Cellular, Mononuclear Cell

 Inflammation, Focal, Chronic Active

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FISCHER 344 RATS FEMALE 100 %

Inflammation, Chronic Active
Ovary (10)
Left, Cyst
Uterus (10)

HEMATOPOIETIC SYSTEM

Bone Marrow (10)
Hyperplasia 7 (70%)
Lymph Node, Mesenteric (10)
Spleen (10)
Thymus (10)

INTEGUMENTARY SYSTEM

Mammary Gland (10)
Skin (10)
Hair Follicle, Site Of Application, Hyperplasia 10 (100%)
Sebaceous Gland, Site Of Application, Hyperplasia 10 (100%)
Site Of Application, Inflammation, Chronic Active 10 (100%)
Site Of Application - Dermis, Fibrosis 10 (100%)
Site Of Application - Epidermis, Hyperkeratosis 10 (100%)
Site Of Application - Epidermis, Hyperplasia 10 (100%)
Site Of Application - Epidermis, Ulcer 10 (100%)

MUSCULOSKELETAL SYSTEM

Bone (10)

NERVOUS SYSTEM

Brain (10)

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FISCHER 344 RATS FEMALE

100 %

RESPIRATORY SYSTEM

Lung	(10)
Infiltration Cellular, Histiocyte	1 (10%)
Inflammation	2 (20%)
Metaplasia, Osseous	
Nose	(10)
Inflammation, Chronic Active	1 (10%)
Vacuolization Cytoplasmic	
Trachea	(10)
Infiltration Cellular, Mononuclear Cell	

SPECIAL SENSES SYSTEM

Eye	(10)
Harderian Gland	(10)
Infiltration Cellular	1 (10%)

URINARY SYSTEM

Kidney	(10)
Infarct, Focal, Chronic	
Mineralization	6 (60%)
Nephropathy	1 (10%)
Urinary Bladder	(10)
Infiltration Cellular, Mononuclear Cell	

*** END OF REPORT ***

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