

**TDMS No.** 99037 - 05  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** RATS/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
alpha/beta Thujone mixture  
**CAS Number:** THUJONEMIXAB

**Date Report Requested:** 08/18/2010  
**Time Report Requested:** 08:14:26  
**First Dose M/F:** 06/09/03 / 06/09/03  
**Lab:** SRI

F2\_R2

**C Number:** C99037B  
**Lock Date:** 11/20/2006  
**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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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>	<b>2</b>		<b>1</b>	
<b>Moribund Sacrifice</b>	<b>14</b>	<b>21</b>	<b>13</b>	<b>1</b>
<b>Natural Death</b>	<b>7</b>	<b>4</b>	<b>19</b>	<b>49</b>
<b>Survivors</b>				
<b>Natural Death</b>	<b>1</b>			
<b>Terminal Sacrifice</b>	<b>26</b>	<b>25</b>	<b>17</b>	
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

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**ALIMENTARY SYSTEM**

Esophagus	(50)	(50)	(50)	(50)
Hemorrhage	1 (2%)			
Hyperkeratosis				1 (2%)
Inflammation, Acute	2 (4%)			
Perforation	1 (2%)			
Intestine Large, Cecum	(48)	(48)	(40)	(39)
Edema	1 (2%)			
Inflammation, Acute	1 (2%)			
Necrosis, Lymphoid				1 (3%)
Intestine Large, Colon	(44)	(47)	(33)	(15)
Edema	2 (5%)	1 (2%)	1 (3%)	
Hemorrhage			1 (3%)	
Necrosis			1 (3%)	
Intestine Large, Rectum	(46)	(48)	(41)	(42)
Inflammation, Chronic				1 (2%)
Intestine Small, Duodenum	(48)	(48)	(37)	(33)
Necrosis, Lymphoid				1 (3%)
Intestine Small, Ileum	(43)	(47)	(30)	(16)
Inflammation, Acute			1 (3%)	1 (6%)
Inflammation, Chronic Active	1 (2%)			
Necrosis	1 (2%)	1 (2%)		
Intestine Small, Jejunum	(43)	(47)	(33)	(25)

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

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Liver	(50)	(50)	(50)	(50)
Basophilic Focus	29 (58%)	26 (52%)	25 (50%)	4 (8%)
Clear Cell Focus	19 (38%)	23 (46%)	11 (22%)	4 (8%)
Degeneration, Cystic	13 (26%)	7 (14%)	4 (8%)	2 (4%)
Eosinophilic Focus	6 (12%)	4 (8%)	4 (8%)	1 (2%)
Fibrosis				1 (2%)
Hematopoietic Cell Proliferation		1 (2%)		
Hepatodiaphragmatic Nodule	8 (16%)	3 (6%)	5 (10%)	3 (6%)
Infiltration Cellular, Mixed Cell	21 (42%)	22 (44%)	18 (36%)	9 (18%)
Mixed Cell Focus	3 (6%)	6 (12%)	3 (6%)	2 (4%)
Necrosis, Focal		1 (2%)		3 (6%)
Thrombosis		1 (2%)		
Bile Duct, Hyperplasia	41 (82%)	45 (90%)	40 (80%)	20 (40%)
Centrilobular, Necrosis		1 (2%)	1 (2%)	5 (10%)
Hepatocyte, Vacuolization Cytoplasmic	7 (14%)	10 (20%)	4 (8%)	1 (2%)
Hepatocyte, Vacuolization Cytoplasmic, Focal		2 (4%)	1 (2%)	1 (2%)
Kupffer Cell, Pigmentation		4 (8%)		
Mesentery	(11)	(10)	(11)	(4)
Accessory Spleen		1 (10%)	1 (9%)	2 (50%)
Hemorrhage			1 (9%)	1 (25%)
Fat, Necrosis	10 (91%)	9 (90%)	8 (73%)	1 (25%)
Oral Mucosa	(0)	(1)	(0)	(1)
Pancreas	(50)	(50)	(50)	(50)
Atrophy	29 (58%)	35 (70%)	30 (60%)	18 (36%)
Cyst	21 (42%)	25 (50%)	15 (30%)	6 (12%)
Hemorrhage				1 (2%)
Necrosis		1 (2%)		1 (2%)
Acinus, Hyperplasia, Focal	8 (16%)	1 (2%)	6 (12%)	
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy	7 (14%)	4 (8%)	9 (18%)	
Hyperplasia				1 (2%)
Inflammation, Acute	1 (2%)		1 (2%)	
Inflammation, Chronic		2 (4%)		
Necrosis				1 (2%)
Duct, Hyperplasia	1 (2%)			
Stomach, Forestomach	(50)	(50)	(50)	(49)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Edema	2 (4%)	4 (8%)	1 (2%)	
Erosion	1 (2%)			
Inflammation, Chronic Active Stromal Hyperplasia			1 (2%)	1 (2%)
Ulcer	1 (2%)	3 (6%)	2 (4%)	
Epithelium, Hyperplasia Stomach, Glandular	9 (18%) (50)	12 (24%) (50)	13 (26%) (49)	3 (6%) (48)
Cyst		1 (2%)		
Edema		2 (4%)	1 (2%)	
Erosion	3 (6%)	6 (12%)	6 (12%)	1 (2%)
Hemorrhage				2 (4%)
Inflammation		1 (2%)		
Necrosis, Lymphoid				2 (4%)
Ulcer	2 (4%)	5 (10%)	2 (4%)	
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	44 (88%)	41 (82%)	47 (94%)	45 (90%)
Hemorrhage				2 (4%)
Hypertrophy		1 (2%)		
Thrombosis	3 (6%)	4 (8%)	2 (4%)	
Epicardium, Inflammation		1 (2%)		
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(50)	(50)	(49)	(50)
Accessory Adrenal Cortical Nodule	21 (42%)	19 (38%)	21 (43%)	4 (8%)
Degeneration, Fatty	26 (52%)	28 (56%)	31 (63%)	34 (68%)
Hematopoietic Cell Proliferation	2 (4%)	2 (4%)		
Hyperplasia, Focal	17 (34%)	11 (22%)	9 (18%)	4 (8%)
Hypertrophy, Focal	6 (12%)	2 (4%)		
Necrosis	1 (2%)	3 (6%)	1 (2%)	2 (4%)
Bilateral, Necrosis	1 (2%)			
Capsule, Hyperplasia	1 (2%)		1 (2%)	

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Adrenal Medulla	(50)	(50)	(49)	(49)
Hyperplasia	18 (36%)	25 (50%)	13 (27%)	1 (2%)
Infiltration Cellular, Lymphocyte		2 (4%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Hyperplasia	3 (6%)		3 (6%)	1 (2%)
Parathyroid Gland	(48)	(49)	(47)	(49)
Hyperplasia, Focal		1 (2%)	1 (2%)	
Pituitary Gland	(50)	(50)	(50)	(49)
Pigmentation	7 (14%)	6 (12%)	9 (18%)	1 (2%)
Pars Distalis, Angiectasis	2 (4%)	2 (4%)	1 (2%)	3 (6%)
Pars Distalis, Atrophy		1 (2%)	1 (2%)	2 (4%)
Pars Distalis, Cyst	6 (12%)	3 (6%)	4 (8%)	2 (4%)
Pars Distalis, Hemorrhage				2 (4%)
Pars Distalis, Hyperplasia, Focal	16 (32%)	13 (26%)	3 (6%)	5 (10%)
Pars Distalis, Necrosis				1 (2%)
Pars Distalis, Pars Intermedia, Necrosis				1 (2%)
Pars Intermedia, Angiectasis		4 (8%)	1 (2%)	1 (2%)
Pars Intermedia, Cyst	4 (8%)		1 (2%)	
Pars Intermedia, Hyperplasia, Focal	2 (4%)	1 (2%)		
Rathke's Cleft, Dilatation		3 (6%)	1 (2%)	3 (6%)
Thyroid Gland	(46)	(48)	(42)	(45)
Degeneration, Cystic	7 (15%)	6 (13%)	4 (10%)	7 (16%)
Ultimobranchial Cyst	2 (4%)	2 (4%)	1 (2%)	2 (4%)
C-cell, Hyperplasia	2 (4%)	7 (15%)	2 (5%)	
Follicular Cell, Hyperplasia, Focal		2 (4%)	1 (2%)	1 (2%)

GENERAL BODY SYSTEM

Tissue NOS	(1)	(1)	(2)	(0)
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GENITAL SYSTEM

Epididymis	(50)	(50)	(50)	(50)
Granuloma Sperm		1 (2%)		
Penis	(0)	(1)	(0)	(1)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Inflammation, Acute		1 (100%)		
Preputial Gland	(49)	(49)	(50)	(50)
Cyst	1 (2%)			
Hyperplasia	2 (4%)		1 (2%)	
Inflammation, Chronic	13 (27%)	19 (39%)	18 (36%)	5 (10%)
Necrosis		1 (2%)		
Prostate	(50)	(50)	(50)	(50)
Fibrosis	1 (2%)		1 (2%)	
Inflammation, Chronic	32 (64%)	20 (40%)	23 (46%)	9 (18%)
Mineralization		1 (2%)		
Necrosis		1 (2%)	1 (2%)	
Epithelium, Hyperplasia	23 (46%)	17 (34%)	18 (36%)	4 (8%)
Seminal Vesicle	(50)	(50)	(50)	(50)
Hyperplasia		1 (2%)		
Infiltration Cellular				1 (2%)
Inflammation, Acute		1 (2%)	1 (2%)	1 (2%)
Inflammation, Chronic		1 (2%)		
Necrosis		1 (2%)		
Testes	(50)	(50)	(50)	(50)
Germinal Epithelium, Atrophy	5 (10%)	2 (4%)	3 (6%)	4 (8%)
Interstitial Cell, Hyperplasia	9 (18%)	5 (10%)	6 (12%)	13 (26%)

**HEMATOPOIETIC SYSTEM**

Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	7 (14%)	7 (14%)	12 (24%)	4 (8%)
Myelofibrosis	5 (10%)	4 (8%)		
Necrosis		1 (2%)		
Thrombosis		1 (2%)		
Lymph Node	(12)	(14)	(12)	(5)
Mediastinal, Ectasia	1 (8%)			
Mediastinal, Hemorrhage	2 (17%)			1 (20%)
Mediastinal, Hyperplasia, Lymphoid	1 (8%)	1 (7%)	3 (25%)	1 (20%)
Mediastinal, Pigmentation			1 (8%)	
Pancreatic, Hemorrhage	1 (8%)			1 (20%)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Pancreatic, Hyperplasia, Lymphoid		1 (7%)		3 (60%)
Pancreatic, Necrosis, Lymphoid				1 (20%)
Pancreatic, Pigmentation	1 (8%)			1 (20%)
Lymph Node, Mandibular Congestion	(2)	(0)	(0)	(3)
Hyperplasia, Lymphoid				1 (33%)
Lymph Node, Mesenteric	(50)	(49)	(50)	(50)
Ectasia	1 (2%)	1 (2%)	1 (2%)	
Hemorrhage	4 (8%)	2 (4%)	10 (20%)	10 (20%)
Hyperplasia, Lymphoid	1 (2%)	2 (4%)	4 (8%)	3 (6%)
Necrosis		1 (2%)	2 (4%)	1 (2%)
Spleen	(50)	(50)	(49)	(48)
Accessory Spleen				1 (2%)
Angiectasis	1 (2%)			
Fibrosis	2 (4%)	3 (6%)	1 (2%)	
Hematopoietic Cell Proliferation	6 (12%)	7 (14%)	1 (2%)	1 (2%)
Hemorrhage	1 (2%)			
Infarct	1 (2%)	1 (2%)	1 (2%)	
Necrosis		1 (2%)	2 (4%)	3 (6%)
Pigmentation	19 (38%)	24 (48%)	30 (61%)	46 (96%)
Lymphoid Follicle, Atrophy		1 (2%)	2 (4%)	1 (2%)
Lymphoid Follicle, Hyperplasia	10 (20%)	12 (24%)	8 (16%)	3 (6%)
Thymus	(44)	(45)	(45)	(47)
Cyst		1 (2%)		
Ectopic Parathyroid Gland			1 (2%)	
Fibrosis		1 (2%)		

**INTEGUMENTARY SYSTEM**

Mammary Gland	(48)	(47)	(49)	(42)
Angiectasis		1 (2%)		
Fibrosis	1 (2%)			
Hyperplasia	2 (4%)	1 (2%)		
Duct, Ectasia	28 (58%)	36 (77%)	34 (69%)	15 (36%)
Skin	(50)	(50)	(50)	(50)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Cyst Epithelial Inclusion		2 (4%)	4 (8%)	
Edema				1 (2%)
Hemorrhage				1 (2%)
Hyperkeratosis	1 (2%)	3 (6%)	5 (10%)	1 (2%)
Inflammation, Granulomatous	1 (2%)			
Inflammation, Chronic			4 (8%)	3 (6%)
Mineralization			1 (2%)	
Necrosis			1 (2%)	
Ulcer				2 (4%)
Ulcer, Multiple				1 (2%)
Epidermis, Hyperkeratosis	1 (2%)			
Epidermis, Hyperplasia		1 (2%)	3 (6%)	
Epidermis, Hyperplasia, Focal	1 (2%)			
Hair Follicle, Cyst		1 (2%)		
Subcutaneous Tissue, Fibrosis			1 (2%)	
<b>MUSCULOSKELETAL SYSTEM</b>				
Bone	(50)	(50)	(50)	(50)
Femur, Osteopetrosis		2 (4%)	2 (4%)	
Skeletal Muscle	(2)	(4)	(2)	(0)
Fibrosis		2 (50%)		
<b>NERVOUS SYSTEM</b>				
Brain	(50)	(50)	(50)	(50)
Compression	9 (18%)	4 (8%)	11 (22%)	1 (2%)
Mineralization			1 (2%)	1 (2%)
Necrosis			1 (2%)	3 (6%)
Pigmentation		1 (2%)		3 (6%)
<b>RESPIRATORY SYSTEM</b>				
Lung	(50)	(50)	(50)	(50)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Infiltration Cellular, Histiocyte	31 (62%)	43 (86%)	33 (66%)	18 (36%)
Inflammation, Chronic	1 (2%)	6 (12%)	2 (4%)	4 (8%)
Metaplasia, Osseous	2 (4%)	5 (10%)	6 (12%)	2 (4%)
Thrombosis				1 (2%)
Alveolar Epithelium, Hyperplasia	11 (22%)	17 (34%)	19 (38%)	3 (6%)
Nose	(50)	(50)	(50)	(50)
Congestion				1 (2%)
Foreign Body	11 (22%)	8 (16%)	9 (18%)	1 (2%)
Inflammation, Chronic	13 (26%)	15 (30%)	13 (26%)	2 (4%)
Goblet Cell, Hyperplasia	2 (4%)	1 (2%)	3 (6%)	1 (2%)
Respiratory Epithelium, Hyperplasia	13 (26%)	7 (14%)	10 (20%)	1 (2%)
Trachea	(50)	(50)	(50)	(50)
Inflammation, Acute	1 (2%)			

**SPECIAL SENSES SYSTEM**

Eye	(49)	(50)	(46)	(48)
Cataract	6 (12%)	9 (18%)	10 (22%)	2 (4%)
Developmental Malformation				1 (2%)
Edema	1 (2%)	1 (2%)		
Hemorrhage		1 (2%)		
Inflammation, Chronic		2 (4%)		
Bilateral, Cataract	1 (2%)	2 (4%)	2 (4%)	
Retina, Degeneration	1 (2%)	2 (4%)		
Harderian Gland	(50)	(50)	(50)	(50)
Hyperplasia, Focal	1 (2%)	1 (2%)		1 (2%)
Inflammation, Chronic	3 (6%)	4 (8%)	4 (8%)	5 (10%)
Pigmentation		1 (2%)		
Zymbal's Gland	(0)	(1)	(1)	(0)

**URINARY SYSTEM**

Kidney	(48)	(48)	(44)	(49)
Casts Granular	1 (2%)			
Casts Protein	18 (38%)	30 (63%)	22 (50%)	11 (22%)

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FISCHER 344 RATS MALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Cyst	1 (2%)	3 (6%)		
Hydronephrosis	1 (2%)	1 (2%)		
Infarct	3 (6%)	1 (2%)		
Inflammation, Suppurative		2 (4%)		1 (2%)
Mineralization	17 (35%)	33 (69%)	41 (93%)	38 (78%)
Nephropathy	45 (94%)	44 (92%)	41 (93%)	46 (94%)
Artery, Thrombosis	1 (2%)			
Papilla, Necrosis	1 (2%)			
Renal Tubule, Accumulation, Hyaline Droplet	1 (2%)			
Renal Tubule, Necrosis				2 (4%)
Transitional Epithelium, Hyperplasia		1 (2%)	4 (9%)	2 (4%)
Urinary Bladder	(50)	(50)	(49)	(50)
Atrophy		1 (2%)		
Hemorrhage				1 (2%)
Inflammation, Acute		1 (2%)		
Inflammation, Chronic		1 (2%)		1 (2%)
Necrosis		1 (2%)		
Transitional Epithelium, Hyperplasia		1 (2%)		1 (2%)

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

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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Moribund Sacrifice</b>	<b>6</b>	<b>9</b>	<b>10</b>	<b>5</b>
<b>Natural Death</b>	<b>9</b>	<b>8</b>	<b>21</b>	<b>45</b>
<b>Survivors</b>				
<b>Terminal Sacrifice</b>	<b>35</b>	<b>33</b>	<b>19</b>	
<b>Animals Examined Microscopically</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

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ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Diverticulum	1 (2%)			
Intestine Large, Cecum	(41)	(44)	(39)	(47)
Hemorrhage		1 (2%)		
Intestine Large, Colon	(41)	(43)	(33)	(25)
Intestine Large, Rectum	(46)	(45)	(41)	(47)
Hemorrhage				1 (2%)
Intestine Small, Duodenum	(44)	(45)	(40)	(47)
Necrosis			1 (3%)	
Necrosis, Lymphoid				1 (2%)
Intestine Small, Jejunum	(41)	(42)	(33)	(31)
Necrosis, Lymphoid				1 (3%)
Liver	(50)	(50)	(49)	(50)
Angiectasis	1 (2%)		1 (2%)	
Basophilic Focus	46 (92%)	46 (92%)	40 (82%)	12 (24%)
Clear Cell Focus	17 (34%)	21 (42%)	11 (22%)	
Eosinophilic Focus	8 (16%)	2 (4%)	2 (4%)	
Hematopoietic Cell Proliferation	1 (2%)	1 (2%)	4 (8%)	
Hepatodiaphragmatic Nodule	5 (10%)	8 (16%)	6 (12%)	4 (8%)
Infiltration Cellular, Histiocyte				1 (2%)
Infiltration Cellular, Mixed Cell	30 (60%)	30 (60%)	32 (65%)	19 (38%)
Inflammation, Chronic			1 (2%)	
Mixed Cell Focus	10 (20%)	4 (8%)	4 (8%)	
Necrosis, Focal	1 (2%)	1 (2%)	5 (10%)	4 (8%)

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TDMS No. 99037 - 05  
 Test Type: CHRONIC  
 Route: GAVAGE  
 Species/Strain: RATS/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
 alpha/beta Thujone mixture  
 CAS Number: THUJONEMIXAB

Date Report Requested: 08/18/2010  
 Time Report Requested: 08:14:26  
 First Dose M/F: 06/09/03 / 06/09/03  
 Lab: SRI

FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Artery, Inflammation		1 (2%)	1 (2%)	
Bile Duct, Hyperplasia	4 (8%)	2 (4%)	7 (14%)	
Capsule, Fibrosis	1 (2%)			
Centrilobular, Necrosis			3 (6%)	
Hepatocyte, Vacuolization Cytoplasmic	5 (10%)	4 (8%)	3 (6%)	
Kupffer Cell, Pigmentation		1 (2%)	1 (2%)	
Mesentery	(13)	(11)	(9)	(2)
Accessory Spleen		1 (9%)	2 (22%)	1 (50%)
Necrosis				1 (50%)
Fat, Necrosis	13 (100%)	10 (91%)	8 (89%)	1 (50%)
Oral Mucosa	(0)	(2)	(0)	(0)
Inflammation, Chronic Active		1 (50%)		
Pancreas	(49)	(49)	(50)	(50)
Atrophy	25 (51%)	24 (49%)	23 (46%)	5 (10%)
Cyst	14 (29%)	11 (22%)	9 (18%)	1 (2%)
Acinus, Hyperplasia, Focal	2 (4%)	1 (2%)	2 (4%)	
Salivary Glands	(50)	(50)	(50)	(50)
Atrophy	9 (18%)	10 (20%)	5 (10%)	2 (4%)
Hyperplasia				1 (2%)
Inflammation, Chronic		1 (2%)		
Mineralization		2 (4%)		1 (2%)
Necrosis				1 (2%)
Vacuolization Cytoplasmic		1 (2%)		1 (2%)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Edema	2 (4%)	1 (2%)		
Inflammation, Chronic Active			1 (2%)	
Ulcer	1 (2%)	2 (4%)		
Epithelium, Hyperplasia	7 (14%)	8 (16%)	2 (4%)	
Epithelium, Hyperplasia, Atypical			1 (2%)	
Stomach, Glandular	(48)	(47)	(48)	(50)
Cyst		1 (2%)		
Edema	1 (2%)			
Erosion	1 (2%)	1 (2%)	1 (2%)	3 (6%)
Ulcer	1 (2%)		3 (6%)	1 (2%)
Tongue	(1)	(3)	(0)	(0)
Hyperplasia	1 (100%)	2 (67%)		

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 alpha/beta Thujone mixture  
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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Ulcer		1 (33%)		
Tooth Degeneration	(0)	(1)	(0)	(0)
		1 (100%)		
<b>CARDIOVASCULAR SYSTEM</b>				
Heart	(50)	(50)	(50)	(50)
Cardiomyopathy	40 (80%)	30 (60%)	30 (60%)	8 (16%)
Hemorrhage				1 (2%)
Artery, Necrosis				1 (2%)
<b>ENDOCRINE SYSTEM</b>				
Adrenal Cortex	(47)	(49)	(46)	(50)
Accessory Adrenal Cortical Nodule	7 (15%)	12 (24%)	13 (28%)	9 (18%)
Degeneration, Fatty	23 (49%)	18 (37%)	19 (41%)	9 (18%)
Hematopoietic Cell Proliferation	1 (2%)	2 (4%)	4 (9%)	
Hemorrhage			1 (2%)	3 (6%)
Hyperplasia, Focal	22 (47%)	14 (29%)	9 (20%)	1 (2%)
Hypertrophy, Focal	7 (15%)	6 (12%)	2 (4%)	1 (2%)
Inflammation, Acute				1 (2%)
Necrosis	2 (4%)	1 (2%)	6 (13%)	4 (8%)
Adrenal Medulla	(48)	(50)	(48)	(50)
Angiectasis				1 (2%)
Hyperplasia	7 (15%)	5 (10%)	3 (6%)	
Infiltration Cellular, Lymphoid		1 (2%)		
Islets, Pancreatic	(49)	(49)	(50)	(50)
Hyperplasia	1 (2%)		1 (2%)	
Pituitary Gland	(50)	(49)	(49)	(48)
Pigmentation	5 (10%)	5 (10%)	9 (18%)	
Pars Distalis, Angiectasis	9 (18%)	4 (8%)	5 (10%)	2 (4%)
Pars Distalis, Atrophy			2 (4%)	12 (25%)
Pars Distalis, Cyst	18 (36%)	20 (41%)	17 (35%)	8 (17%)
Pars Distalis, Dilatation			1 (2%)	
Pars Distalis, Hyperplasia, Focal	5 (10%)	13 (27%)	6 (12%)	1 (2%)

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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Pars Intermedia, Angiectasis	2 (4%)			
Pars Intermedia, Cyst	1 (2%)	2 (4%)	2 (4%)	2 (4%)
Pars Intermedia, Hyperplasia	1 (2%)			
Rathke's Cleft, Dilatation	7 (14%)	1 (2%)	13 (27%)	26 (54%)
Thyroid Gland	(42)	(46)	(44)	(50)
Degeneration, Cystic	1 (2%)	2 (4%)	5 (11%)	
Ectopic Thymus				1 (2%)
Ultimobranchial Cyst	2 (5%)	1 (2%)	3 (7%)	2 (4%)
C-cell, Hyperplasia	1 (2%)	11 (24%)	2 (5%)	
Follicular Cell, Hyperplasia, Focal		1 (2%)	1 (2%)	
<b>GENERAL BODY SYSTEM</b>				
Tissue NOS	(1)	(1)	(0)	(0)
Fat, Mediastinum, Necrosis	1 (100%)			
<b>GENITAL SYSTEM</b>				
Clitoral Gland	(50)	(50)	(50)	(50)
Cyst	2 (4%)		1 (2%)	
Hyperplasia	9 (18%)	7 (14%)	11 (22%)	
Infiltration Cellular, Lymphocyte				1 (2%)
Inflammation, Chronic			1 (2%)	1 (2%)
Ovary	(50)	(50)	(50)	(50)
Cyst	3 (6%)	6 (12%)	2 (4%)	1 (2%)
Bilateral, Cyst			1 (2%)	
Uterus	(50)	(50)	(49)	(50)
Cyst	1 (2%)			
Hyperplasia, Cystic	22 (44%)	17 (34%)	19 (39%)	9 (18%)
Cervix, Cyst			1 (2%)	
Fat, Necrosis		1 (2%)		
Vagina	(2)	(2)	(1)	(0)

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**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
<b>HEMATOPOIETIC SYSTEM</b>				
Bone Marrow	(50)	(50)	(50)	(50)
Hyperplasia	4 (8%)	6 (12%)	6 (12%)	
Infiltration Cellular, Histiocyte	1 (2%)	1 (2%)	2 (4%)	4 (8%)
Myelofibrosis		1 (2%)		
Necrosis				1 (2%)
Lymph Node	(7)	(8)	(6)	(7)
Deep Cervical, Hyperplasia		1 (13%)		
Deep Cervical, Pigmentation		1 (13%)		
Iliac, Hemorrhage				1 (14%)
Iliac, Hyperplasia, Lymphoid				1 (14%)
Iliac, Pigmentation				1 (14%)
Mediastinal, Hemorrhage		2 (25%)	2 (33%)	2 (29%)
Mediastinal, Hyperplasia, Lymphoid		6 (75%)	3 (50%)	2 (29%)
Mediastinal, Pigmentation		5 (63%)	1 (17%)	1 (14%)
Pancreatic, Hemorrhage		1 (13%)	2 (33%)	1 (14%)
Pancreatic, Hyperplasia, Lymphoid			1 (17%)	4 (57%)
Pancreatic, Pigmentation		1 (13%)	1 (17%)	1 (14%)
Lymph Node, Mandibular	(1)	(4)	(1)	(4)
Hyperplasia, Lymphoid	1 (100%)	4 (100%)		2 (50%)
Pigmentation		1 (25%)		
Lymph Node, Mesenteric	(50)	(50)	(47)	(50)
Atrophy	1 (2%)	1 (2%)		
Ectasia	1 (2%)			
Hemorrhage	8 (16%)	9 (18%)	6 (13%)	3 (6%)
Hyperplasia, Lymphoid	4 (8%)	5 (10%)	4 (9%)	5 (10%)
Necrosis			1 (2%)	1 (2%)
Pigmentation			1 (2%)	
Spleen	(48)	(49)	(48)	(50)
Ectopic Spleen, Multiple		1 (2%)		
Fibrosis	1 (2%)			
Hematopoietic Cell Proliferation	21 (44%)	31 (63%)	21 (44%)	
Hemorrhage	1 (2%)			
Inflammation		1 (2%)		
Necrosis		1 (2%)	3 (6%)	4 (8%)

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TDMS No. 99037 - 05  
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 Species/Strain: RATS/F 344/N

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
 alpha/beta Thujone mixture  
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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Pigmentation	39 (81%)	40 (82%)	39 (81%)	45 (90%)
Lymphoid Follicle, Atrophy	2 (4%)	3 (6%)	2 (4%)	2 (4%)
Lymphoid Follicle, Hyperplasia	3 (6%)	3 (6%)	2 (4%)	8 (16%)
Lymphoid Follicle, Hyperplasia, Focal			1 (2%)	
Thymus	(48)	(45)	(50)	(50)
Cyst		2 (4%)		
Ectopic Parathyroid Gland	1 (2%)			
Necrosis			1 (2%)	3 (6%)

**INTEGUMENTARY SYSTEM**

Mammary Gland	(50)	(50)	(50)	(50)
Fibrosis	1 (2%)			
Hyperplasia	19 (38%)	21 (42%)	10 (20%)	
Hyperplasia, Focal	3 (6%)	1 (2%)		
Malformation			1 (2%)	
Duct, Ectasia	47 (94%)	45 (90%)	39 (78%)	
Skin	(50)	(50)	(50)	(50)
Cyst Epithelial Inclusion	2 (4%)		1 (2%)	
Hyperkeratosis	1 (2%)	1 (2%)	1 (2%)	
Inflammation, Chronic	1 (2%)			
Ulcer		1 (2%)		
Epidermis, Hyperplasia	2 (4%)	1 (2%)		
Subcutaneous Tissue, Fibrosis	1 (2%)			

**MUSCULOSKELETAL SYSTEM**

Bone	(50)	(50)	(50)	(50)
Femur, Osteopetrosis	1 (2%)	1 (2%)		
Skeletal Muscle	(0)	(0)	(1)	(0)

**NERVOUS SYSTEM**

Brain	(50)	(50)	(50)	(50)
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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Compression	9 (18%)	10 (20%)	6 (12%)	
Gliosis			1 (2%)	
Mineralization	1 (2%)		1 (2%)	
Necrosis			3 (6%)	
Pigmentation	1 (2%)	3 (6%)	5 (10%)	19 (38%)

**RESPIRATORY SYSTEM**

Lung	(50)	(50)	(50)	(50)
Hemorrhage				1 (2%)
Hyperplasia		1 (2%)		
Infiltration Cellular, Histiocyte	46 (92%)	43 (86%)	36 (72%)	8 (16%)
Inflammation, Suppurative		1 (2%)		
Inflammation, Chronic	10 (20%)	3 (6%)	5 (10%)	1 (2%)
Metaplasia, Osseous		1 (2%)	2 (4%)	
Necrosis				1 (2%)
Alveolar Epithelium, Hyperplasia	23 (46%)	25 (50%)	17 (34%)	4 (8%)
Nose	(50)	(50)	(50)	(50)
Congestion				2 (4%)
Foreign Body	7 (14%)	5 (10%)	3 (6%)	1 (2%)
Inflammation, Chronic	11 (22%)	11 (22%)	9 (18%)	1 (2%)
Thrombosis	1 (2%)			
Goblet Cell, Hyperplasia	1 (2%)			
Nasolacrimal Duct, Cyst				1 (2%)
Respiratory Epithelium, Hyperplasia	5 (10%)	4 (8%)	2 (4%)	

**SPECIAL SENSES SYSTEM**

Eye	(44)	(47)	(41)	(49)
Cataract		5 (11%)	2 (5%)	
Edema		1 (2%)	2 (5%)	
Hemorrhage	1 (2%)	1 (2%)		
Inflammation, Acute		1 (2%)		
Inflammation, Chronic	1 (2%)	1 (2%)		
Synechia		1 (2%)		

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FISCHER 344 RATS FEMALE	0 MG/KG	12.5 MG/KG	25 MG/KG	50 MG/KG
Bilateral, Cataract			1 (2%)	
Bilateral, Edema		1 (2%)		
Bilateral, Retinal Detachment		1 (2%)		
Retina, Degeneration		1 (2%)	2 (5%)	1 (2%)
Harderian Gland	(50)	(50)	(49)	(50)
Hemorrhage			4 (8%)	
Hyperplasia			1 (2%)	
Inflammation, Chronic	9 (18%)	11 (22%)	9 (18%)	6 (12%)

URINARY SYSTEM

Kidney	(44)	(45)	(40)	(50)
Casts Protein	14 (32%)	8 (18%)	12 (30%)	
Cyst	1 (2%)	1 (2%)		
Infarct	2 (5%)	1 (2%)	1 (3%)	
Inflammation, Suppurative	1 (2%)			
Inflammation, Chronic		1 (2%)	3 (8%)	
Mineralization	16 (36%)	24 (53%)	17 (43%)	8 (16%)
Nephropathy	33 (75%)	36 (80%)	26 (65%)	4 (8%)
Renal Tubule, Accumulation, Hyaline Droplet	2 (5%)	5 (11%)	4 (10%)	
Renal Tubule, Necrosis			1 (3%)	
Transitional Epithelium, Hyperplasia	2 (5%)	1 (2%)		
Urinary Bladder	(50)	(50)	(50)	(50)
Inflammation, Chronic				1 (2%)
Transitional Epithelium, Hyperplasia		1 (2%)		

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

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