

**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)   |

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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<br>Stromal Hyperplasia |                 |                  | 1 (2%)           | 1 (2%)         |
| Ulcer   | 1 (2%)          | 3 (6%)           | 2 (4%)           |                |
| Epithelium, Hyperplasia<br>Stomach, Glandular       | 9 (18%)<br>(50) | 12 (24%)<br>(50) | 13 (26%)<br>(49) | 3 (6%)<br>(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%)           |                |

**CARDIOVASCULAR SYSTEM**

|                          |          |          |          |          |
|--------------------------|----------|----------|----------|----------|
| 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%)   |          |          |

**ENDOCRINE SYSTEM**

|                                   |          |          |          |          |
|-----------------------------------|----------|----------|----------|----------|
| 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%)   |
| <b>GENERAL BODY SYSTEM</b>               |          |            |          |          |
| Tissue NOS                               | (1)      | (1)        | (2)      | (0)      |
| <b>GENITAL SYSTEM</b>                    |          |            |          |          |
| 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            | (2)      | (0)        | (0)      | (3)      |
| Congestion                        |          |            |          | 1 (33%)  |
| 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%) |

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

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

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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%)   |

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

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

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

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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%)   |

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

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%)    |          |          |

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

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 |
|-------------------------|---------|------------|----------|----------|
| Ulcer                   |         | 1 (33%)    |          |          |
| Tooth Degeneration      | (0)     | (1)        | (0)      | (0)      |
|                         |         | 1 (100%)   |          |          |

**CARDIOVASCULAR SYSTEM**

|                  |          |          |          |         |
|------------------|----------|----------|----------|---------|
| Heart            | (50)     | (50)     | (50)     | (50)    |
| Cardiomyopathy   | 40 (80%) | 30 (60%) | 30 (60%) | 8 (16%) |
| Hemorrhage       |          |          |          | 1 (2%)  |
| Artery, Necrosis |          |          |          | 1 (2%)  |

**ENDOCRINE SYSTEM**

|                                   |          |          |          |          |
|-----------------------------------|----------|----------|----------|----------|
| 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%)   |

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

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 |
|-------------------------------------|----------|------------|----------|----------|
| 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)      |

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

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 |
|------------------------------------|----------|------------|----------|----------|
| <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%)   |

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

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 |
|---------------------------------------|----------|------------|----------|----------|
| 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) |
|-------|------|------|------|------|

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

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 |
|-------------------------|---------|------------|----------|----------|
| 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%)  |        |      |

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

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 |
|-------------------------------|---------|------------|----------|----------|
| 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 \*\*\*

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