

TDMS No. 95011 - 07

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

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

5-(HYDROXYMETHYL)-2-FURFURAL

CAS Number: 67-47-0

Pathologist: TOFT, J. - Unknown, U.

F1\_R2

Date Report Reqsted: 09/01/2006

Time Report Reqsted: 08:20:21

First Dose M/F: 03/06/02 / 03/07/02

Lab: BAT

**C Number:** C95011B  
**Lock Date:** 11/09/2004  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL

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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Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

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| FISCHER 344 RATS MALE                | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|--------------------------------------|----------|-----------|-----------|-----------|
| <b>Disposition Summary</b>           |          |           |           |           |
| Animals Initially in Study           | 50       | 50        | 50        | 50        |
| Early Deaths                         |          |           |           |           |
| Dosing Accident                      |          |           | 1         | 1         |
| Moribund Sacrifice                   | 20       | 9         | 9         | 10        |
| Natural Death                        | 8        | 7         | 9         | 4         |
| Survivors                            |          |           |           |           |
| Terminal Sacrifice                   | 22       | 34        | 31        | 35        |
| Animals Examined Microscopically     | 50       | 50        | 50        | 50        |
| <b>ALIMENTARY SYSTEM</b>             |          |           |           |           |
| Esophagus                            | (50)     | (50)      | (50)      | (50)      |
| Periesophageal Tissue, Hemorrhage    |          |           | 1 [3.0]   |           |
| Intestine Large, Cecum               | (50)     | (50)      | (50)      | (50)      |
| Intestine Large, Colon               | (50)     | (50)      | (50)      | (50)      |
| Inflammation, Chronic Active         | 1 [3.0]  |           |           |           |
| Parasite Metazoan                    | 3        | 5         | 3         | 7         |
| Epithelium, Ulcer                    | 1 [4.0]  |           |           |           |
| Intestine Large, Rectum              | (50)     | (50)      | (50)      | (50)      |
| Parasite Metazoan                    | 4        | 7         | 4         | 7         |
| Intestine Small, Duodenum            | (50)     | (50)      | (50)      | (50)      |
| Intestine Small, Ileum               | (50)     | (50)      | (50)      | (50)      |
| Parasite Metazoan                    | 1        |           |           |           |
| Intestine Small, Jejunum             | (50)     | (50)      | (50)      | (50)      |
| Peyer's Patch, Hyperplasia, Lymphoid | 1 [4.0]  |           |           |           |
| Liver                                | (50)     | (50)      | (50)      | (50)      |
| Angiectasis                          | 1 [2.0]  | 1 [1.0]   |           | 2 [1.0]   |
| Basophilic Focus                     | 25       | 32        | 27        | 34        |
| Clear Cell Focus                     | 4        | 6         | 11        | 20        |
| Degeneration, Cystic                 |          |           | 1 [2.0]   |           |
| Eosinophilic Focus                   | 1        |           | 2         | 2         |
| Fibrosis                             | 1 [2.0]  |           |           | 1 [1.0]   |
| Hematopoietic Cell Proliferation     | 5 [1.6]  | 5 [1.0]   | 3 [1.7]   | 7 [1.1]   |
| Hemorrhage                           | 1 [3.0]  |           |           | 1 [3.0]   |
| Hepatodiaphragmatic Nodule           | 4        | 6         | 6         | 3         |
| Inflammation, Chronic Active         | 25 [1.4] | 34 [1.3]  | 30 [1.2]  | 38 [1.2]  |

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Lab: BAT

| FISCHER 344 RATS MALE                   | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---|----------|-----------|-----------|-----------|
| Mixed Cell Focus                        | 16       | 17        | 16        | 17        |
| Bile Duct, Hyperplasia                  | 49 [2.0] | 47 [2.0]  | 47 [2.1]  | 48 [2.0]  |
| Centrilobular, Hepatocyte, Degeneration | 2 [3.0]  | 1 [4.0]   | 5 [3.6]   | 3 [3.3]   |
| Hepatocyte, Degeneration, Cystic        | 8 [1.8]  | 17 [1.5]  | 15 [2.1]  | 10 [1.8]  |
| Hepatocyte, Fatty Change                | 14 [2.0] | 7 [2.1]   | 7 [1.9]   | 2 [3.0]   |
| Hepatocyte, Hyperplasia                 |          | 1 [4.0]   | 1 [3.0]   |           |
| Hepatocyte, Necrosis                    |          | 4 [2.5]   | 2 [2.0]   |           |
| Hepatocyte, Vacuolization Cytoplasmic   | 18 [1.6] | 24 [1.7]  | 16 [1.4]  | 24 [1.4]  |
| Mesentery                               | (9)      | (8)       | (7)       | (6)       |
| Fat, Fibrosis                           | 5 [2.4]  | 6 [2.7]   | 4 [2.8]   | 3 [2.0]   |
| Fat, Hemorrhage                         |          | 1 [2.0]   |           |           |
| Fat, Inflammation, Chronic Active       | 5 [3.4]  | 5 [2.8]   | 2 [2.0]   | 2 [2.0]   |
| Fat, Mineralization                     | 2 [1.5]  | 1 [2.0]   | 2 [2.0]   | 1 [1.0]   |
| Fat, Necrosis                           | 6 [4.0]  | 6 [3.8]   | 4 [4.0]   | 4 [4.0]   |
| Fat, Pigmentation                       |          | 2 [1.5]   |           | 1 [1.0]   |
| Pancreas                                | (50)     | (50)      | (50)      | (50)      |
| Basophilic Focus                        |          | 1         |           |           |
| Cyst                                    | 1 [3.0]  |           |           |           |
| Inflammation, Chronic Active            | 1 [1.0]  |           |           |           |
| Pigmentation                            | 1 [1.0]  |           |           |           |
| Acinus, Atrophy                         | 23 [2.1] | 21 [1.5]  | 25 [2.0]  | 23 [1.5]  |
| Acinus, Hyperplasia                     |          | 1 [4.0]   | 3 [3.3]   | 1 [3.0]   |
| Duct, Cyst                              |          |           | 1 [4.0]   |           |
| Salivary Glands                         | (50)     | (50)      | (49)      | (49)      |
| Atrophy, Focal                          |          |           |           | 1 [4.0]   |
| Inflammation, Chronic Active            |          |           | 1 [2.0]   |           |
| Stomach, Forestomach                    | (50)     | (50)      | (50)      | (50)      |
| Inflammation, Chronic Active            | 4 [2.5]  |           | 1 [2.0]   |           |
| Epithelium, Hyperplasia                 | 2 [2.5]  | 1 [2.0]   |           |           |
| Epithelium, Ulcer                       | 3 [4.0]  |           | 1 [4.0]   |           |
| Stomach, Glandular                      | (50)     | (50)      | (50)      | (50)      |
| Inflammation, Chronic Active            | 1 [2.0]  |           |           | 1 [1.0]   |
| Epithelium, Erosion                     | 1 [2.0]  | 2 [2.0]   | 2 [3.0]   |           |
| Epithelium, Hyperplasia                 |          |           |           | 1 [2.0]   |
| Tongue                                  | (0)      | (1)       | (0)       | (0)       |

## CARDIOVASCULAR SYSTEM

|       |      |      |      |      |
|-------|------|------|------|------|
| Heart | (50) | (50) | (50) | (50) |
|-------|------|------|------|------|

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| FISCHER 344 RATS MALE                 | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---------------------------------------|----------|-----------|-----------|-----------|
| Cardiomyopathy                        | 48 [2.1] | 49 [2.1]  | 49 [2.2]  | 48 [2.0]  |
| Mineralization                        |          |           | 1 [2.0]   | 1 [3.0]   |
| Pigmentation                          |          | 1 [1.0]   |           |           |
| Atrium, Fibrosis                      |          |           |           | 2 [2.5]   |
| Atrium, Thrombosis                    | 5 [3.4]  | 4 [3.8]   | 3 [3.7]   | 2 [3.0]   |
| Valve, Thrombosis                     |          |           |           | 1 [4.0]   |
| <b>ENDOCRINE SYSTEM</b>               |          |           |           |           |
| Adrenal Cortex                        | (50)     | (50)      | (50)      | (50)      |
| Accessory Adrenal Cortical Nodule     |          |           | 1 [3.0]   | 1 [4.0]   |
| Degeneration, Fatty                   |          |           | 1 [2.0]   |           |
| Hematopoietic Cell Proliferation      | 9 [1.0]  | 6 [1.0]   | 2 [1.0]   | 9 [1.0]   |
| Hyperplasia                           | 20 [1.4] | 7 [2.1]   | 11 [1.4]  | 18 [1.4]  |
| Hypertrophy                           | 1 [2.0]  | 2 [1.5]   | 4 [1.8]   | 2 [2.0]   |
| Necrosis                              |          | 1 [3.0]   | 1 [4.0]   |           |
| Vacuolization Cytoplasmic             | 36 [1.5] | 25 [1.5]  | 25 [1.3]  | 28 [1.3]  |
| Capsule, Inflammation, Chronic Active |          |           | 1 [2.0]   |           |
| Adrenal Medulla                       | (50)     | (50)      | (50)      | (50)      |
| Angiectasis                           |          |           |           | 1 [3.0]   |
| Fibrosis                              | 2 [3.0]  |           |           |           |
| Hemorrhage                            |          | 1 [4.0]   |           |           |
| Hyperplasia                           | 19 [1.9] | 26 [1.8]  | 17 [2.1]  | 13 [1.7]  |
| Pigmentation                          | 1 [2.0]  |           |           |           |
| Islets, Pancreatic                    | (50)     | (50)      | (50)      | (50)      |
| Hyperplasia                           | 1 [2.0]  |           | 2 [2.0]   |           |
| Parathyroid Gland                     | (49)     | (48)      | (48)      | (48)      |
| Pituitary Gland                       | (50)     | (50)      | (50)      | (50)      |
| Pars Distalis, Angiectasis            | 15 [2.7] | 16 [2.6]  | 19 [2.8]  | 14 [3.0]  |
| Pars Distalis, Cyst                   | 8 [1.6]  | 3 [2.7]   | 3 [2.7]   | 4 [2.0]   |
| Pars Distalis, Cyst, Multiple         | 1 [2.0]  | 1 [4.0]   | 2 [3.0]   | 1 [1.0]   |
| Pars Distalis, Hyperplasia            | 20 [2.2] | 20 [2.2]  | 18 [2.2]  | 23 [2.1]  |
| Pars Distalis, Pigmentation           | 14 [1.4] | 18 [1.4]  | 14 [1.5]  | 11 [1.5]  |
| Pars Intermedia, Angiectasis          |          | 1 [3.0]   |           |           |
| Pars Intermedia, Cyst                 |          |           | 1 [2.0]   |           |
| Pars Intermedia, Pigmentation         | 3 [2.0]  | 2 [1.0]   |           |           |
| Thyroid Gland                         | (50)     | (49)      | (48)      | (48)      |
| Pigmentation                          | 1 [2.0]  |           |           |           |
| Ultimobranchial Cyst                  | 2 [2.0]  |           | 1 [2.0]   | 1 [2.0]   |

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| FISCHER 344 RATS MALE             | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|-----------------------------------|----------|-----------|-----------|-----------|
| Bilateral, C-cell, Hyperplasia    |          | 1 [2.0]   |           |           |
| C-cell, Hyperplasia               | 11 [2.2] | 16 [1.4]  | 8 [1.4]   | 11 [2.0]  |
| Follicle, Cyst                    |          | 4 [3.0]   | 1 [2.0]   | 3 [3.0]   |
| Follicular Cell, Hyperplasia      | 1 [2.0]  |           | 1 [2.0]   | 1 [1.0]   |
| <b>GENERAL BODY SYSTEM</b>        |          |           |           |           |
| Peritoneum                        | (1)      | (0)       | (0)       | (0)       |
| <b>GENITAL SYSTEM</b>             |          |           |           |           |
| Coagulating Gland                 | (1)      | (0)       | (0)       | (4)       |
| Inflammation                      |          |           |           | 1 [4.0]   |
| Epididymis                        | (50)     | (50)      | (50)      | (50)      |
| Granuloma Sperm                   | 4 [3.3]  |           |           | 2 [2.5]   |
| Preputial Gland                   | (50)     | (50)      | (50)      | (50)      |
| Hyperplasia                       | 4 [2.3]  | 2 [3.0]   | 1 [4.0]   | 1 [3.0]   |
| Inflammation, Chronic Active      | 43 [2.1] | 46 [1.7]  | 44 [1.8]  | 46 [1.9]  |
| Mineralization                    |          |           |           | 1 [2.0]   |
| Bilateral, Hyperplasia            |          | 1 [3.0]   |           |           |
| Duct, Ectasia                     | 3 [3.7]  | 2 [4.0]   | 2 [3.0]   | 2 [2.0]   |
| Prostate                          | (50)     | (50)      | (50)      | (50)      |
| Cyst, Multiple                    |          |           | 1 [3.0]   |           |
| Inflammation, Chronic Active      | 22 [1.7] | 27 [1.8]  | 36 [1.7]  | 30 [1.8]  |
| Epithelium, Hyperplasia           | 10 [1.6] | 13 [1.3]  | 14 [1.6]  | 17 [1.4]  |
| Epithelium, Hypertrophy           | 14 [1.6] | 14 [1.8]  | 21 [1.7]  | 17 [1.4]  |
| Seminal Vesicle                   | (50)     | (50)      | (50)      | (50)      |
| Testes                            | (50)     | (50)      | (50)      | (50)      |
| Mineralization                    | 32 [1.3] | 34 [1.0]  | 30 [1.1]  | 24 [1.2]  |
| Germinal Epithelium, Degeneration | 5 [3.0]  | 7 [3.6]   | 8 [2.5]   | 5 [3.6]   |
| Interstitial Cell, Hyperplasia    | 10 [1.4] | 11 [1.0]  | 10 [1.4]  | 5 [1.2]   |
| <b>HEMATOPOIETIC SYSTEM</b>       |          |           |           |           |
| Bone Marrow                       | (50)     | (50)      | (50)      | (50)      |
| Fibrosis                          |          |           |           | 1 [2.0]   |
| Hyperplasia                       | 19 [3.9] | 20 [3.9]  | 27 [3.7]  | 16 [3.6]  |
| Lymph Node                        | (10)     | (6)       | (4)       | (4)       |

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|----------------------------------|---------|-----------|-----------|-----------|
| Deep Cervical, Pigmentation      | 1 [2.0] |           |           |           |
| Pancreatic, Hemorrhage           |         | 1 [4.0]   |           |           |
| Lymph Node, Mesenteric           | (50)    | (50)      | (50)      | (49)      |
| Necrosis, Lymphoid               |         | 1 [4.0]   |           |           |
| Spleen                           | (50)    | (50)      | (50)      | (50)      |
| Hematopoietic Cell Proliferation | 5 [2.4] |           |           | 2 [3.0]   |
| Necrosis                         | 1 [3.0] |           |           |           |
| Capsule, Fibrosis                |         |           | 1 [3.0]   |           |
| Lymphoid Follicle, Atrophy       |         |           | 1 [4.0]   |           |
| Lymphoid Follicle, Hyperplasia   |         |           | 1 [4.0]   |           |
| Thymus                           | (48)    | (47)      | (49)      | (46)      |
| Ectopic Parathyroid Gland        |         |           | 1 [2.0]   | 1 [2.0]   |
| Thymocyte, Necrosis              |         | 1 [3.0]   |           |           |
| <b>INTEGUMENTARY SYSTEM</b>      |         |           |           |           |
| Mammary Gland                    | (50)    | (49)      | (50)      | (50)      |
| Cyst                             |         |           |           | 2 [2.0]   |
| Galactocele                      |         |           | 1 [4.0]   |           |
| Duct, Dilatation                 | 7 [2.4] | 15 [2.1]  | 8 [1.9]   | 4 [2.0]   |
| Skin                             | (50)    | (49)      | (50)      | (50)      |
| Cyst Epithelial Inclusion        |         |           |           | 1 [4.0]   |
| Inflammation, Chronic Active     |         |           | 1 [2.0]   |           |
| Epidermis, Hyperplasia           |         |           | 1 [4.0]   |           |
| <b>MUSCULOSKELETAL SYSTEM</b>    |         |           |           |           |
| Bone                             | (50)    | (50)      | (50)      | (50)      |
| Hyperostosis                     |         | 1 [4.0]   |           |           |
| Skeletal Muscle                  | (3)     | (1)       | (2)       | (2)       |
| Lymphatic, Angiectasis           |         |           |           | 1 [4.0]   |
| <b>NERVOUS SYSTEM</b>            |         |           |           |           |
| Brain                            | (50)    | (50)      | (50)      | (50)      |
| Compression                      | 1 [4.0] | 2 [3.5]   |           |           |
| Hemorrhage                       | 4 [2.8] | 2 [2.5]   | 1 [2.0]   |           |
| Hydrocephalus                    |         | 1 [3.0]   |           | 2 [2.5]   |

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|--|----------|-----------|-----------|-----------|
| Cerebellum, Necrosis                                   |          | 1 [4.0]   |           |           |
| Spinal Cord  | (1)      | (1)       | (1)       | (0)       |
| Hemorrhage   |          | 1 [3.0]   |           |           |
| <b>RESPIRATORY SYSTEM</b>                              |          |           |           |           |
| Lung   | (50)     | (50)      | (50)      | (50)      |
| Congestion   |          |           |           | 1 [2.0]   |
| Fibrosis   | 1 [2.0]  |           |           |           |
| Hemorrhage   |          |           |           | 1 [3.0]   |
| Inflammation, Suppurative                              |          |           |           | 1 [4.0]   |
| Inflammation, Chronic Active                           | 22 [1.5] | 19 [1.3]  | 24 [1.3]  | 30 [1.3]  |
| Metaplasia, Osseous                                    | 1 [2.0]  | 2 [1.0]   | 1 [1.0]   | 1 [2.0]   |
| Metaplasia, Squamous                                   |          | 1 [3.0]   |           |           |
| Pigmentation   |          |           |           | 1 [2.0]   |
| Alveolar Epithelium, Hyperplasia                       | 9 [2.0]  | 15 [2.3]  | 13 [2.4]  | 9 [2.0]   |
| Alveolar Epithelium, Metaplasia,<br>Squamous           | 1 [2.0]  |           |           |           |
| Alveolus, Infiltration Cellular, Histiocyte            | 28 [1.0] | 30 [1.0]  | 34 [1.1]  | 36 [1.1]  |
| Bronchus, Foreign Body                                 |          |           |           | 1         |
| Bronchus, Hyperplasia                                  |          |           |           | 1 [4.0]   |
| Perivascular, Infiltration Cellular,<br>Lymphoid       | 29 [1.3] | 28 [1.0]  | 28 [1.1]  | 32 [1.2]  |
| Nose   | (50)     | (49)      | (48)      | (49)      |
| Foreign Body   | 10       | 14        | 7         | 9         |
| Inflammation, Suppurative                              | 3 [1.7]  | 7 [1.7]   | 5 [2.2]   | 9 [1.7]   |
| Inflammation, Chronic Active                           | 6 [1.3]  | 9 [1.8]   | 2 [1.5]   | 5 [1.6]   |
| Thrombosis   | 2 [4.0]  | 4 [3.5]   | 6 [4.0]   | 1 [4.0]   |
| Glands, Dilatation                                     | 1 [2.0]  | 1 [2.0]   |           |           |
| Nasolacrimal Duct, Cyst                                |          |           | 1         |           |
| Nasolacrimal Duct, Inflammation,<br>Suppurative        | 2 [2.0]  | 1 [2.0]   |           |           |
| Nasolacrimal Duct, Inflammation, Chronic               | 3 [2.0]  | 4 [2.3]   | 3 [2.0]   | 1 [2.0]   |
| Olfactory Epithelium, Accumulation,<br>Hyaline Droplet | 6 [1.3]  |           |           |           |
| Olfactory Epithelium, Cyst                             |          | 1         |           |           |
| Olfactory Epithelium, Degeneration                     | 18 [1.1] | 22 [1.1]  | 26 [1.2]  | 29 [1.5]  |
| Olfactory Epithelium, Metaplasia,<br>Respiratory       | 2 [2.0]  | 5 [1.4]   | 3 [1.3]   | 11 [1.4]  |

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|--|----------|-----------|-----------|-----------|
| Olfactory Epithelium, Metaplasia,<br>Squamous            |          |           |           | 1 [2.0]   |
| Olfactory Epithelium, Necrosis                           | 1 [3.0]  |           |           |           |
| Respiratory Epithelium, Accumulation,<br>Hyaline Droplet | 7 [1.6]  |           |           |           |
| Respiratory Epithelium, Hyperplasia                      | 28 [1.9] | 24 [1.7]  | 18 [1.6]  | 23 [1.9]  |
| Respiratory Epithelium, Metaplasia,<br>Squamous          |          | 2 [1.5]   | 1 [1.0]   | 16 [2.0]  |
| Respiratory Epithelium, Necrosis                         | 1 [2.0]  |           |           |           |
| Trachea  | (50)     | (50)      | (50)      | (50)      |
| Inflammation, Chronic Active                             |          |           |           | 1 [2.0]   |
| <b>SPECIAL SENSES SYSTEM</b>                             |          |           |           |           |
| Ear  | (0)      | (0)       | (0)       | (2)       |
| Eye  | (50)     | (50)      | (50)      | (50)      |
| Lens, Cataract   | 3 [3.3]  | 1 [4.0]   |           | 1 [4.0]   |
| Retina, Degeneration                                     | 3 [3.3]  | 1 [4.0]   |           | 1 [4.0]   |
| Harderian Gland  | (49)     | (50)      | (50)      | (50)      |
| Hyperplasia  |          |           |           | 1 [2.0]   |
| Inflammation, Chronic Active                             | 5 [1.2]  | 6 [1.5]   | 3 [1.7]   | 7 [1.1]   |
| Zymbal's Gland   | (0)      | (0)       | (0)       | (1)       |
| <b>URINARY SYSTEM</b>                                    |          |           |           |           |
| Kidney   | (50)     | (50)      | (50)      | (50)      |
| Hydronephrosis   |          |           |           | 1 [2.0]   |
| Infarct  |          | 1 [4.0]   | 1 [4.0]   |           |
| Inflammation, Suppurative                                |          |           |           | 1 [2.0]   |
| Mineralization   | 19 [1.0] | 30 [1.0]  | 22 [1.0]  | 30 [1.0]  |
| Nephropathy  | 50 [1.9] | 49 [1.9]  | 45 [2.0]  | 47 [1.7]  |
| Thrombosis   |          |           | 1 [4.0]   | 1 [3.0]   |
| Bilateral, Infarct                                       |          | 1 [4.0]   |           |           |
| Cortex, Cyst   | 1 [2.0]  | 1 [4.0]   |           |           |
| Renal Tubule, Accumulation, Hyaline<br>Droplet           |          | 1 [4.0]   | 1 [3.0]   | 1 [4.0]   |
| Renal Tubule, Hyperplasia                                |          |           | 2 [1.0]   |           |
| Urinary Bladder  | (50)     | (50)      | (50)      | (50)      |
| Inflammation, Chronic Active                             |          |           |           | 1 [3.0]   |

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)

TDMS No. 95011 - 07

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

Date Report Reqsted: 09/01/2006

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Reqsted: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

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FISCHER 344 RATS MALE

0 MG/KG

188 MG/KG

375 MG/KG

750 MG/KG

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

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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE          | 0 MG/KG | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|----------------------------------|---------|-----------|-----------|-----------|
| <b>Disposition Summary</b>       |         |           |           |           |
| Animals Initially in Study       | 50      | 50        | 50        | 50        |
| Early Deaths                     |         |           |           |           |
| Dosing Accident                  |         |           |           | 2         |
| Moribund Sacrifice               | 14      | 7         | 13        | 7         |
| Natural Death                    | 5       | 11        | 10        | 11        |
| Survivors                        |         |           |           |           |
| Natural Death                    |         |           |           | 1         |
| Terminal Sacrifice               | 31      | 32        | 27        | 29        |
| Animals Examined Microscopically | 50      | 50        | 50        | 50        |

## ALIMENTARY SYSTEM

|   |          |          |          |          |
|---|----------|----------|----------|----------|
| Intestine Large, Cecum                  | (50)     | (50)     | (50)     | (49)     |
| Intestine Large, Colon                  | (50)     | (50)     | (50)     | (49)     |
| Parasite Metazoan                       | 1        |          | 1        | 4        |
| Intestine Large, Rectum                 | (50)     | (49)     | (50)     | (50)     |
| Diverticulum                            |          | 1 [4.0]  |          |          |
| Parasite Metazoan                       | 3        | 6        | 3        | 3        |
| Intestine Small, Ileum                  | (50)     | (50)     | (50)     | (49)     |
| Parasite Metazoan                       |          |          | 1        |          |
| Intestine Small, Jejunum                | (50)     | (50)     | (50)     | (49)     |
| Peyer's Patch, Hyperplasia, Lymphoid    |          | 1 [3.0]  |          |          |
| Liver                                   | (50)     | (50)     | (50)     | (49)     |
| Angiectasis                             |          | 1 [2.0]  | 1 [3.0]  | 2 [1.0]  |
| Basophilic Focus                        | 44       | 47       | 45       | 42       |
| Clear Cell Focus                        |          | 2        | 2        | 1        |
| Eosinophilic Focus                      |          |          | 1 [2.0]  | 1        |
| Hematopoietic Cell Proliferation        | 7 [1.0]  | 10 [1.0] | 8 [1.0]  | 4 [1.0]  |
| Hemorrhage                              |          |          | 1 [4.0]  |          |
| Hepatodiaphragmatic Nodule              | 6        | 8        | 8        | 7        |
| Inflammation, Chronic Active            | 43 [1.1] | 40 [1.2] | 41 [1.1] | 39 [1.2] |
| Mineralization                          |          |          | 1 [1.0]  |          |
| Mixed Cell Focus                        | 9        | 13       | 8        | 8        |
| Bile Duct, Hyperplasia                  | 23 [1.1] | 22 [1.1] | 29 [1.1] | 24 [1.2] |
| Centrilobular, Hepatocyte, Degeneration | 2 [3.0]  |          |          | 2 [3.5]  |
| Hepatocyte, Degeneration, Cystic        |          |          | 1 [1.0]  | 1 [1.0]  |

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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE               | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---------------------------------------|----------|-----------|-----------|-----------|
| Hepatocyte, Fatty Change              | 6 [2.5]  | 5 [1.4]   |           | 2 [2.0]   |
| Hepatocyte, Hyperplasia               |          | 1 [3.0]   |           |           |
| Hepatocyte, Necrosis                  |          |           |           | 2 [2.0]   |
| Hepatocyte, Vacuolization Cytoplasmic | 9 [1.0]  | 5 [1.8]   | 2 [2.0]   | 2 [1.5]   |
| Mesentery                             | (7)      | (10)      | (9)       | (9)       |
| Fat, Fibrosis                         | 5 [2.8]  | 8 [2.8]   | 7 [2.6]   | 8 [2.9]   |
| Fat, Inflammation, Chronic Active     | 5 [3.0]  | 7 [3.0]   | 7 [2.6]   | 5 [2.6]   |
| Fat, Mineralization                   | 4 [1.8]  | 6 [1.5]   | 3 [1.7]   | 5 [1.4]   |
| Fat, Necrosis                         | 7 [4.0]  | 9 [4.0]   | 7 [4.0]   | 9 [4.0]   |
| Fat, Pigmentation                     |          |           |           | 3 [1.7]   |
| Lymphatic, Angiectasis                |          |           | 1 [4.0]   |           |
| Pancreas                              | (50)     | (50)      | (50)      | (49)      |
| Infiltration Cellular, Lymphoid       |          | 1 [4.0]   |           |           |
| Inflammation, Chronic Active          |          | 2 [1.5]   | 1 [1.0]   |           |
| Acinus, Atrophy                       | 10 [1.7] | 11 [1.6]  | 5 [1.0]   | 10 [1.5]  |
| Acinus, Hyperplasia                   |          |           | 1 [2.0]   |           |
| Duct, Cyst                            |          | 1 [2.0]   |           | 3 [2.0]   |
| Salivary Glands                       | (50)     | (49)      | (50)      | (50)      |
| Stomach, Forestomach                  | (50)     | (50)      | (50)      | (49)      |
| Inflammation, Chronic Active          | 1 [3.0]  | 2 [2.5]   |           | 3 [2.7]   |
| Epithelium, Hyperplasia               | 2 [2.5]  |           |           | 3 [2.0]   |
| Epithelium, Ulcer                     | 1 [4.0]  | 2 [3.0]   |           | 2 [4.0]   |
| Stomach, Glandular                    | (50)     | (50)      | (50)      | (49)      |
| <b>CARDIOVASCULAR SYSTEM</b>          |          |           |           |           |
| Heart                                 | (50)     | (50)      | (50)      | (50)      |
| Cardiomyopathy                        | 47 [1.8] | 49 [2.0]  | 46 [1.8]  | 47 [1.8]  |
| Mineralization                        | 1 [3.0]  |           |           |           |
| Atrium, Thrombosis                    | 2 [4.0]  |           |           | 1 [4.0]   |
| Valve, Inflammation, Suppurative      |          |           | 1 [3.0]   |           |
| <b>ENDOCRINE SYSTEM</b>               |          |           |           |           |
| Adrenal Cortex                        | (50)     | (50)      | (50)      | (49)      |
| Accessory Adrenal Cortical Nodule     |          |           | 1 [2.0]   | 2 [2.0]   |
| Hematopoietic Cell Proliferation      | 7 [1.0]  | 14 [1.0]  | 9 [1.0]   | 7 [1.0]   |
| Hyperplasia                           | 12 [1.5] | 14 [2.2]  | 13 [1.7]  | 4 [2.0]   |
| Hypertrophy                           | 5 [1.6]  | 5 [1.8]   | 1 [3.0]   | 3 [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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE                         | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---|----------|-----------|-----------|-----------|
| Karyomegaly                                     |          |           |           | 1 [2.0]   |
| Necrosis  | 1 [3.0]  | 1 [2.0]   |           |           |
| Pigmentation                                    |          |           | 1 [2.0]   |           |
| Vacuolization Cytoplasmic                       | 22 [1.7] | 25 [1.7]  | 16 [1.5]  | 20 [1.4]  |
| Bilateral, Hemorrhage                           |          | 1 [3.0]   |           |           |
| Adrenal Medulla                                 | (50)     | (50)      | (50)      | (49)      |
| Hyperplasia                                     | 4 [2.3]  | 3 [2.0]   | 2 [1.0]   | 4 [2.3]   |
| Infiltration Cellular, Lymphoid                 |          |           |           | 2 [2.0]   |
| Islets, Pancreatic                              | (50)     | (50)      | (50)      | (49)      |
| Pituitary Gland                                 | (50)     | (50)      | (50)      | (50)      |
| Hemorrhage                                      |          | 1 [4.0]   |           |           |
| Pars Distalis, Pars Intermedia,<br>Pigmentation |          |           | 1 [2.0]   | 1 [1.0]   |
| Pars Distalis, Angiectasis                      | 34 [2.8] | 34 [2.9]  | 29 [2.7]  | 34 [2.8]  |
| Pars Distalis, Cyst                             | 7 [1.9]  | 9 [2.3]   | 11 [1.9]  | 7 [2.1]   |
| Pars Distalis, Cyst, Multiple                   | 10 [2.2] | 12 [2.5]  | 14 [2.1]  | 9 [2.2]   |
| Pars Distalis, Hyperplasia                      | 20 [2.6] | 13 [2.4]  | 20 [2.4]  | 20 [2.7]  |
| Pars Distalis, Pigmentation                     | 27 [1.6] | 27 [1.4]  | 27 [1.3]  | 30 [1.3]  |
| Pars Distalis, Vacuolization Cytoplasmic        | 1 [2.0]  |           |           |           |
| Pars Intermedia, Angiectasis                    |          |           |           | 1 [2.0]   |
| Pars Intermedia, Cyst                           | 1 [3.0]  |           |           | 4 [2.0]   |
| Pars Intermedia, Cyst, Multiple                 | 1 [3.0]  |           |           | 1 [3.0]   |
| Pars Intermedia, Pigmentation                   | 2 [1.0]  | 1 [2.0]   | 2 [1.5]   |           |
| Rathke's Cleft, Cyst                            |          |           | 1 [3.0]   |           |
| Thyroid Gland                                   | (50)     | (50)      | (50)      | (50)      |
| Ultimobranchial Cyst                            |          | 1 [2.0]   |           | 1 [2.0]   |
| C-cell, Hyperplasia                             | 14 [1.8] | 13 [1.5]  | 13 [1.3]  | 13 [1.4]  |
| Follicle, Cyst                                  | 1 [2.0]  |           |           | 1 [3.0]   |
| Follicular Cell, Hyperplasia                    |          |           |           | 1 [2.0]   |
| <b>GENERAL BODY SYSTEM</b>                      |          |           |           |           |
| Peritoneum                                      | (0)      | (1)       | (0)       | (0)       |
| Tissue NOS                                      | (0)      | (0)       | (0)       | (1)       |
| <b>GENITAL SYSTEM</b>                           |          |           |           |           |
| Clitoral Gland                                  | (50)     | (50)      | (50)      | (50)      |
| Hyperplasia                                     | 10 [3.1] | 13 [2.5]  | 7 [2.6]   | 8 [2.5]   |

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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE                              | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|--|----------|-----------|-----------|-----------|
| Inflammation, Chronic Active                         | 12 [2.0] | 26 [1.7]  | 18 [1.7]  | 10 [1.3]  |
| Bilateral, Hyperplasia                               |          | 1 [3.0]   | 3 [2.3]   | 1 [4.0]   |
| Duct, Cyst   | 1 [2.0]  | 1 [2.0]   | 1 [2.0]   | 2 [2.5]   |
| Ovary  | (49)     | (50)      | (50)      | (49)      |
| Atrophy  |          | 1 [4.0]   |           |           |
| Cyst   | 11 [3.4] | 9 [3.3]   | 6 [3.3]   | 5 [2.8]   |
| Bilateral, Cyst                                      |          | 1 [4.0]   |           |           |
| Uterus   | (50)     | (50)      | (50)      | (49)      |
| Hemorrhage   | 1 [4.0]  |           | 1 [4.0]   |           |
| Endometrium, Cyst                                    |          | 2 [2.5]   | 2 [2.0]   | 1 [4.0]   |
| Vagina   | (0)      | (0)       | (3)       | (0)       |
| <b>HEMATOPOIETIC SYSTEM</b>                          |          |           |           |           |
| Bone Marrow  | (50)     | (50)      | (50)      | (50)      |
| Hyperplasia  | 9 [3.8]  | 9 [3.6]   | 9 [3.7]   | 8 [3.5]   |
| Hyperplasia, Histiocytic                             |          |           | 1 [4.0]   |           |
| Lymph Node   | (1)      | (1)       | (1)       | (4)       |
| Lymph Node, Mesenteric                               | (50)     | (49)      | (50)      | (49)      |
| Hyperplasia, Lymphoid                                | 1 [3.0]  |           |           |           |
| Spleen   | (50)     | (50)      | (50)      | (49)      |
| Accessory Spleen                                     |          |           |           | 1         |
| Hematopoietic Cell Proliferation                     | 2 [3.5]  | 3 [2.3]   | 6 [2.2]   | 2 [3.0]   |
| Lymphoid Follicle, Hyperplasia                       |          | 1 [4.0]   |           |           |
| Thymus   | (48)     | (47)      | (48)      | (43)      |
| Ectopic Parathyroid Gland                            | 2 [2.0]  | 6 [2.0]   | 2 [1.5]   | 1 [2.0]   |
| Ectopic Thyroid                                      |          |           | 1 [2.0]   |           |
| <b>INTEGUMENTARY SYSTEM</b>                          |          |           |           |           |
| Mammary Gland  | (50)     | (50)      | (50)      | (49)      |
| Cyst   |          |           |           | 1 [4.0]   |
| Galactocele  | 17 [3.9] | 17 [3.8]  | 21 [3.8]  | 17 [3.8]  |
| Hyperplasia, Cystic                                  |          | 1 [2.0]   | 1 [3.0]   |           |
| Duct, Dilatation                                     | 37 [2.6] | 40 [2.4]  | 35 [2.3]  | 38 [2.2]  |
| Skin   | (50)     | (50)      | (50)      | (50)      |
| Cyst Epithelial Inclusion                            | 1 [4.0]  |           |           | 1 [4.0]   |
| Subcutaneous Tissue, Inflammation,<br>Chronic Active |          |           |           | 1 [3.0]   |

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Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE                       | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---|----------|-----------|-----------|-----------|
| <b>MUSCULOSKELETAL SYSTEM</b>                 |          |           |           |           |
| Bone  | (50)     | (50)      | (50)      | (50)      |
| Osteopetrosis                                 | 1 [3.0]  |           |           |           |
| Skeletal Muscle                               | (1)      | (0)       | (0)       | (0)       |
| <b>NERVOUS SYSTEM</b>                         |          |           |           |           |
| Brain   | (50)     | (50)      | (50)      | (50)      |
| Compression                                   | 2 [3.0]  | 1 [4.0]   | 2 [3.5]   | 4 [3.3]   |
| Hemorrhage                                    | 1 [3.0]  |           |           |           |
| Hydrocephalus                                 | 2 [2.0]  | 3 [2.3]   | 1 [3.0]   | 1 [3.0]   |
| Inflammation, Chronic Active                  | 1 [3.0]  |           |           |           |
| Necrosis                                      | 1 [4.0]  |           |           |           |
| Spinal Cord                                   | (0)      | (0)       | (1)       | (0)       |
| Hemorrhage                                    |          |           | 1 [2.0]   |           |
| <b>RESPIRATORY SYSTEM</b>                     |          |           |           |           |
| Lung  | (50)     | (50)      | (50)      | (50)      |
| Cyst  |          |           |           | 1 [3.0]   |
| Fibrosis                                      |          |           |           | 3 [2.3]   |
| Hemorrhage                                    |          |           |           | 1 [3.0]   |
| Inflammation, Suppurative                     |          | 1 [1.0]   |           |           |
| Inflammation, Chronic Active                  | 31 [1.3] | 30 [1.4]  | 28 [1.5]  | 37 [1.7]  |
| Metaplasia, Osseous                           | 2 [1.0]  | 1 [1.0]   | 1 [1.0]   |           |
| Pigmentation                                  | 3 [2.0]  | 3 [1.7]   | 5 [1.2]   | 2 [1.5]   |
| Alveolar Epithelium, Hyperplasia              | 11 [2.4] | 10 [1.6]  | 10 [2.3]  | 8 [2.4]   |
| Alveolus, Infiltration Cellular, Histiocyte   | 45 [1.0] | 46 [1.0]  | 46 [1.0]  | 37 [1.1]  |
| Bronchus, Hyperplasia                         |          |           |           | 3 [3.7]   |
| Bronchus, Metaplasia, Squamous                |          |           |           | 3 [2.7]   |
| Perivascular, Infiltration Cellular, Lymphoid | 40 [1.1] | 45 [1.2]  | 43 [1.3]  | 42 [1.2]  |
| Nose  | (50)     | (49)      | (49)      | (49)      |
| Foreign Body                                  | 3        | 2         | 1         | 8         |
| Inflammation, Suppurative                     |          |           |           | 8 [1.5]   |
| Inflammation, Chronic Active                  | 4 [1.8]  | 3 [1.3]   | 2 [1.0]   | 7 [1.4]   |

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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE                                  | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|--|----------|-----------|-----------|-----------|
| Thrombosis   |          |           |           | 1 [1.0]   |
| Glands, Dilatation                                       |          | 1 [2.0]   | 1 [2.0]   |           |
| Nasolacrimal Duct, Inflammation,<br>Suppurative          | 1 [2.0]  | 1 [2.0]   | 1 [2.0]   | 2 [2.0]   |
| Nasolacrimal Duct, Inflammation, Chronic                 | 2 [2.0]  | 2 [2.0]   | 3 [1.7]   | 12 [2.0]  |
| Olfactory Epithelium, Accumulation,<br>Hyaline Droplet   | 34 [1.9] | 15 [1.3]  | 22 [1.5]  |           |
| Olfactory Epithelium, Degeneration                       | 21 [1.2] | 35 [1.2]  | 36 [1.2]  | 28 [1.3]  |
| Olfactory Epithelium, Metaplasia,<br>Respiratory         | 1 [1.0]  | 1 [2.0]   |           | 11 [1.8]  |
| Olfactory Epithelium, Metaplasia,<br>Squamous            |          |           |           | 2 [1.0]   |
| Olfactory Epithelium, Necrosis                           |          |           | 1 [2.0]   |           |
| Respiratory Epithelium, Accumulation,<br>Hyaline Droplet | 9 [1.8]  | 3 [1.3]   | 4 [1.3]   |           |
| Respiratory Epithelium, Hyperplasia                      | 18 [1.9] | 13 [1.8]  | 21 [2.0]  | 20 [2.1]  |
| Respiratory Epithelium, Metaplasia,<br>Squamous          | 1 [2.0]  | 1 [2.0]   |           | 24 [2.1]  |
| Respiratory Epithelium, Necrosis                         |          | 1 [2.0]   |           | 2 [2.0]   |
| <b>SPECIAL SENSES SYSTEM</b>                             |          |           |           |           |
| Ear  | (1)      | (1)       | (0)       | (1)       |
| Eye  | (50)     | (50)      | (50)      | (50)      |
| Atrophy  |          | 1 [4.0]   |           |           |
| Lens, Cataract   | 2 [3.5]  | 1 [4.0]   | 1 [4.0]   | 1 [4.0]   |
| Retina, Degeneration                                     | 2 [3.0]  | 1 [4.0]   | 1 [3.0]   | 1 [4.0]   |
| Harderian Gland  | (50)     | (50)      | (49)      | (50)      |
| Hyperplasia  |          | 1 [2.0]   |           |           |
| Inflammation, Chronic Active                             | 12 [1.3] | 12 [1.4]  | 18 [1.2]  | 15 [1.4]  |
| Zymbal's Gland   | (0)      | (0)       | (1)       | (0)       |
| <b>URINARY SYSTEM</b>                                    |          |           |           |           |
| Kidney   | (50)     | (50)      | (50)      | (49)      |
| Hydronephrosis   | 1 [4.0]  | 1 [3.0]   |           |           |
| Infarct  | 1 [3.0]  |           | 1 [4.0]   |           |
| Inflammation, Suppurative                                |          |           | 1 [1.0]   |           |
| Inflammation, Chronic Active                             |          | 1 [4.0]   |           | 1 [3.0]   |

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)

Test Type: CHRONIC

5-(HYDROXYMETHYL)-2-FURFURAL

Time Report Requested: 08:20:21

Route: GAVAGE

CAS Number: 67-47-0

First Dose M/F: 03/06/02 / 03/07/02

Species/Strain: RATS/F 344

Pathologist: TOFT, J. - Unknown, U.

Lab: BAT

| FISCHER 344 RATS FEMALE                         | 0 MG/KG  | 188 MG/KG | 375 MG/KG | 750 MG/KG |
|---|----------|-----------|-----------|-----------|
| Mineralization                                  | 28 [1.0] | 17 [1.1]  | 19 [1.1]  | 25 [1.0]  |
| Nephropathy                                     | 43 [1.3] | 42 [1.2]  | 39 [1.1]  | 35 [1.2]  |
| Cortex, Pelvis, Cyst, Multiple                  | 1 [3.0]  |           |           |           |
| Cortex, Cyst                                    | 2 [3.0]  | 1 [2.0]   |           | 1 [1.0]   |
| Pelvis, Transitional Epithelium,<br>Hyperplasia | 1 [3.0]  |           |           |           |
| Pelvis, Inflammation, Chronic Active            | 1 [3.0]  |           |           |           |
| Urinary Bladder                                 | (50)     | (50)      | (50)      | (50)      |

\*\*\* 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)