

**TDMS No.** 88123 - 05

**Test Type:** CHRONIC

**Route:** GAVAGE

**Species/Strain:** RATS/F 344

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC  
LESIONS ABRIDGED) (a)**

FORMAMIDE

**CAS Number:** 75-12-7

**Pathologist:** SELLS, D. - KURTZ, F.

Final 1 Rats

**Date Report Reqsted:** 12/05/2005

**Time Report Reqsted:** 14:23:30

**First Dose M/F:** 03/21/01 / 03/20/01

**Lab:** BAT

**C Number:** C88123B  
**Lock Date:** 11/20/2003  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL

Test Type: CHRONIC

Time Report Requested: 14:23:30

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS MALE                  | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|--|---------|----------|----------|----------|
| <b>Disposition Summary</b>             |         |          |          |          |
| Animals Initially in Study             | 50      | 50       | 50       | 50       |
| Early Deaths                           |         |          |          |          |
| Moribund Sacrifice                     | 24      | 15       | 22       | 18       |
| Natural Death                          |         | 8        | 2        | 3        |
| Survivors                              |         |          |          |          |
| Terminal Sacrifice                     | 26      | 27       | 26       | 29       |
| Animals Examined Microscopically       | 50      | 50       | 50       | 50       |
| <b>ALIMENTARY SYSTEM</b>               |         |          |          |          |
| Esophagus                              | (50)    | (49)     | (50)     | (50)     |
| Intestine Large, Cecum                 | (49)    | (50)     | (50)     | (50)     |
| Intestine Large, Colon                 | (50)    | (50)     | (50)     | (50)     |
| Intestine Large, Rectum                | (50)    | (50)     | (50)     | (50)     |
| Intestine Small, Duodenum              | (50)    | (50)     | (50)     | (50)     |
| Intestine Small, Ileum                 | (50)    | (50)     | (50)     | (50)     |
| Intestine Small, Jejunum               | (50)    | (50)     | (50)     | (50)     |
| Liver                                  | (50)    | (50)     | (50)     | (50)     |
| Carcinoma, Metastatic, Pancreas        |         | 1 (2%)   |          |          |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (2%)  | 1 (2%)   |          |          |
| Hepatocellular Adenoma                 |         | 1 (2%)   | 1 (2%)   | 1 (2%)   |
| Hepatocellular Carcinoma               |         |          |          | 2 (4%)   |
| Ito Cell Tumor Benign                  |         |          |          | 1 (2%)   |
| Mesentery                              | (10)    | (12)     | (7)      | (10)     |
| Carcinoma, Metastatic, Pancreas        |         | 1 (8%)   |          |          |
| Oral Mucosa                            | (22)    | (27)     | (29)     | (20)     |
| Squamous Cell Carcinoma                |         | 1 (4%)   |          |          |
| Pancreas                               | (50)    | (50)     | (50)     | (50)     |
| Acinus, Carcinoma                      |         | 1 (2%)   |          |          |
| Salivary Glands                        | (50)    | (50)     | (50)     | (50)     |
| Stomach, Forestomach                   | (50)    | (50)     | (50)     | (50)     |
| Stomach, Glandular                     | (50)    | (50)     | (50)     | (50)     |
| Tongue                                 | (0)     | (1)      | (0)      | (0)      |
| Squamous Cell Papilloma                |         | 1 (100%) |          |          |
| Tooth                                  | (25)    | (32)     | (30)     | (25)     |

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

Test Type: CHRONIC

Time Report Requested: 14:23:30

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS MALE  | 0 MG/KG  | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|--|----------|----------|----------|----------|
| <b>CARDIOVASCULAR SYSTEM</b>                                     |          |          |          |          |
| Blood Vessel   | (50)     | (50)     | (50)     | (50)     |
| Heart  | (50)     | (50)     | (50)     | (50)     |
| Fibrous Histiocytoma, Metastatic, Skin                           | 1 (2%)   |          |          |          |
| Epicardium, Alveolar/Bronchiolar<br>Carcinoma, Metastatic, Lung  | 1 (2%)   |          |          |          |
| Pericardium, Alveolar/Bronchiolar<br>Carcinoma, Metastatic, Lung | 1 (2%)   |          |          |          |
| <b>ENDOCRINE SYSTEM</b>  |          |          |          |          |
| Adrenal Cortex   | (50)     | (50)     | (50)     | (50)     |
| Adenoma  |          |          | 1 (2%)   |          |
| Carcinoma  | 1 (2%)   |          |          |          |
| Adrenal Medulla  | (50)     | (50)     | (50)     | (50)     |
| Pheochromocytoma Benign  | 7 (14%)  | 9 (18%)  | 1 (2%)   | 6 (12%)  |
| Pheochromocytoma Malignant                                       |          | 1 (2%)   | 1 (2%)   | 1 (2%)   |
| Bilateral, Pheochromocytoma Benign                               | 2 (4%)   |          | 1 (2%)   |          |
| Islets, Pancreatic   | (50)     | (50)     | (50)     | (50)     |
| Adenoma  | 2 (4%)   |          | 4 (8%)   | 2 (4%)   |
| Carcinoma  | 1 (2%)   |          |          |          |
| Parathyroid Gland  | (48)     | (49)     | (49)     | (49)     |
| Pituitary Gland  | (50)     | (50)     | (50)     | (50)     |
| Pars Distalis, Adenoma   | 11 (22%) | 15 (30%) | 21 (42%) | 18 (36%) |
| Pars Intermedia, Adenoma   |          | 1 (2%)   |          |          |
| Thyroid Gland  | (50)     | (50)     | (50)     | (50)     |
| Bilateral, C-cell, Adenoma                                       |          | 1 (2%)   |          |          |
| C-cell, Adenoma  | 6 (12%)  | 5 (10%)  | 6 (12%)  | 2 (4%)   |
| C-cell, Carcinoma  |          | 1 (2%)   |          |          |
| Follicular Cell, Carcinoma                                       | 1 (2%)   |          | 1 (2%)   |          |
| <b>GENERAL BODY SYSTEM</b>                                       |          |          |          |          |
| None   |          |          |          |          |
| <b>GENITAL SYSTEM</b>  |          |          |          |          |

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

Test Type: CHRONIC

Time Report Requested: 14:23:30

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS MALE                  | 0 MG/KG  | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|--|----------|----------|----------|----------|
| Coagulating Gland                      | (0)      | (1)      | (1)      | (0)      |
| Epididymis                             | (50)     | (50)     | (50)     | (50)     |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (2%)   |          |          |          |
| Preputial Gland                        | (50)     | (50)     | (50)     | (50)     |
| Adenoma                                | 1 (2%)   |          | 2 (4%)   | 2 (4%)   |
| Carcinoma                              | 1 (2%)   | 3 (6%)   | 2 (4%)   | 2 (4%)   |
| Prostate                               | (50)     | (50)     | (50)     | (50)     |
| Adenoma                                |          | 3 (6%)   | 2 (4%)   |          |
| Seminal Vesicle                        | (50)     | (50)     | (50)     | (49)     |
| Testes                                 | (50)     | (50)     | (50)     | (50)     |
| Bilateral, Interstitial Cell, Adenoma  | 32 (64%) | 41 (82%) | 44 (88%) | 38 (76%) |
| Interstitial Cell, Adenoma             | 12 (24%) | 7 (14%)  | 2 (4%)   | 7 (14%)  |

## HEMATOPOIETIC SYSTEM

|  |         |      |        |        |
|--|---------|------|--------|--------|
| Bone Marrow                            | (50)    | (50) | (50)   | (50)   |
| Lymph Node                             | (7)     | (8)  | (8)    | (5)    |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (14%) |      |        |        |
| Lymph Node, Mandibular                 | (0)     | (1)  | (0)    | (3)    |
| Lymph Node, Mesenteric                 | (50)    | (50) | (50)   | (50)   |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (2%)  |      |        |        |
| Spleen                                 | (50)    | (50) | (50)   | (50)   |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (2%)  |      |        |        |
| Osteosarcoma, Metastatic, Skin         |         |      | 1 (2%) |        |
| Thymus                                 | (49)    | (45) | (47)   | (48)   |
| Thymoma Malignant                      |         |      |        | 1 (2%) |

## INTEGUMENTARY SYSTEM

|                           |         |        |        |        |
|---------------------------|---------|--------|--------|--------|
| Mammary Gland             | (50)    | (48)   | (50)   | (50)   |
| Adenoma                   | 1 (2%)  |        |        |        |
| Carcinoma                 |         | 1 (2%) |        |        |
| Fibroadenoma              | 2 (4%)  | 4 (8%) |        | 1 (2%) |
| Fibroma                   | 1 (2%)  |        |        |        |
| Skin                      | (50)    | (50)   | (50)   | (50)   |
| Basal Cell Adenoma        | 1 (2%)  |        | 3 (6%) |        |
| Keratoacanthoma           | 8 (16%) | 3 (6%) | 4 (8%) | 2 (4%) |
| Squamous Cell Papilloma   | 1 (2%)  |        |        |        |
| Pinna, Neural Crest Tumor |         |        | 1 (2%) |        |

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

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CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS MALE  | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|--|---------|----------|----------|----------|
| Subcutaneous Tissue, Fibroma                                     | 5 (10%) | 4 (8%)   | 2 (4%)   | 2 (4%)   |
| Subcutaneous Tissue, Fibroma, Multiple                           | 1 (2%)  |          | 1 (2%)   |          |
| Subcutaneous Tissue, Fibrosarcoma                                |         | 1 (2%)   |          |          |
| Subcutaneous Tissue, Fibrous<br>Histiocytoma                     | 1 (2%)  | 1 (2%)   |          |          |
| Subcutaneous Tissue, Osteosarcoma                                |         |          | 1 (2%)   |          |
| Subcutaneous Tissue, Schwannoma<br>Malignant                     | 1 (2%)  |          |          | 1 (2%)   |
| <b>MUSCULOSKELETAL SYSTEM</b>                                    |         |          |          |          |
| Bone   | (50)    | (50)     | (50)     | (50)     |
| Chordoma   | 1 (2%)  | 1 (2%)   | 1 (2%)   |          |
| <b>NERVOUS SYSTEM</b>  |         |          |          |          |
| Brain  | (50)    | (50)     | (50)     | (50)     |
| Astrocytoma Malignant  |         | 1 (2%)   |          |          |
| Fibrous Histiocytoma, Metastatic, Skin                           | 1 (2%)  |          |          |          |
| <b>RESPIRATORY SYSTEM</b>  |         |          |          |          |
| Lung   | (50)    | (50)     | (50)     | (50)     |
| Alveolar/Bronchiolar Adenoma                                     |         | 2 (4%)   | 2 (4%)   | 2 (4%)   |
| Alveolar/Bronchiolar Carcinoma                                   | 1 (2%)  | 2 (4%)   |          |          |
| Carcinoma, Metastatic, Pancreas                                  |         | 1 (2%)   |          |          |
| Chordoma, Metastatic, Bone                                       | 1 (2%)  | 1 (2%)   | 1 (2%)   |          |
| Fibrous Histiocytoma, Metastatic, Skin                           | 1 (2%)  | 1 (2%)   |          |          |
| Osteosarcoma, Metastatic, Skin                                   |         |          | 1 (2%)   |          |
| Pheochromocytoma Malignant, Metastatic,<br>Adrenal Medulla       |         |          | 1 (2%)   |          |
| Mediastinum, Alveolar/Bronchiolar<br>Carcinoma, Metastatic, Lung | 1 (2%)  |          |          |          |
| Nose   | (50)    | (50)     | (50)     | (50)     |
| Sarcoma  |         |          | 1 (2%)   |          |
| Trachea  | (50)    | (50)     | (50)     | (50)     |
| <b>SPECIAL SENSES SYSTEM</b>                                     |         |          |          |          |

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CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS MALE                  | 0 MG/KG  | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|--|----------|----------|----------|----------|
| Eye                                    | (50)     | (50)     | (50)     | (50)     |
| Harderian Gland                        | (50)     | (50)     | (50)     | (50)     |
| Zymbal's Gland                         | (0)      | (0)      | (1)      | (1)      |
| Carcinoma                              |          |          | 1 (100%) | 1 (100%) |
| <b>URINARY SYSTEM</b>                  |          |          |          |          |
| Kidney                                 | (50)     | (50)     | (50)     | (50)     |
| Fibrous Histiocytoma, Metastatic, Skin | 1 (2%)   |          |          |          |
| Stromal Nephroma                       |          |          | 1 (2%)   |          |
| Renal Tubule, Adenoma                  | 1 (2%)   |          |          |          |
| Urinary Bladder                        | (50)     | (50)     | (50)     | (50)     |
| <b>SYSTEMIC LESIONS</b>                |          |          |          |          |
| Multiple Organs                        | *(50)    | *(50)    | *(50)    | *(50)    |
| Histiocytic Sarcoma                    | 1 (2%)   | 2 (4%)   |          | 2 (4%)   |
| Leukemia Mononuclear                   | 15 (30%) | 14 (28%) | 17 (34%) | 18 (36%) |
| Mesothelioma Malignant                 | 2 (4%)   | 2 (4%)   | 1 (2%)   | 1 (2%)   |

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

\* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Time Report Requested: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

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| FISCHER 344 RATS MALE | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|-----------------------|---------|----------|----------|----------|
|-----------------------|---------|----------|----------|----------|

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**Tumor Summary for Males**

|  |     |     |     |     |
|--|-----|-----|-----|-----|
| Total Animals with Primary Neoplasms (b)                         | 48  | 50  | 49  | 50  |
| Total Primary Neoplasms  | 120 | 129 | 125 | 113 |
| Total Animals with Benign Neoplasms                              | 45  | 50  | 48  | 49  |
| Total Benign Neoplasms   | 94  | 97  | 97  | 84  |
| Total Animals with Malignant Neoplasms                           | 25  | 27  | 26  | 25  |
| Total Malignant Neoplasms  | 26  | 32  | 27  | 29  |
| Total Animals with Metastatic Neoplasms                          | 3   | 3   | 3   | 1   |
| Total Metastatic Neoplasms                                       | 13  | 6   | 4   | 1   |
| Total Animals with Malignant Neoplasms<br>Uncertain Primary Site |     |     |     |     |
| Total Animals with Neoplasms<br>Uncertain-Benign or Malignant    |     |     | 1   |     |
| Total Uncertain Neoplasms  |     |     | 1   |     |

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

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

b - Primary tumors: all tumors except metastatic tumors

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First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS FEMALE           | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|-----------------------------------|---------|----------|----------|----------|
| <b>Disposition Summary</b>        |         |          |          |          |
| Animals Initially in Study        | 50      | 50       | 50       | 50       |
| Early Deaths                      |         |          |          |          |
| Moribund Sacrifice                | 10      | 16       | 14       | 14       |
| Natural Death                     | 2       | 4        | 2        | 4        |
| Survivors                         |         |          |          |          |
| Natural Death                     |         | 1        |          |          |
| Terminal Sacrifice                | 38      | 29       | 34       | 32       |
| Animals Examined Microscopically  | 50      | 50       | 50       | 50       |
| <b>ALIMENTARY SYSTEM</b>          |         |          |          |          |
| Esophagus                         | (50)    | (50)     | (50)     | (50)     |
| Lipoma                            |         |          | 1 (2%)   |          |
| Intestine Large, Cecum            | (50)    | (49)     | (50)     | (50)     |
| Intestine Large, Colon            | (50)    | (50)     | (50)     | (50)     |
| Intestine Large, Rectum           | (50)    | (50)     | (50)     | (50)     |
| Intestine Small, Ileum            | (50)    | (50)     | (50)     | (49)     |
| Liver                             | (50)    | (50)     | (50)     | (50)     |
| Hepatocellular Adenoma            | 1 (2%)  |          | 1 (2%)   |          |
| Hepatocellular Adenoma, Multiple  | 1 (2%)  |          |          |          |
| Mesentery                         | (18)    | (16)     | (12)     | (9)      |
| Oral Mucosa                       | (15)    | (9)      | (12)     | (7)      |
| Gingival, Squamous Cell Carcinoma | 1 (7%)  |          |          |          |
| Pancreas                          | (50)    | (50)     | (50)     | (50)     |
| Salivary Glands                   | (50)    | (50)     | (50)     | (50)     |
| Adenoma                           |         |          |          | 1 (2%)   |
| Stomach, Forestomach              | (50)    | (50)     | (50)     | (50)     |
| Squamous Cell Papilloma           |         |          | 1 (2%)   |          |
| Stomach, Glandular                | (50)    | (50)     | (50)     | (50)     |
| Tongue                            | (0)     | (0)      | (1)      | (0)      |
| Tooth                             | (19)    | (11)     | (11)     | (14)     |
| <b>CARDIOVASCULAR SYSTEM</b>      |         |          |          |          |
| Blood Vessel                      | (50)    | (50)     | (50)     | (50)     |

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



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Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS FEMALE      | 0 MG/KG  | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|------------------------------|----------|----------|----------|----------|
| Heart                        | (50)     | (50)     | (50)     | (50)     |
| <b>ENDOCRINE SYSTEM</b>      |          |          |          |          |
| Adrenal Cortex               | (50)     | (50)     | (50)     | (50)     |
| Adrenal Medulla              | (50)     | (50)     | (50)     | (50)     |
| Pheochromocytoma Benign      |          | 1 (2%)   |          |          |
| Islets, Pancreatic           | (50)     | (50)     | (50)     | (50)     |
| Adenoma                      | 1 (2%)   |          |          |          |
| Parathyroid Gland            | (46)     | (47)     | (46)     | (47)     |
| Adenoma                      |          |          | 1 (2%)   |          |
| Pituitary Gland              | (50)     | (50)     | (50)     | (50)     |
| Pars Distalis, Adenoma       | 22 (44%) | 21 (42%) | 15 (30%) | 15 (30%) |
| Pars Distalis, Carcinoma     | 2 (4%)   |          | 1 (2%)   |          |
| Pars Intermedia, Carcinoma   |          |          | 1 (2%)   |          |
| Thyroid Gland                | (50)     | (50)     | (50)     | (50)     |
| Bilateral, C-cell, Adenoma   | 1 (2%)   | 1 (2%)   |          |          |
| C-cell, Adenoma              | 4 (8%)   | 7 (14%)  | 6 (12%)  | 5 (10%)  |
| C-cell, Carcinoma            |          | 1 (2%)   |          | 1 (2%)   |
| Follicular Cell, Adenoma     |          | 2 (4%)   | 1 (2%)   | 3 (6%)   |
| <b>GENERAL BODY SYSTEM</b>   |          |          |          |          |
| None                         |          |          |          |          |
| <b>GENITAL SYSTEM</b>        |          |          |          |          |
| Clitoral Gland               | (50)     | (50)     | (50)     | (49)     |
| Adenoma                      | 2 (4%)   | 1 (2%)   | 4 (8%)   | 3 (6%)   |
| Carcinoma                    |          |          | 1 (2%)   |          |
| Ovary                        | (50)     | (50)     | (50)     | (50)     |
| Granulosa-Theca Tumor Benign |          | 1 (2%)   |          |          |
| Uterus                       | (50)     | (50)     | (50)     | (50)     |
| Carcinoma                    |          |          | 2 (4%)   |          |
| Polyp Stromal                | 7 (14%)  | 7 (14%)  | 5 (10%)  | 10 (20%) |
| Sarcoma                      |          | 1 (2%)   | 1 (2%)   | 1 (2%)   |
| Sarcoma Stromal              |          |          | 1 (2%)   |          |
| Schwannoma Malignant         | 1 (2%)   |          |          |          |

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

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Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

| FISCHER 344 RATS FEMALE               | 0 MG/KG  | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|---------------------------------------|----------|----------|----------|----------|
| Cervix, Sarcoma Stromal               |          |          |          | 1 (2%)   |
| Vagina                                | (0)      | (2)      | (0)      | (0)      |
| Leiomyosarcoma                        |          | 1 (50%)  |          |          |
| <b>HEMATOPOIETIC SYSTEM</b>           |          |          |          |          |
| Bone Marrow                           | (50)     | (50)     | (50)     | (50)     |
| Lymph Node                            | (6)      | (5)      | (3)      | (2)      |
| Deep Cervical, Carcinoma, Metastatic, |          |          |          | 1 (50%)  |
| Thyroid Gland                         |          |          |          |          |
| Lymph Node, Mandibular                | (1)      | (0)      | (1)      | (1)      |
| Lymph Node, Mesenteric                | (50)     | (50)     | (50)     | (50)     |
| Spleen                                | (50)     | (50)     | (50)     | (50)     |
| Thymus                                | (48)     | (47)     | (47)     | (46)     |
| <b>INTEGUMENTARY SYSTEM</b>           |          |          |          |          |
| Mammary Gland                         | (50)     | (50)     | (50)     | (50)     |
| Carcinoma                             | 2 (4%)   | 1 (2%)   | 1 (2%)   |          |
| Fibroadenoma                          | 19 (38%) | 17 (34%) | 14 (28%) | 20 (40%) |
| Fibroadenoma, Multiple                | 14 (28%) | 7 (14%)  | 4 (8%)   | 5 (10%)  |
| Fibroma                               | 1 (2%)   | 1 (2%)   |          |          |
| Skin                                  | (50)     | (50)     | (50)     | (50)     |
| Basal Cell Adenoma                    | 1 (2%)   |          |          | 1 (2%)   |
| Basal Cell Carcinoma                  |          | 1 (2%)   |          |          |
| Fibroma                               |          | 1 (2%)   |          |          |
| Keratoacanthoma                       | 2 (4%)   | 1 (2%)   |          | 1 (2%)   |
| Squamous Cell Papilloma               |          | 1 (2%)   |          |          |
| Trichoepithelioma                     | 1 (2%)   |          |          |          |
| Subcutaneous Tissue, Fibroma          | 1 (2%)   |          |          |          |
| Subcutaneous Tissue, Schwannoma       |          |          | 1 (2%)   |          |
| Malignant                             |          |          |          |          |
| <b>MUSCULOSKELETAL SYSTEM</b>         |          |          |          |          |
| Bone                                  | (50)     | (50)     | (50)     | (50)     |
| Osteosarcoma                          |          |          |          | 1 (2%)   |
| Skeletal Muscle                       | (1)      | (0)      | (1)      | (0)      |

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

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Time Report Requested: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

| FISCHER 344 RATS FEMALE                     | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|---|---------|----------|----------|----------|
| <b>NERVOUS SYSTEM</b>                       |         |          |          |          |
| Brain                                       | (50)    | (50)     | (50)     | (50)     |
| Carcinoma, Metastatic, Pituitary Gland      | 2 (4%)  |          | 1 (2%)   |          |
| Granular Cell Tumor Benign                  | 1 (2%)  |          |          |          |
| Meningioma Malignant                        |         |          |          | 1 (2%)   |
| Neuroblastoma                               |         |          | 1 (2%)   |          |
| <b>RESPIRATORY SYSTEM</b>                   |         |          |          |          |
| Lung  | (50)    | (50)     | (50)     | (50)     |
| Alveolar/Bronchiolar Adenoma                | 1 (2%)  | 1 (2%)   |          | 1 (2%)   |
| Alveolar/Bronchiolar Carcinoma              | 1 (2%)  |          |          |          |
| Mediastinum, Alveolar/Bronchiolar Carcinoma | 1 (2%)  |          |          |          |
| Nose  | (50)    | (50)     | (50)     | (50)     |
| Astrocytoma Malignant, Metastatic, Brain    |         |          | 1 (2%)   |          |
| Trachea                                     | (50)    | (50)     | (50)     | (50)     |
| <b>SPECIAL SENSES SYSTEM</b>                |         |          |          |          |
| Eye   | (50)    | (50)     | (50)     | (50)     |
| Harderian Gland                             | (50)    | (50)     | (50)     | (50)     |
| Carcinoma                                   |         |          | 1 (2%)   |          |
| Zymbal's Gland                              | (0)     | (0)      | (0)      | (1)      |
| Carcinoma                                   |         |          |          | 1 (100%) |
| <b>URINARY SYSTEM</b>                       |         |          |          |          |
| Kidney                                      | (50)    | (50)     | (50)     | (50)     |
| Renal Tubule, Adenoma                       |         |          | 1 (2%)   |          |
| Urinary Bladder                             | (50)    | (50)     | (50)     | (50)     |
| <b>SYSTEMIC LESIONS</b>                     |         |          |          |          |
| Multiple Organs                             | *(50)   | *(50)    | *(50)    | *(50)    |

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

TDMS No. 88123 - 05

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)**  
FORMAMIDE

Date Report Reqsted: 12/05/2005

Test Type: CHRONIC

Time Report Reqsted: 14:23:30

Route: GAVAGE

CAS Number: 75-12-7

First Dose M/F: 03/21/01 / 03/20/01

Species/Strain: RATS/F 344

Pathologist: SELLS, D. - KURTZ, F.

Lab: BAT

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| <b>FISCHER 344 RATS FEMALE</b> | <b>0 MG/KG</b> | <b>20 MG/KG</b> | <b>40 MG/KG</b> | <b>80 MG/KG</b> |
|--------------------------------|----------------|-----------------|-----------------|-----------------|
| Leukemia Granulocytic          |                |                 | 1 (2%)          |                 |
| Leukemia Mononuclear           | 10 (20%)       | 11 (22%)        | 12 (24%)        | 11 (22%)        |
| Lymphoma Malignant             |                | 1 (2%)          |                 |                 |
| Mesothelioma Malignant         | 2 (4%)         |                 |                 |                 |

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

\* Number of animals with any tissue examined microscopically

Test Type: CHRONIC

Route: GAVAGE

Species/Strain: RATS/F 344

CAS Number: 75-12-7

Pathologist: SELLS, D. - KURTZ, F.

Time Report Requested: 14:23:30

First Dose M/F: 03/21/01 / 03/20/01

Lab: BAT

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| FISCHER 344 RATS FEMALE | 0 MG/KG | 20 MG/KG | 40 MG/KG | 80 MG/KG |
|-------------------------|---------|----------|----------|----------|
|-------------------------|---------|----------|----------|----------|

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**Tumor Summary for Females**

|  |     |    |    |    |
|--|-----|----|----|----|
| Total Animals with Primary Neoplasms (b)   | 49  | 46 | 40 | 46 |
| Total Primary Neoplasms  | 100 | 87 | 78 | 82 |
| Total Animals with Benign Neoplasms  | 43  | 39 | 31 | 41 |
| Total Benign Neoplasms   | 80  | 70 | 54 | 65 |
| Total Animals with Malignant Neoplasms   | 15  | 16 | 20 | 16 |
| Total Malignant Neoplasms  | 20  | 17 | 24 | 17 |
| Total Animals with Metastatic Neoplasms  | 3   |    | 2  | 1  |
| Total Metastatic Neoplasms   | 3   |    | 2  | 1  |
| Total Animals with Malignant Neoplasms<br>Uncertain Primary Site                           |     |    |    |    |
| Total Animals with Neoplasms<br>Uncertain-Benign or Malignant<br>Total Uncertain Neoplasms |     |    |    |    |

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

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

b - Primary tumors: all tumors except metastatic tumors