

Experiment Number: 99032 - 03

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

Date Report Requested: 05/30/2012

Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

F2_R2

NTP Study Number: C99032
Lock Date: 09/07/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.6.0.0_007
PWG Approval Date: 12/19/2009

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Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS MALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|-----------------------|---------|---------|----------|----------|
|-----------------------|---------|---------|----------|----------|

Disposition Summary

| | | | | |
|-----------------------------------------|-----------|-----------|-----------|-----------|
| Animals Initially In Study | 50 | 50 | 50 | 50 |
| Early Deaths | | | | |
| Moribund Sacrifice | 17 | 14 | 15 | 17 |
| Natural Death | 10 | 8 | 7 | 5 |
| Survivors | | | | |
| Natural Death | | 2 | | |
| Terminal Sacrifice | 23 | 26 | 28 | 28 |
| Animals Examined Microscopically | 50 | 50 | 50 | 50 |

ALIMENTARY SYSTEM

| | | | | |
|--------------------------------------------|---------|---------|---------|---------|
| Esophagus | (50) | (50) | (50) | (50) |
| Periesophageal Tissue, Hemorrhage | 1 [4.0] | | | |
| Periesophageal Tissue, Inflammation | 1 [2.0] | | | |
| Intestine Large, Cecum | (49) | (50) | (50) | (50) |
| Inflammation | | 2 [2.5] | | |
| Necrosis | | 1 [3.0] | | |
| Thrombosis | | 1 [3.0] | 1 [3.0] | |
| Intestine Large, Colon | (50) | (50) | (50) | (50) |
| Hyperplasia, Lymphoid | | 1 [3.0] | | |
| Parasite Metazoan | 2 | | 1 | 6 |
| Intestine Large, Rectum | (50) | (50) | (50) | (50) |
| Parasite Metazoan | 4 | 5 | 3 | 4 |
| Intestine Small, Duodenum | (50) | (50) | (50) | (50) |
| Inflammation | | | 1 [4.0] | |
| Ulcer | | | 1 [4.0] | |
| Intestine Small, Ileum | (50) | (50) | (50) | (50) |
| Inflammation | | | 1 [2.0] | |
| Epithelium, Dysplasia | 1 [2.0] | | | |
| Intestine Small, Jejunum | (50) | (50) | (50) | (50) |
| Inflammation | | | | 1 [2.0] |
| Peyer's Patch, Inflammation, Granulomatous | | 1 [1.0] | | |
| Liver | (50) | (50) | (50) | (50) |
| Angiectasis | 3 [2.0] | 2 [2.0] | | 1 [2.0] |

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| FISCHER 344 RATS MALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|---------------------------------------|----------|----------|----------|----------|
| Basophilic Focus | 8 | 8 | 11 | 8 |
| Clear Cell Focus | 18 | 17 | 21 | 21 |
| Congestion, Acute | 1 [2.0] | | | |
| Degeneration, Cystic | 1 [2.0] | 6 [1.5] | 1 [2.0] | 1 [1.0] |
| Eosinophilic Focus | 3 | 2 | | 2 |
| Fatty Change | 1 [2.0] | 3 [2.3] | 1 [3.0] | 3 [3.0] |
| Hematopoietic Cell Proliferation | | | | 2 [1.0] |
| Hemorrhage | | | 1 [3.0] | |
| Hepatodiaphragmatic Nodule | 3 | 2 | 5 | 4 |
| Inflammation | 19 [1.0] | 17 [1.1] | 17 [1.1] | 17 [1.1] |
| Mixed Cell Focus | 8 | 6 | 6 | 5 |
| Bile Duct, Cyst | | | 1 [3.0] | |
| Bile Duct, Hyperplasia | 28 [1.1] | 24 [1.0] | 27 [1.1] | 26 [1.1] |
| Centrilobular, Fibrosis | 1 [1.0] | | 1 [3.0] | |
| Hepatocyte, Atrophy | | 1 [2.0] | 1 [4.0] | |
| Hepatocyte, Degeneration | 1 [1.0] | 1 [2.0] | | |
| Hepatocyte, Necrosis | 1 [3.0] | 5 [2.2] | 4 [1.3] | 5 [1.8] |
| Hepatocyte, Regeneration | 1 [2.0] | | 1 [3.0] | |
| Hepatocyte, Vacuolization Cytoplasmic | 19 [1.2] | 20 [1.2] | 24 [1.2] | 18 [1.1] |
| Kupffer Cell, Pigmentation | | | | 1 [1.0] |
| Portal, Fibrosis | 3 [1.0] | 6 [1.0] | 9 [1.0] | 6 [1.0] |
| Vein, Thrombosis | | 1 [4.0] | | |
| Mesentery | (9) | (2) | (3) | (5) |
| Necrosis | 7 [3.0] | 2 [3.0] | 3 [3.0] | 4 [3.0] |
| Oral Mucosa | (2) | (1) | (4) | (3) |
| Gingival, Inflammation | 2 [2.0] | 1 [3.0] | 2 [2.0] | 3 [2.7] |
| Pharyngeal, Hyperplasia | | | 2 [3.5] | |
| Pancreas | (50) | (50) | (50) | (50) |
| Acinus, Atrophy | 28 [1.6] | 31 [1.8] | 28 [1.7] | 31 [2.0] |
| Acinus, Hyperplasia | 3 [1.3] | 8 [1.8] | 4 [2.0] | 1 [3.0] |
| Duct, Cyst | 5 [1.4] | 4 [1.5] | 3 [1.7] | 4 [1.5] |
| Salivary Glands | (50) | (50) | (50) | (50) |
| Hyperplasia | | 1 [1.0] | | |
| Inflammation | | | 1 [4.0] | 1 [1.0] |
| Duct, Cyst | | | 1 [4.0] | |
| Stomach, Forestomach | (50) | (50) | (50) | (50) |

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Lab: BAT

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|-------------------------|---------|---------|----------|----------|
| Fibrosis | 1 [3.0] | | | |
| Inflammation | 2 [1.5] | 1 [2.0] | 1 [4.0] | 5 [1.8] |
| Perforation | | 1 | | |
| Ulcer | 4 [4.0] | 6 [3.7] | 7 [3.7] | 4 [3.5] |
| Epithelium, Hyperplasia | 2 [1.5] | 2 [2.5] | 4 [2.5] | 6 [2.0] |
| Stomach, Glandular | (50) | (50) | (50) | (50) |
| Congestion | | 1 [4.0] | | |
| Erosion | 2 [2.0] | 4 [2.8] | | 3 [2.0] |
| Inflammation | | 4 [1.3] | | 3 [1.0] |
| Ulcer | | | 1 [2.0] | |
| Epithelium, Hyperplasia | | 2 [2.0] | 1 [3.0] | |
| Glands, Cyst | | 1 [1.0] | 1 [3.0] | |
| Tongue | (1) | (0) | (0) | (2) |
| Epithelium, Hyperplasia | | | | 1 [3.0] |

CARDIOVASCULAR SYSTEM

| | | | | |
|--------------------------|----------|----------|----------|----------|
| Blood Vessel | (50) | (50) | (50) | (50) |
| Heart | (50) | (50) | (50) | (50) |
| Cardiomyopathy | 46 [2.3] | 45 [2.4] | 46 [2.4] | 47 [2.1] |
| Atrium, Thrombosis | | 2 [3.0] | | 1 [4.0] |
| Myocardium, Inflammation | | | | 1 [3.0] |
| Valve, Thrombosis | | | | 1 [4.0] |
| Ventricle, Thrombosis | | | | 2 [3.0] |

ENDOCRINE SYSTEM

| | | | | |
|----------------------------------|----------|----------|----------|----------|
| Adrenal Cortex | (50) | (50) | (50) | (50) |
| Atrophy | | | | 1 [4.0] |
| Degeneration, Cystic | | 1 [3.0] | 1 [3.0] | |
| Hematopoietic Cell Proliferation | | | 1 [1.0] | |
| Hemorrhage | | 1 [3.0] | 1 [2.0] | |
| Hyperplasia | 19 [1.2] | 21 [1.4] | 29 [1.5] | 20 [1.5] |
| Hypertrophy | 7 [1.9] | 10 [1.5] | 10 [1.3] | 4 [2.3] |
| Mineralization | | | | 1 [1.0] |

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|-------------------------------------------------------|----------|----------|----------|----------|
| Necrosis | | | 1 [4.0] | 1 [4.0] |
| Vacuolization Cytoplasmic Capsule, Fibrosis, Focal | 27 [1.6] | 18 [1.5] | 23 [1.5] | 19 [1.4] |
| Adrenal Medulla | (50) | (50) | (50) | (50) |
| Angiectasis | | | | 1 [2.0] |
| Hemorrhage | | 1 [3.0] | | 1 [3.0] |
| Hyperplasia | 16 [1.8] | 18 [2.2] | 20 [2.1] | 18 [1.8] |
| Infiltration Cellular, Mononuclear Cell | | | | 1 [2.0] |
| Mineralization | | | | 1 [2.0] |
| Necrosis | | | 1 [4.0] | |
| Islets, Pancreatic | (50) | (50) | (50) | (50) |
| Hyperplasia | | | | 1 [3.0] |
| Parathyroid Gland | (50) | (49) | (47) | (49) |
| Cyst | | 1 [3.0] | | |
| Hyperplasia | | 3 [2.0] | | |
| Pituitary Gland | (50) | (49) | (50) | (50) |
| Hemorrhage | | 1 [4.0] | | 2 [2.0] |
| Pigmentation, Hemosiderin | | | | 1 [2.0] |
| Pars Distalis, Atrophy | 1 [3.0] | | | 3 [4.0] |
| Pars Distalis, Cyst | | 2 [1.5] | | 4 [1.0] |
| Pars Distalis, Hyperplasia | 11 [1.8] | 10 [2.3] | 12 [2.8] | 13 [2.2] |
| Pars Intermedia, Hyperplasia | | 1 [1.0] | 1 [1.0] | |
| Thyroid Gland | (50) | (50) | (50) | (50) |
| Cyst | | 1 [3.0] | | |
| Inflammation | | | | 1 [1.0] |
| C-cell, Hyperplasia | 18 [1.4] | 19 [1.3] | 21 [1.4] | 18 [1.8] |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | |
|-------------------|------|------|------|------|
| Coagulating Gland | (1) | (0) | (0) | (0) |
| Epididymis | (50) | (50) | (50) | (50) |

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|-----------------------------------------|----------|----------|----------|----------|
| Inflammation | | 1 [2.0] | 2 [1.0] | |
| Penis | (0) | (0) | (1) | (0) |
| Congestion | | | 1 [1.0] | |
| Preputial Gland | (50) | (50) | (50) | (50) |
| Inflammation | 2 [1.5] | 8 [2.4] | 5 [1.2] | 7 [1.7] |
| Duct, Hyperplasia, Squamous | | | | 1 [1.0] |
| Prostate | (50) | (50) | (50) | (50) |
| Inflammation | 44 [1.6] | 45 [2.2] | 48 [2.4] | 44 [1.9] |
| Epithelium, Hyperplasia | 4 [1.0] | 8 [1.5] | 5 [1.0] | 5 [1.4] |
| Epithelium, Metaplasia, Squamous | | | 1 [2.0] | 1 [1.0] |
| Seminal Vesicle | (50) | (50) | (50) | (50) |
| Inflammation | | 1 [3.0] | | |
| Bilateral, Atrophy | | | 1 [2.0] | |
| Testes | (50) | (50) | (50) | (50) |
| Cyst | | | 2 [4.0] | 1 [4.0] |
| Mineralization | | | 2 [1.5] | |
| Arteriole, Inflammation | | 1 [2.0] | | |
| Bilateral, Germinal Epithelium, Atrophy | | 3 [2.7] | | 1 [4.0] |
| Germinal Epithelium, Atrophy | 5 [1.6] | 4 [3.8] | 7 [3.1] | 9 [2.6] |
| Interstitial Cell, Hyperplasia | 11 [1.2] | 13 [1.4] | 5 [2.0] | 8 [1.5] |

HEMATOPOIETIC SYSTEM

| | | | | |
|-------------------------------------|----------|----------|----------|---------|
| Bone Marrow | (50) | (50) | (50) | (50) |
| Hemorrhage | | 1 [3.0] | | |
| Hyperplasia | 10 [3.9] | 11 [3.4] | 11 [3.6] | 9 [3.9] |
| Infiltration Cellular, Histiocyte | | | | 1 [1.0] |
| Myelofibrosis | | 1 [3.0] | 1 [2.0] | |
| Lymph Node | (10) | (8) | (4) | (7) |
| Degeneration, Cystic | | | 1 [2.0] | |
| Deep Cervical, Degeneration, Cystic | | 1 [3.0] | | |
| Deep Cervical, Hemorrhage | | | | 2 [2.5] |
| Mediastinal, Degeneration, Cystic | 2 [2.0] | 1 [3.0] | | |
| Mediastinal, Hemorrhage | | 2 [2.5] | | |
| Mediastinal, Hyperplasia | | 1 [3.0] | | |

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Lab: BAT

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|---------------------------------------|---------|---------|----------|----------|
| Mediastinal, Hyperplasia, Lymphoid | | 1 [2.0] | | |
| Mediastinal, Hyperplasia, Plasma Cell | 2 [2.5] | 1 [2.0] | 1 [3.0] | |
| Pancreatic, Degeneration, Cystic | 1 [3.0] | | | |
| Lymph Node, Mesenteric | (50) | (50) | (50) | (50) |
| Degeneration, Cystic | | 4 [1.5] | 1 [2.0] | 5 [2.0] |
| Hemorrhage | | | | 2 [3.5] |
| Hyperplasia, Histiocytic | | | 2 [1.5] | |
| Hyperplasia, Plasma Cell | | | 1 [3.0] | |
| Infiltration Cellular, Histiocyte | | | | 1 [2.0] |
| Necrosis, Lymphoid | | 2 [2.5] | | |
| Spleen | (50) | (50) | (50) | (50) |
| Congestion | | | 1 [3.0] | |
| Hematopoietic Cell Proliferation | | | | 1 [2.0] |
| Hyperplasia, Lymphoid | 3 [1.7] | 3 [2.0] | 1 [2.0] | 2 [1.5] |
| Infarct | 2 [3.5] | 2 [2.5] | 3 [3.7] | 1 [3.0] |
| Necrosis, Lymphoid | | 1 [3.0] | | |
| Necrosis, Focal | | 1 [3.0] | | |
| Thrombosis | | | | 1 [3.0] |
| Capsule, Fibrosis | | 1 [2.0] | | 1 [2.0] |
| Capsule, Inflammation | | | | 1 [2.0] |
| Lymphoid Follicle, Atrophy | | 1 [3.0] | 2 [2.0] | |
| Lymphoid Follicle, Depletion Cellular | | 1 [4.0] | | |
| Thymus | (47) | (48) | (48) | (47) |
| Cyst | | | 1 [2.0] | |
| Ectopic Parathyroid Gland | | | | 1 [1.0] |
| Fibrosis | | | 1 [2.0] | |
| Epithelial Cell, Hyperplasia | | | | 1 [4.0] |

INTEGUMENTARY SYSTEM

| | | | | |
|------------------|---------|---------|------|------|
| Mammary Gland | (50) | (49) | (50) | (50) |
| Inflammation | | 1 [1.0] | | |
| Duct, Cyst | 1 [3.0] | | | |
| Duct, Dilatation | 1 [2.0] | | | |
| Skin | (50) | (50) | (50) | (50) |

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|------------------------------------------------------|---------|---------|----------|----------|
| Abscess | | 1 [4.0] | | |
| Fibrosis | | | | 1 [3.0] |
| Hyperkeratosis | | | | 1 [3.0] |
| Hyperplasia | | | | 2 [3.0] |
| Inflammation | | | | 1 [3.0] |
| Ulcer | | | 1 [4.0] | 1 [2.0] |
| Control, Hyperkeratosis | | | | 1 [2.0] |
| Control, Hyperplasia | | | | 1 [2.0] |
| Control, Inflammation | | | | 1 [1.0] |
| Control, Sebaceous Gland, Hyperplasia | | | | 1 [1.0] |
| Sebaceous Gland, Site Of Application, Hyperplasia | | | 12 [1.0] | 48 [1.1] |
| Site Of Application, Hyperkeratosis | | 2 [1.0] | 21 [1.0] | 48 [1.6] |
| Site Of Application, Hyperplasia | | 6 [1.0] | 20 [1.0] | 50 [1.2] |
| Site Of Application, Inflammation | | | | 46 [1.3] |
| Site Of Application, Ulcer | | | | 1 [1.0] |

MUSCULOSKELETAL SYSTEM

| | | | | |
|------------------------|------|---------|---------|---------|
| Bone | (50) | (50) | (50) | (50) |
| Fibrosis | | | | 1 [1.0] |
| Hemorrhage | | 1 [3.0] | | |
| Osteopetrosis | | | | 1 [3.0] |
| Epiphysis, Femur, Cyst | | 1 [2.0] | | |
| Mandible, Cyst | | | 1 [4.0] | |

NERVOUS SYSTEM

| | | | | |
|------------------------|---------|---------|---------|---------|
| Brain | (50) | (50) | (50) | (50) |
| Hemorrhage | 3 [2.3] | 4 [2.8] | | 2 [2.5] |
| Hydrocephalus | 2 [1.5] | 3 [1.7] | 4 [1.8] | |
| Cerebrum, Inflammation | | | | 1 [1.0] |

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|---------------------------------------------|----------|----------|----------|----------|
| RESPIRATORY SYSTEM | | | | |
| Lung | (50) | (50) | (50) | (50) |
| Congestion | 1 [3.0] | | 1 [2.0] | |
| Hemorrhage | 1 [1.0] | 3 [3.0] | | |
| Hyperplasia | | | 1 [3.0] | |
| Inflammation | 6 [1.5] | 12 [1.6] | 13 [1.2] | 8 [1.1] |
| Metaplasia, Squamous | | | 1 [1.0] | |
| Pigmentation, Hemosiderin | | 1 [3.0] | | |
| Thrombosis | 2 [1.5] | 1 [2.0] | | |
| Alveolar Epithelium, Hyperplasia | 9 [1.9] | 7 [2.0] | 10 [1.8] | 6 [1.5] |
| Alveolus, Infiltration Cellular, Histiocyte | 6 [1.3] | 6 [1.5] | 5 [1.4] | 4 [1.3] |
| Bronchiole, Fibrosis | | | 1 [3.0] | |
| Serosa, Hyperplasia | 1 [1.0] | | | |
| Nose | (50) | (50) | (50) | (50) |
| Inflammation | 21 [1.5] | 28 [2.0] | 21 [2.0] | 18 [1.9] |
| Metaplasia, Squamous | 1 [2.0] | | | |
| Polyp, Inflammatory | | 1 [4.0] | | |
| Thrombosis | | 2 [2.5] | | |
| Nasolacrimal Duct, Inflammation | | | | 1 [2.0] |
| Trachea | (50) | (50) | (50) | (50) |
| Infiltration Cellular, Mononuclear Cell | | 1 [1.0] | | |
| Inflammation | 1 [1.0] | | 2 [1.5] | |
| Metaplasia, Squamous | | | 1 [1.0] | |

SPECIAL SENSES SYSTEM

| | | | | |
|------------------------------------|---------|---------|---------|---------|
| Eye | (50) | (50) | (50) | (50) |
| Cataract | | 2 [2.5] | | 1 [3.0] |
| Anterior Chamber, Inflammation | 1 [2.0] | | | |
| Cornea, Inflammation | 1 [4.0] | | | |
| Retina, Atrophy | 1 [2.0] | 3 [3.0] | | 1 [3.0] |
| Retina, Developmental Malformation | | | 1 | |
| Harderian Gland | (50) | (50) | (50) | (50) |
| Hyperplasia | 1 [1.0] | 1 [2.0] | 2 [2.0] | |

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|--------------------------------|----------------|----------------|----------------|----------------|
| Inflammation Zymbal's Gland | 1 [2.0] (1) | 1 [3.0] (0) | 1 [1.0] (0) | 2 [2.0] (0) |

URINARY SYSTEM

| | | | | |
|-----------------------------------------|----------|----------|----------|----------|
| Kidney | (50) | (50) | (50) | (50) |
| Cyst, Multiple | | | | 1 [3.0] |
| Hyperplasia, Tubular | | | 2 [1.0] | 3 [2.0] |
| Inflammation | 1 [1.0] | 1 [2.0] | | 2 [2.0] |
| Nephropathy | 45 [2.0] | 47 [2.3] | 49 [2.2] | 48 [2.3] |
| Thrombosis | | | 1 [1.0] | |
| Pelvis, Calculus Micro Observation Only | | | | 1 [2.0] |
| Transitional Epithelium, Hyperplasia | | | | 1 [3.0] |
| Urethra | (0) | (0) | (0) | (1) |
| Bulbourethral Gland, Hyperplasia | | | | 1 [4.0] |
| Urinary Bladder | (50) | (50) | (50) | (50) |
| Hemorrhage | | | | 1 [1.0] |
| Inflammation | | 1 [3.0] | | |
| Transitional Epithelium, Hyperplasia | | | 1 [1.0] | 1 [1.0] |

*** 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

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|-------------------------|---------|---------|----------|----------|
|-------------------------|---------|---------|----------|----------|

Disposition Summary

| | | | | |
|----------------------------------|----|----|----|----|
| Animals Initially In Study | 50 | 50 | 50 | 50 |
| Early Deaths | | | | |
| Accidentally Killed | | 1 | | |
| Moribund Sacrifice | 12 | 7 | 18 | 9 |
| Natural Death | 9 | 9 | 6 | 10 |
| Survivors | | | | |
| Natural Death | | | 1 | |
| Terminal Sacrifice | 29 | 33 | 25 | 31 |
| Animals Examined Microscopically | 50 | 50 | 50 | 50 |

ALIMENTARY SYSTEM

| | | | | |
|----------------------------|---------|---------|---------|---------|
| Esophagus | (50) | (50) | (50) | (50) |
| Intestine Large, Cecum | (50) | (50) | (50) | (50) |
| Erosion | 1 [1.0] | | | |
| Inflammation | 1 [2.0] | | 1 [4.0] | 2 [1.0] |
| Thrombosis | | | 1 [2.0] | |
| Ulcer | 1 [4.0] | 1 [2.0] | 1 [2.0] | |
| Intestine Large, Colon | (50) | (50) | (50) | (50) |
| Inflammation | 1 [1.0] | | | |
| Parasite Metazoan | 2 | 5 | 2 | 1 |
| Intestine Large, Rectum | (50) | (50) | (50) | (50) |
| Parasite Metazoan | 3 | 8 | 5 | 5 |
| Intestine Small, Duodenum | (50) | (50) | (50) | (50) |
| Parasite Metazoan | 1 | | | |
| Intestine Small, Ileum | (50) | (50) | (50) | (50) |
| Inflammation | | 1 [2.0] | 1 [1.0] | |
| Parasite Metazoan | | | 1 | |
| Intestine Small, Jejunum | (50) | (50) | (50) | (50) |
| Peyer's Patch, Hyperplasia | 1 [2.0] | | | |
| Serosa, Fibrosis | 1 [1.0] | | | |
| Liver | (50) | (50) | (50) | (50) |
| Angiectasis | 1 [1.0] | 2 [2.0] | | 3 [2.7] |
| Atypia Cellular, Focal | | | 1 [1.0] | |

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Test Type: CHRONIC

Pyrogallol

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Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|---------------------------------------|----------|----------|----------|----------|
| Basophilic Focus | 31 | 34 | 28 | 34 |
| Clear Cell Focus | 9 | 1 | 2 | 4 |
| Congestion, Diffuse | | | | 1 [3.0] |
| Degeneration, Cystic | | 1 [1.0] | 1 [1.0] | |
| Eosinophilic Focus | 2 | 4 | 2 | 1 |
| Fatty Change | 4 [2.5] | 1 [3.0] | 6 [2.3] | 4 [2.5] |
| Hematopoietic Cell Proliferation | | 1 [1.0] | | |
| Hemorrhage | | | 1 [1.0] | 1 [1.0] |
| Hepatodiaphragmatic Nodule | 1 | 6 | 3 | 7 |
| Inflammation | 23 [1.1] | 26 [1.2] | 10 [1.1] | 16 [1.1] |
| Mixed Cell Focus | 5 | 5 | 3 | 4 |
| Bile Duct, Hyperplasia | 10 [1.0] | 7 [1.0] | 7 [1.0] | 7 [1.0] |
| Hepatocyte, Hypertrophy | | 1 [2.0] | | |
| Hepatocyte, Necrosis | 1 [1.0] | 1 [1.0] | 3 [2.0] | |
| Hepatocyte, Regeneration | | | 1 [3.0] | 1 [1.0] |
| Hepatocyte, Vacuolization Cytoplasmic | 12 [1.3] | 15 [1.1] | 8 [1.1] | 6 [1.2] |
| Hepatocyte, Midzonal, Degeneration | 1 [1.0] | | | |
| Portal, Fibrosis | 4 [1.0] | 1 [1.0] | 3 [1.0] | 1 [1.0] |
| Serosa, Fibrosis | | | | 1 [2.0] |
| Mesentery | (8) | (11) | (13) | (10) |
| Necrosis | 6 [3.0] | 11 [3.0] | 13 [3.0] | 10 [3.0] |
| Oral Mucosa | (2) | (2) | (0) | (0) |
| Gingival, Cyst | 1 [3.0] | 1 [4.0] | | |
| Gingival, Inflammation | 1 [4.0] | 1 [4.0] | | |
| Pancreas | (50) | (50) | (50) | (50) |
| Basophilic Focus | | 1 | | |
| Acinus, Atrophy | 16 [1.4] | 13 [2.0] | 17 [1.7] | 15 [1.5] |
| Acinus, Hyperplasia | 3 [2.0] | 8 [1.6] | 1 [3.0] | 5 [2.0] |
| Duct, Cyst | 4 [2.0] | 2 [1.5] | 2 [3.0] | 2 [2.5] |
| Salivary Glands | (50) | (50) | (50) | (50) |
| Hyperplasia | | | 1 [1.0] | |
| Inflammation | | | 1 [2.0] | |
| Mineralization | | | 1 [1.0] | |
| Stomach, Forestomach | (50) | (50) | (50) | (50) |
| Inflammation | 1 [1.0] | | 2 [1.0] | 3 [1.7] |
| Ulcer | 5 [3.2] | 3 [4.0] | 7 [3.7] | 3 [4.0] |

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

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|-------------------------|---------|---------|----------|----------|
| Epithelium, Hyperplasia | 3 [2.0] | | 1 [2.0] | 3 [2.3] |
| Stomach, Glandular | (50) | (50) | (50) | (50) |
| Erosion | 1 [3.0] | 1 [3.0] | 1 [3.0] | |
| Inflammation | 2 [1.5] | | 1 [4.0] | 2 [1.0] |
| Ulcer | | | 1 [4.0] | |
| Epithelium, Cyst | | | | 1 [1.0] |

CARDIOVASCULAR SYSTEM

| | | | | |
|--------------------------|----------|----------|----------|----------|
| Blood Vessel | (50) | (50) | (50) | (50) |
| Thrombosis | | | 1 [4.0] | |
| Heart | (50) | (50) | (50) | (50) |
| Cardiomyopathy | 44 [2.0] | 45 [1.7] | 46 [2.1] | 45 [1.4] |
| Inflammation | 1 [1.0] | | | |
| Atrium, Thrombosis | 1 [3.0] | 1 [4.0] | 1 [4.0] | |
| Myocardium, Inflammation | | 1 [1.0] | | |

ENDOCRINE SYSTEM

| | | | | |
|-----------------------------------------|----------|----------|----------|----------|
| Adrenal Cortex | (50) | (50) | (50) | (50) |
| Angiectasis | | | 1 [2.0] | |
| Atrophy | | | 1 [3.0] | 1 [2.0] |
| Atypia Cellular | | | 1 [1.0] | |
| Degeneration, Cystic | 8 [2.1] | 4 [2.5] | 4 [2.3] | 2 [2.0] |
| Hematopoietic Cell Proliferation | 1 [2.0] | | | 1 [2.0] |
| Hemorrhage | | | | 2 [2.5] |
| Hyperplasia | 29 [1.6] | 24 [1.5] | 26 [1.6] | 29 [1.8] |
| Hypertrophy | 17 [1.2] | 15 [1.5] | 24 [1.5] | 21 [1.4] |
| Necrosis | | | 1 [3.0] | |
| Thrombosis | | | 1 [1.0] | |
| Vacuolization Cytoplasmic | 14 [1.6] | 13 [1.5] | 13 [1.3] | 18 [1.8] |
| Adrenal Medulla | (50) | (50) | (50) | (50) |
| Hyperplasia | 5 [1.4] | 1 [1.0] | 6 [1.2] | 4 [1.3] |
| Infiltration Cellular, Mononuclear Cell | | | | 1 [2.0] |
| Islets, Pancreatic | (50) | (50) | (50) | (50) |

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

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Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|------------------------------|----------|----------|----------|----------|
| Parathyroid Gland | (49) | (49) | (50) | (49) |
| Hyperplasia | | | 2 [2.0] | |
| Pituitary Gland | (50) | (50) | (50) | (50) |
| Angiectasis | | | 1 [2.0] | |
| Cyst | | | 1 [3.0] | 1 [3.0] |
| Hemorrhage | 1 [3.0] | | | 2 [3.0] |
| Pars Distalis, Cyst | 4 [3.8] | 8 [3.1] | 7 [3.0] | 7 [3.3] |
| Pars Distalis, Hyperplasia | 19 [2.4] | 16 [2.6] | 17 [2.4] | 19 [2.9] |
| Pars Distalis, Inflammation | | 1 [1.0] | | |
| Thyroid Gland | (50) | (50) | (50) | (50) |
| Cyst | | | | 1 [3.0] |
| C-cell, Hyperplasia | 22 [1.5] | 31 [1.4] | 23 [1.5] | 31 [1.7] |
| Follicle, Cyst | | 1 [2.0] | | |
| Follicular Cell, Hyperplasia | | | | 1 [1.0] |

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

| | | | | |
|--------------------------|---------|---------|---------|---------|
| Clitoral Gland | (50) | (50) | (50) | (50) |
| Atrophy | | | 1 [3.0] | |
| Fibrosis | | | 1 [3.0] | |
| Hyperplasia | 3 [3.0] | 1 [3.0] | 4 [2.8] | 1 [4.0] |
| Inflammation | 3 [2.0] | 4 [2.3] | 6 [2.2] | 6 [2.2] |
| Duct, Dilatation | 1 [4.0] | | 2 [3.0] | |
| Ovary | (50) | (50) | (50) | (50) |
| Cyst | 3 [2.3] | 3 [3.0] | 6 [2.5] | 1 [3.0] |
| Uterus | (50) | (50) | (50) | (50) |
| Hemorrhage | | 1 [4.0] | | |
| Hyperplasia, Adenomatous | | | | 1 [4.0] |
| Inflammation | 3 [2.3] | | | 1 [4.0] |
| Cervix, Fibrosis | 1 [4.0] | | | |
| Endometrium, Cyst | | | 1 [3.0] | |

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Pyrogallol

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Route: SKIN APPLICATION

CAS Number: 87-66-1

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Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|----------------------------------|---------|---------|----------|----------|
| Endometrium, Edema | | | 1 [4.0] | |
| Endometrium, Hyperplasia, Cystic | 5 [1.8] | 5 [2.0] | 4 [1.8] | |
| Vagina | (0) | (1) | (0) | (0) |
| Inflammation | | 1 [4.0] | | |

HEMATOPOIETIC SYSTEM

| | | | | |
|-----------------------------------------|----------|---------|----------|----------|
| Bone Marrow | (50) | (50) | (50) | (50) |
| Fibrosis | 1 [2.0] | | | |
| Hyperplasia | 10 [3.1] | 6 [3.8] | 10 [4.0] | 10 [3.8] |
| Myelofibrosis | | | 2 [2.5] | 1 [3.0] |
| Lymph Node | (3) | (2) | (4) | (2) |
| Hemorrhage | | | 1 [3.0] | |
| Deep Cervical, Hyperplasia, Plasma Cell | 1 [3.0] | | | |
| Mediastinal, Congestion | | 1 [3.0] | | |
| Mediastinal, Hemorrhage | 2 [3.0] | | 1 [3.0] | |
| Mediastinal, Hyperplasia, Plasma Cell | 1 [2.0] | 1 [3.0] | 1 [2.0] | |
| Pancreatic, Hemorrhage | | | 1 [4.0] | |
| Lymph Node, Mesenteric | (50) | (50) | (50) | (50) |
| Degeneration, Cystic | 3 [2.0] | | | 1 [2.0] |
| Hyperplasia, Lymphoid | | | | 1 [3.0] |
| Hyperplasia, Plasma Cell | | | 1 [2.0] | 1 [2.0] |
| Infiltration Cellular, Histiocyte | | 1 [3.0] | | |
| Inflammation | | 2 [1.5] | | |
| Spleen | (50) | (50) | (50) | (50) |
| Accessory Spleen | | | 1 | 1 |
| Hematopoietic Cell Proliferation | | 3 [2.3] | 1 [3.0] | |
| Hyperplasia, Lymphoid | | 1 [3.0] | 1 [3.0] | 2 [2.5] |
| Infarct | | 2 [3.0] | 4 [3.0] | 1 [4.0] |
| Pigmentation, Hemosiderin | | 1 [2.0] | | 1 [2.0] |
| Capsule, Hyperplasia | | | 1 [1.0] | |
| Capsule, Inflammation | | | 1 [1.0] | |
| Lymphoid Follicle, Atrophy | | 1 [2.0] | 1 [2.0] | 1 [2.0] |
| Thymus | (50) | (50) | (49) | (50) |
| Cyst | | | | 1 [3.0] |

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Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE

0 MG/KG

5 MG/KG

20 MG/KG

75 MG/KG

INTEGUMENTARY SYSTEM

| | | | | |
|---------------------------------------------------|---------|---------|----------|----------|
| Mammary Gland | (50) | (50) | (50) | (50) |
| Inflammation | 1 [3.0] | 4 [2.3] | | 1 [1.0] |
| Duct, Cyst | 1 [4.0] | 1 [4.0] | 1 [3.0] | 5 [3.4] |
| Duct, Hyperplasia, Cystic | 1 [3.0] | | | |
| Skin | (50) | (50) | (50) | (50) |
| Hyperkeratosis | | 2 [1.0] | | |
| Hyperplasia | | | | 1 [4.0] |
| Ulcer | | | | 1 [4.0] |
| Control, Hyperplasia | | | 1 [1.0] | |
| Control, Inflammation | | | 1 [1.0] | |
| Sebaceous Gland, Site Of Application, Hyperplasia | | | 5 [1.0] | 41 [1.7] |
| Site Of Application, Hyperkeratosis | | 6 [1.0] | 23 [1.0] | 49 [1.8] |
| Site Of Application, Hyperplasia | | 9 [1.0] | 11 [1.0] | 49 [1.1] |
| Site Of Application, Inflammation | | 3 [1.0] | 6 [1.0] | 49 [1.4] |

MUSCULOSKELETAL SYSTEM

| | | | | |
|-------------------------|---------|------|---------|------|
| Bone | (50) | (50) | (50) | (50) |
| Osteopetrosis | | | 1 [4.0] | |
| Osteosclerosis | 1 [2.0] | | | |
| Fibula, Tibia, Fracture | 1 [4.0] | | | |
| Skeletal Muscle | (0) | (0) | (2) | (0) |

NERVOUS SYSTEM

| | | | | |
|---------------------|---------|---------|---------|---------|
| Brain | (50) | (50) | (50) | (50) |
| Hemorrhage | 1 [3.0] | 1 [3.0] | | 1 [3.0] |
| Hydrocephalus | 1 [2.0] | 3 [1.7] | 3 [1.7] | 3 [2.0] |
| Thrombosis | | | 1 [2.0] | |
| Cerebellum, Gliosis | 1 [1.0] | | | |

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Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|-------------------------|---------|---------|----------|----------|
| Cerebrum, Necrosis | 1 [3.0] | | | |
| Peripheral Nerve | (0) | (0) | (1) | (0) |
| Spinal Cord | (0) | (0) | (1) | (0) |

RESPIRATORY SYSTEM

| | | | | |
|--------------------------------------------------------|----------|----------|----------|----------|
| Larynx | (0) | (1) | (0) | (0) |
| Foreign Body | | 1 | | |
| Inflammation | | 1 [2.0] | | |
| Lung | (50) | (50) | (50) | (50) |
| Congestion | | 1 [4.0] | 1 [3.0] | 1 [2.0] |
| Fibrosis | 2 [1.0] | | | |
| Hemorrhage | | 2 [3.0] | | |
| Inflammation | 8 [1.3] | 9 [1.0] | 2 [1.0] | 10 [1.1] |
| Thrombosis | 1 [1.0] | | | |
| Alveolar Epithelium, Hyperplasia | 6 [2.0] | 11 [2.3] | 5 [1.8] | 12 [2.3] |
| Alveolus, Infiltration Cellular, Histiocyte | 2 [2.0] | 3 [1.0] | 2 [1.5] | 6 [1.5] |
| Alveolus, Pigmentation, Hemoglobin | | | | 1 [1.0] |
| Bronchiole, Hyperplasia | | | | 1 [2.0] |
| Serosa, Fibrosis | | 1 [1.0] | | |
| Nose | (50) | (50) | (50) | (50) |
| Inflammation | 11 [1.7] | 10 [2.3] | 12 [2.2] | 8 [2.0] |
| Metaplasia, Squamous | 1 [1.0] | 1 [1.0] | | |
| Thrombosis | 1 [3.0] | 1 [3.0] | 1 [3.0] | |
| Goblet Cell, Hyperplasia | 2 [1.5] | 2 [1.5] | | |
| Nasolacrimal Duct, Inflammation | | 1 [3.0] | | |
| Nasolacrimal Duct, Squamous Epithelium, Hyperplasia | 1 [3.0] | | | |
| Nasopharyngeal Duct, Inflammation | | | 2 [2.5] | |
| Olfactory Epithelium, Hyperplasia | | | 1 [2.0] | |
| Respiratory Epithelium, Necrosis | | 1 [2.0] | | |
| Squamous Epithelium, Necrosis | | 1 [1.0] | | |
| Vomeronasal Organ, Necrosis | | 1 [3.0] | | |
| Trachea | (50) | (50) | (50) | (50) |
| Infiltration Cellular, Mononuclear Cell | 1 [1.0] | | | |

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Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

| FISCHER 344 RATS FEMALE | 0 MG/KG | 5 MG/KG | 20 MG/KG | 75 MG/KG |
|-------------------------|---------|---------|----------|----------|
| Inflammation | 1 [1.0] | | 1 [1.0] | |

SPECIAL SENSES SYSTEM

| | | | | |
|------------------------------------|---------|---------|---------|---------|
| Eye | (50) | (50) | (50) | (50) |
| Cataract | 3 [3.0] | 4 [3.5] | 1 [4.0] | 1 [3.0] |
| Synechia | 1 [3.0] | 1 [2.0] | | |
| Anterior Chamber, Exudate | | | | 1 [3.0] |
| Bilateral, Retina, Atrophy | | 1 [4.0] | | |
| Optic Nerve, Atrophy | 1 [3.0] | | 1 [4.0] | |
| Posterior Chamber, Exudate | | | | 1 [3.0] |
| Retina, Atrophy | 3 [4.0] | 3 [3.3] | 2 [3.0] | |
| Retina, Developmental Malformation | 1 [1.0] | | | |
| Retina, Dysplasia | | 1 [2.0] | | 1 [3.0] |
| Harderian Gland | (50) | (50) | (50) | (50) |
| Hyperplasia | 1 [1.0] | 2 [2.0] | 4 [2.8] | 3 [2.3] |
| Inflammation | 2 [1.0] | 4 [1.5] | | 4 [1.5] |
| Metaplasia, Squamous | 1 [1.0] | | | |
| Pigmentation, Porphyrin | | 3 [2.0] | 6 [1.8] | 1 [3.0] |

URINARY SYSTEM

| | | | | |
|--------------------------------------|----------|----------|----------|----------|
| Kidney | (50) | (50) | (50) | (50) |
| Accumulation, Hyaline Droplet | | 2 [2.0] | | |
| Atrophy | | | 1 [3.0] | |
| Cyst | | 1 [2.0] | 1 [1.0] | |
| Hypertrophy | | | 1 [2.0] | |
| Infiltration Cellular, Lipocyte | | 1 [4.0] | | |
| Inflammation | 1 [1.0] | | 3 [2.7] | |
| Nephropathy | 46 [1.5] | 42 [1.7] | 42 [1.6] | 44 [1.6] |
| Papilla, Necrosis | | | 1 [3.0] | |
| Transitional Epithelium, Hyperplasia | | | 1 [2.0] | |
| Urinary Bladder | (50) | (50) | (50) | (49) |
| Transitional Epithelium, Hyperplasia | | 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)

Experiment Number: 99032 - 03

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

Date Report Requested: 05/30/2012

Test Type: CHRONIC

Pyrogallol

Time Report Requested: 11:40:45

Route: SKIN APPLICATION

CAS Number: 87-66-1

First Dose M/F: 09/15/04 / 09/16/04

Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE

0 MG/KG

5 MG/KG

20 MG/KG

75 MG/KG

*** 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)