

Experiment Number: 99032 - 01
Test Type: 90-DAY
Route: SKIN APPLICATION
Species/Strain: RATS/F 344/N

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)
Pyrogallol
CAS Number: 87-66-1

Date Report Requested: 09/19/2016
Time Report Requested: 11:26:21
First Dose M/F: 11/03/03 / 11/04/03
Lab: BAT

NTP Study Number: C99032
Lock Date: 06/02/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

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| FISCHER 344 RATS MALE | 0 MG/KG | 9.5 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|-----------------------|---------|-----------|-------------|------------|----------|-----------|
|-----------------------|---------|-----------|-------------|------------|----------|-----------|

Disposition Summary

| | | | | | | |
|----------------------------------|----|----|----|----|----|----|
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |

ALIMENTARY SYSTEM

| | | | | | | |
|---|---------|-----|-----|-----|-----|-----------|
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Parasite Metazoan | 1 (10%) | | | | | |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Parasite Metazoan | 1 (10%) | | | | | |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (0) | (0) | (0) | (0) | (10) |
| Hematopoietic Cell Proliferation | | | | | | 1 (10%) |
| Hepatodiaphragmatic Nodule | 1 (10%) | | | | | |
| Infiltration Cellular, Mononuclear Cell | 9 (90%) | | | | | 10 (100%) |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Acinus, Atrophy | | | | | | 1 (10%) |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |

CARDIOVASCULAR SYSTEM

| | | | | | | |
|----------------|---------|-----|-----|-----|-----|---------|
| Blood Vessel | (10) | (0) | (0) | (0) | (0) | (10) |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |
| Cardiomyopathy | 9 (90%) | | | | | 9 (90%) |

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

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| FISCHER 344 RATS MALE | 0 MG/KG | 9.5 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|-----------------------------|---------|-----------|-------------|------------|----------|-----------|
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (0) | (10) |
| Parathyroid Gland | (10) | (0) | (0) | (0) | (0) | (9) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Cyst | | | | | | 1 (10%) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Epididymis | (10) | (0) | (0) | (0) | (0) | (10) |
| Preputial Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | 2 (20%) | | | | | 2 (20%) |
| Prostate | (10) | (0) | (0) | (0) | (0) | (10) |
| Seminal Vesicle | (10) | (0) | (0) | (0) | (0) | (10) |
| Testes | (10) | (0) | (0) | (0) | (0) | (10) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (9) | (0) | (0) | (0) | (0) | (10) |

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| FISCHER 344 RATS MALE | 0 MG/KG | 9.5 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|---|---------|-----------|-------------|------------|-----------|-----------|
| Skin | (10) | (10) | (10) | (10) | (10) | (10) |
| Site Of Application, Hyperkeratosis | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Site Of Application, Hyperplasia, Squamous | 1 (10%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Site Of Application, Inflammation | 1 (10%) | | | | | |
| Site Of Application, Inflammation, Chronic Active | | 9 (90%) | 9 (90%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Site Of Application, Ulcer | | | | | | 1 (10%) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | 2 (20%) | | | | | 3 (30%) |
| Metaplasia, Osseous | 1 (10%) | | | | | |
| Alveolar Epithelium, Hyperplasia | | | | | | 1 (10%) |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Retina, Atrophy | | | | | | 1 (10%) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |

URINARY SYSTEM

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

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First Dose M/F: 11/03/03 / 11/04/03

Lab: BAT

| FISCHER 344 RATS MALE | 0 MG/KG | 9.5 MG/KG | 18.75 MG/KG | 37.5 MG/KG | 75 MG/KG | 150 MG/KG |
|------------------------------|----------------|------------------|--------------------|-------------------|-----------------|------------------|
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Mineralization | 3 (30%) | | | | | 2 (20%) |
| Nephropathy | 7 (70%) | | | | | 9 (90%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

*** END OF MALE ***

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|-------------------------|---------|-----------|-------------|------------|----------|-----------|
|-------------------------|---------|-----------|-------------|------------|----------|-----------|

Disposition Summary

| | | | | | | |
|---|-----------|-----------|-----------|-----------|-----------|-----------|
| Animals Initially In Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Moribund Sacrifice | 1 | | | | | |
| Survivors | | | | | | |
| Terminal Sacrifice | 9 | 10 | 10 | 10 | 10 | 10 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |

ALIMENTARY SYSTEM

| | | | | | | |
|---|---------|----------|----------|-----|----------|---------|
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Duodenum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Intestine Small, Jejunum | (10) | (0) | (0) | (0) | (0) | (10) |
| Liver | (10) | (0) | (2) | (0) | (2) | (10) |
| Hepatodiaphragmatic Nodule | | | 2 (100%) | | 2 (100%) | 1 (10%) |
| Infiltration Cellular, Mononuclear Cell | 7 (70%) | | | | | 5 (50%) |
| Inflammation | 2 (20%) | | | | | 2 (20%) |
| Mesentery | (0) | (1) | (0) | (0) | (0) | (0) |
| Inflammation, Chronic Active | | 1 (100%) | | | | |
| Necrosis | | 1 (100%) | | | | |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Acinus, Atrophy | 1 (10%) | | | | | |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Forestomach | (10) | (0) | (0) | (0) | (0) | (10) |
| Stomach, Glandular | (10) | (0) | (0) | (0) | (0) | (10) |

CARDIOVASCULAR SYSTEM

| | | | | | | |
|--------------|------|-----|-----|-----|-----|------|
| Blood Vessel | (10) | (0) | (0) | (0) | (0) | (10) |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |

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|-----------------------------------|---------|-----------|-------------|------------|----------|-----------|
| Cardiomyopathy | 7 (70%) | | | | | 9 (90%) |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
| Accessory Adrenal Cortical Nodule | | | | | | 1 (10%) |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |
| Islets, Pancreatic | (10) | (0) | (0) | (0) | (0) | (10) |
| Parathyroid Gland | (10) | (0) | (0) | (0) | (0) | (9) |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Thyroid Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Clitoral Gland | (10) | (0) | (0) | (0) | (0) | (9) |
| Inflammation | 1 (10%) | | | | | 1 (11%) |
| Ovary | (10) | (1) | (0) | (0) | (0) | (10) |
| Cyst | 1 (10%) | 1 (100%) | | | | |
| Uterus | (10) | (0) | (0) | (0) | (0) | (10) |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | | | | | | 1 (10%) |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Spleen | (10) | (0) | (0) | (0) | (0) | (10) |
| Thymus | (10) | (0) | (0) | (0) | (0) | (10) |

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|---|---------|-----------|-------------|------------|-----------|-----------|
| INTEGUMENTARY SYSTEM | | | | | | |
| Mammary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Skin | (10) | (10) | (10) | (10) | (10) | (10) |
| Control Dermis, Inflammation | | 1 (10%) | | | | |
| Site Of Application, Hyperkeratosis | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Site Of Application, Hyperplasia, Squamous | | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) | 10 (100%) |
| Site Of Application, Inflammation, Chronic Active | | 8 (80%) | 10 (100%) | 9 (90%) | 10 (100%) | 10 (100%) |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| Bone | (10) | (0) | (0) | (0) | (0) | (10) |
| NERVOUS SYSTEM | | | | | | |
| Brain | (10) | (0) | (0) | (0) | (0) | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | 2 (20%) | | | | | 2 (20%) |
| Alveolar Epithelium, Hyperplasia | 2 (20%) | | | | | |
| Alveolus, Infiltration Cellular, Histiocyte | | | | | | 2 (20%) |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| SPECIAL SENSES SYSTEM | | | | | | |
| Eye | (10) | (0) | (0) | (0) | (0) | (10) |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | | | | | | 1 (10%) |

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|-------------------------|---------|-----------|-------------|------------|----------|-----------|
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation | | | | | | 1 (10%) |
| Mineralization | 4 (40%) | | | | | 3 (30%) |
| Nephropathy | 1 (10%) | | | | | 1 (10%) |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |

*** END OF REPORT ***

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