

TDMS No. 20214 - 01

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

Date Report Reqsted: 04/02/2008

Test Type: 90-DAY

5-Amino-o-cresol

Time Report Reqsted: 09:24:09

Route: SKIN APPLICATION

CAS Number: 2835-95-2

First Dose M/F: 05/08/06 / 05/09/06

Species/Strain: RATS/F344/N Tac

Lab: BAT

F1_RD

C Number: C20214

Lock Date: 12/04/2006

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

TDMSE Version: 1.9.1

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| Fischer 344-Taconic RATS MALE | 0 mg/kg | 2 mg/kg | 4 mg/kg | 8 mg/kg | 16 mg/kg | 32 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 | | | | | | |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Parasite Metazoan | | | | | | 2 [1.0] |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Hepatodiaphragmatic Nodule | | | | 1 | | |
| Inflammation, Chronic Active | 9 [1.0] | | | 1 [1.0] | | 9 [1.0] |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Chronic Active | 1 [1.0] | | | | | |
| Acinus, Atrophy | | | | | | 2 [1.0] |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |
| Cardiomyopathy | 10 [1.0] | | | | | 10 [1.0] |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Medulla | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | 1 [1.0] | | | | | 2 [1.0] |
| Pituitary Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Cyst | 1 [1.0] | | | | | |
| Thyroid Gland | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 [1.0] |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |

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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|---|--------------------|---------|---------|---------|----------|--------------------|
| GENITAL SYSTEM | | | | | | |
| Epididymis | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell Inflammation, Chronic Active | 1 [1.0] | | | | | 2 [1.0] |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Histiocytic | | | | | | 1 [1.0] |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte Inflammation, Chronic Active | 2 [1.0] 3 [1.3] | | | | | 4 [1.0] 5 [1.2] |
| Metaplasia, Osseous Interstitialium, Inflammation, Chronic Active | 2 [1.0] | 5 [1.0] | 7 [1.0] | 8 [1.0] | 6 [1.2] | 1 [1.0] |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | 5 [1.0] | | | | | 3 [1.0] |
| SPECIAL SENSES SYSTEM | | | | | | |

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|---|----------|---------|---------|---------|----------|----------|
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 [1.0] |
| Inflammation, Chronic Active | 1 [3.0] | | | | | 1 [3.0] |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | 1 [1.0] | | | | | 1 [1.0] |
| Mineralization | 6 [1.0] | | | | | 6 [1.0] |
| Nephropathy | 10 [1.0] | | | | | 10 [1.0] |

*** END OF MALE ***

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| 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 | | | | | | |
| Intestine Large, Rectum | (10) | (0) | (0) | (0) | (0) | (10) |
| Parasite Metazoan | 1 [1.0] | | | | | |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Hematopoietic Cell Proliferation | | | | 1 [1.0] | | |
| Hepatodiaphragmatic Nodule | 2 | 3 | 2 | 3 | 2 | 1 |
| Inflammation, Chronic Active | 10 [1.1] | 1 [1.0] | 2 [1.0] | 2 [1.0] | 2 [1.0] | 10 [1.5] |
| Pancreas | (10) | (0) | (0) | (0) | (0) | (10) |
| Acinus, Atrophy | 2 [1.0] | | | | | 1 [1.0] |
| Salivary Glands | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 [1.0] |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (0) | (0) | (0) | (0) | (10) |
| Cardiomyopathy | 10 [1.0] | | | | | 9 [1.0] |
| ENDOCRINE SYSTEM | | | | | | |
| Thyroid Gland | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 1 [1.0] |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |

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|--|---------|---------|---------|---------|----------|----------|
| GENITAL SYSTEM | | | | | | |
| Ovary | (10) | (0) | (0) | (1) | (0) | (10) |
| Left, Cyst | | | | 1 [2.0] | | |
| Left, Inflammation | | | | 1 [2.0] | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Bone Marrow | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Histiocyte | | | | | | 1 [2.0] |
| Lymph Node, Mesenteric | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Histiocytic | | | | | | 5 [2.0] |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (10) | (10) | (10) | (10) | (10) |
| Infiltration Cellular, Histiocyte | | | | | | 1 [1.0] |
| Inflammation, Chronic Active | 2 [1.0] | | | | | 6 [1.0] |
| Interstitial, Inflammation, Chronic Active | | 2 [1.0] | 6 [1.7] | 3 [1.3] | 5 [1.2] | |
| Nose | (10) | (0) | (0) | (0) | (0) | (10) |
| Inflammation, Chronic Active | | | | | | 2 [2.0] |
| Trachea | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | 3 [1.0] | | | | | 1 [1.0] |

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|---|---------|---------|---------|---------|----------|----------|
| SPECIAL SENSES SYSTEM | | | | | | |
| Harderian Gland | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | | | | | | 2 [1.0] |
| Inflammation, Chronic Active | 1 [1.0] | | | | | 3 [1.0] |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Lipocyte | 1 [1.0] | | | | | |
| Infiltration Cellular, Mononuclear Cell | 1 [1.0] | | | | | |
| Mineralization | 7 [1.0] | | | | | 7 [1.0] |
| Nephropathy | 3 [1.0] | | | | | |
| Urinary Bladder | (10) | (0) | (0) | (0) | (0) | (10) |
| Infiltration Cellular, Mononuclear Cell | 1 [1.0] | | | | | 1 [1.0] |

*** END OF REPORT ***