

TDMs No. 20203 - 02

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

Date Report Requested: 04/15/2009

Test Type: 90-DAY

Green tea extract

Time Report Requested: 08:55:24

Route: GAVAGE

CAS Number: GREENTEAEXTR

First Dose M/F: 04/20/06 / 04/19/06

Species/Strain: MICE/B6C3F1

Lab: BAT

F_M3

C Number: C20203
Lock Date: 01/04/2007
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.1.0

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Lab: BAT

| B6C3F1 MICE MALE | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|-----------------------------------|---------|------------|-----------|-----------|-----------|------------|
| Disposition Summary | | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Natural Death | | | | | | 6 |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 4 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Intestine Large, Colon | (10) | (0) | (0) | (0) | (10) | (10) |
| Peyer's Patch, Atrophy | | | | | | 1 [1.0] |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (10) | (10) |
| Peyer's Patch, Atrophy | | | | | | 2 [2.0] |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Depletion Glycogen | 2 [1.0] | | 2 [1.5] | 8 [1.5] | 10 [1.7] | 4 [2.5] |
| Infiltration Cellular, Mixed Cell | 8 [1.0] | 6 [1.0] | 8 [1.0] | 7 [1.0] | 4 [1.0] | 2 [1.0] |
| Karyomegaly | | | | | | 2 [1.0] |
| Mitosis | | | | | | 3 [1.3] |
| Pigmentation | | | | | | 2 [1.0] |
| Centrilobular, Necrosis | | | 2 [1.0] | | | 8 [3.1] |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Cardiomyopathy | 1 [1.0] | | | | | |
| Myocardium, Hemorrhage | | | | | | 1 [1.0] |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (10) | (10) |
| Subcapsular, Hyperplasia | 3 [1.0] | | | | 5 [1.0] | 3 [1.0] |
| GENERAL BODY SYSTEM | | | | | | |

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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|---|-----------------|------------|-----------|-----------|-----------------|-----------------|
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| Prostate Infiltration Cellular, Mononuclear Cell | (10) 6 [1.2] | (0) | (0) | (0) | (10) 6 [1.0] | (10) 3 [1.0] |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Lymph Node, Mandibular Atrophy | (10) 1 [1.0] | (10) | (10) | (10) | (10) 2 [1.0] | (10) 7 [1.9] |
| Hyperplasia, Lymphoid | 1 [2.0] | 1 [2.0] | | | | |
| Lymph Node, Mesenteric Atrophy | (10) 4 [1.0] | (10) | (10) | (10) | (10) 2 [1.0] | (10) 8 [1.4] |
| Hyperplasia, Lymphoid | | 4 [1.8] | 3 [1.7] | 1 [2.0] | | |
| Spleen | (10) | (10) | (10) | (10) | (10) | (10) |
| Lymphoid Follicle, Hyperplasia | 2 [1.5] | | 1 [1.0] | | 1 [1.0] | 1 [1.0] |
| Thymus Atrophy | (10) | (10) | (10) | (10) | (10) | (10) 6 [3.3] |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |
| Brain Hydrocephalus | (10) | (0) | (0) | (0) | (10) 1 [1.0] | (10) |
| RESPIRATORY SYSTEM | | | | | | |
| Lung | (10) | (0) | (0) | (0) | (10) | (10) |
| Nose | (10) | (10) | (10) | (10) | (10) | (10) |

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|--|---------|------------|-----------|-----------|-----------|------------|
| Foreign Body | | | | | 1 | |
| Inflammation | | | 1 [3.0] | | 1 [2.0] | 1 [2.0] |
| Glands, Olfactory Epithelium, Hyperplasia | | | | | | 3 [1.3] |
| Lamina Propria, Pigmentation, Histiocyte Nerve, Atrophy | | | | 5 [1.2] | 7 [1.1] | 1 [1.0] |
| Olfactory Epithelium, Atrophy | | 1 [1.0] | | 4 [1.3] | 4 [1.8] | 5 [1.8] |
| Olfactory Epithelium, Hyperplasia, Basal Cell | | | | | 4 [1.8] | 4 [1.3] |
| Olfactory Epithelium, Metaplasia | | | | 5 [1.0] | 5 [1.2] | 3 [2.3] |
| Olfactory Epithelium, Necrosis | | | 1 [3.0] | | 1 [3.0] | 5 [2.2] |
| Olfactory Epithelium, Pigmentation | | | | | | 3 [1.7] |
| Respiratory Epithelium, Hyaline Droplet | | | | | 1 [1.0] | 1 [1.0] |
| Respiratory Epithelium, Hyperplasia | | | | | | 3 [1.0] |
| Respiratory Epithelium, Metaplasia, Squamous | | | | | | 1 [2.0] |
| Respiratory Epithelium, Necrosis | | | | | 1 [4.0] | 1 [2.0] |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (10) | (10) |
| Nephropathy | 5 [1.0] | | | | 4 [1.0] | 4 [1.0] |
| Urinary Bladder | (10) | (0) | (0) | (0) | (10) | (10) |
| Infiltration Cellular, Lymphocyte | 1 [1.0] | | | | 2 [1.0] | |

*** END OF MALE ***

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| Disposition Summary | | | | | | |
| Animals Initially in Study | 10 | 10 | 10 | 10 | 10 | 10 |
| Early Deaths | | | | | | |
| Moribund Sacrifice | | | | | | 4 |
| Survivors | | | | | | |
| Terminal Sacrifice | 10 | 10 | 10 | 10 | 10 | 6 |
| Animals Examined Microscopically | 10 | 10 | 10 | 10 | 10 | 10 |
| ALIMENTARY SYSTEM | | | | | | |
| Esophagus | (10) | (0) | (0) | (0) | (0) | (10) |
| Muscularis, Degeneration | 1 [1.0] | | | | | 1 [2.0] |
| Intestine Large, Cecum | (10) | (0) | (0) | (0) | (0) | (10) |
| Peyer's Patch, Atrophy | | | | | | 1 [1.0] |
| Intestine Small, Ileum | (10) | (0) | (0) | (0) | (0) | (10) |
| Peyer's Patch, Atrophy | | | | | | 2 [2.5] |
| Liver | (10) | (10) | (10) | (10) | (10) | (10) |
| Depletion Glycogen | | | | 1 [1.0] | 4 [1.5] | 7 [2.1] |
| Fatty Change | | | | | | 1 [2.0] |
| Infiltration Cellular, Mixed Cell | 10 [1.0] | 9 [1.0] | 10 [1.0] | 10 [1.0] | 10 [1.0] | 3 [1.0] |
| Inflammation, Chronic | | | | | | 3 [2.0] |
| Karyomegaly | | | | | | 5 [1.0] |
| Mitosis | | | | | | 2 [2.0] |
| Pigmentation | | | | | | 2 [1.0] |
| Centrilobular, Necrosis | | | | | | 7 [2.4] |
| CARDIOVASCULAR SYSTEM | | | | | | |
| Heart | (10) | (10) | (10) | (10) | (10) | (10) |
| Myocardium, Hemorrhage | | | | | | 1 [1.0] |
| Myocardium, Necrosis | | | | | | 1 [1.0] |
| ENDOCRINE SYSTEM | | | | | | |
| Adrenal Cortex | (10) | (0) | (0) | (0) | (0) | (10) |
| Subcapsular, Hyperplasia | 10 [1.0] | | | | | 8 [1.0] |

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

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|--|-----------------|------------|-----------|-----------------|-----------------|-----------------|
| Thyroid Gland Infiltration Cellular, Mononuclear Cell | (10) 1 [2.0] | (0) | (0) | (0) | (0) | (10) |
| GENERAL BODY SYSTEM | | | | | | |
| None | | | | | | |
| GENITAL SYSTEM | | | | | | |
| None | | | | | | |
| HEMATOPOIETIC SYSTEM | | | | | | |
| Lymph Node, Mandibular Atrophy | (10) | (10) | (10) | (10) 2 [1.0] | (10) 2 [1.5] | (10) 4 [2.0] |
| Hemorrhage | | 1 [1.0] | | | | |
| Hyperplasia, Lymphoid | | 1 [3.0] | | | | |
| Lymph Node, Mesenteric Atrophy | (10) 2 [1.0] | (10) | (10) | (10) | (10) 2 [1.5] | (9) 3 [2.3] |
| Hyperplasia, Lymphoid | | | | | 1 [1.0] | |
| Spleen Atrophy, Lymphoid | (10) | (10) | (10) | (10) 1 [1.0] | (10) 4 [1.0] | (10) 4 [2.8] |
| Lymphoid Follicle, Hyperplasia | | | | | 1 [1.0] | |
| Thymus Atrophy | (10) | (10) | (10) | (10) | (10) | (10) 4 [3.3] |
| Necrosis | | | | | | 2 [3.0] |
| INTEGUMENTARY SYSTEM | | | | | | |
| None | | | | | | |
| MUSCULOSKELETAL SYSTEM | | | | | | |
| None | | | | | | |
| NERVOUS SYSTEM | | | | | | |

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

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|---|---------|------------|-----------|-----------|-----------|------------|
| None | | | | | | |
| RESPIRATORY SYSTEM | | | | | | |
| Nose | (10) | (10) | (10) | (10) | (10) | (10) |
| Inflammation | | 1 [2.0] | 1 [2.0] | | | 1 [1.0] |
| Glands, Olfactory Epithelium, Hyperplasia | | | | | | 1 [1.0] |
| Nasopharyngeal Duct, Degeneration | | | | | | 1 [1.0] |
| Nerve, Atrophy | | | 1 [1.0] | 1 [1.0] | 7 [1.3] | 5 [1.4] |
| Olfactory Epithelium, Atrophy | | | 1 [2.0] | | 4 [1.0] | 4 [1.8] |
| Olfactory Epithelium, Hyperplasia, Basal Cell | | | | | | 1 [2.0] |
| Olfactory Epithelium, Metaplasia | | | 1 [1.0] | 1 [1.0] | 7 [1.6] | 6 [1.3] |
| Olfactory Epithelium, Necrosis | | | | | 1 [1.0] | 4 [1.5] |
| Respiratory Epithelium, Hyaline Droplet | | | | 1 [2.0] | 4 [1.8] | |
| Respiratory Epithelium, Hyperplasia | | | | | | 2 [2.0] |
| Respiratory Epithelium, Metaplasia, Squamous | | | | | | 1 [1.0] |
| Respiratory Epithelium, Necrosis | | | | | | 1 [3.0] |
| SPECIAL SENSES SYSTEM | | | | | | |
| None | | | | | | |
| URINARY SYSTEM | | | | | | |
| Kidney | (10) | (0) | (0) | (0) | (0) | (10) |
| Nephropathy | 2 [1.0] | | | | | 2 [1.5] |

*** END OF REPORT ***