

**TDMS No.** 20203 - 02  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**

Green tea extract  
**CAS Number:** GREENTEAEXTR

**Date Report Requested:** 04/15/2009  
**Time Report Requested:** 08:55:24  
**First Dose M/F:** 04/20/06 / 04/19/06  
**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

| B6C3F1 MICE MALE                  | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|-----------------------------------|---------|------------|-----------|-----------|-----------|------------|
| <b>Disposition Summary</b>        |         |            |           |           |           |            |
| 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         |
| <b>ALIMENTARY SYSTEM</b>          |         |            |           |           |           |            |
| Intestine Large, Colon            | (10)    | (0)        | (0)       | (0)       | (10)      | (10)       |
| Peyer's Patch, Atrophy            |         |            |           |           |           | 1 (10%)    |
| Intestine Small, Ileum            | (10)    | (0)        | (0)       | (0)       | (10)      | (10)       |
| Peyer's Patch, Atrophy            |         |            |           |           |           | 2 (20%)    |
| Liver                             | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Depletion Glycogen                | 2 (20%) |            | 2 (20%)   | 8 (80%)   | 10 (100%) | 4 (40%)    |
| Infiltration Cellular, Mixed Cell | 8 (80%) | 6 (60%)    | 8 (80%)   | 7 (70%)   | 4 (40%)   | 2 (20%)    |
| Karyomegaly                       |         |            |           |           |           | 2 (20%)    |
| Mitosis                           |         |            |           |           |           | 3 (30%)    |
| Pigmentation                      |         |            |           |           |           | 2 (20%)    |
| Centrilobular, Necrosis           |         |            | 2 (20%)   |           |           | 8 (80%)    |
| <b>CARDIOVASCULAR SYSTEM</b>      |         |            |           |           |           |            |
| Heart                             | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Cardiomyopathy                    | 1 (10%) |            |           |           |           |            |
| Myocardium, Hemorrhage            |         |            |           |           |           | 1 (10%)    |
| <b>ENDOCRINE SYSTEM</b>           |         |            |           |           |           |            |
| Adrenal Cortex                    | (10)    | (0)        | (0)       | (0)       | (10)      | (10)       |
| Subcapsular, Hyperplasia          | 3 (30%) |            |           |           | 5 (50%)   | 3 (30%)    |
| <b>GENERAL BODY SYSTEM</b>        |         |            |           |           |           |            |
| None                              |         |            |           |           |           |            |
| <b>GENITAL SYSTEM</b>             |         |            |           |           |           |            |

| B6C3F1 MICE MALE                                    | 0 mg/kg         | 62.5 mg/kg | 125 mg/kg       | 250 mg/kg | 500 mg/kg          | 1000 mg/kg      |
|---|-----------------|------------|-----------------|-----------|--------------------|-----------------|
| Prostate<br>Infiltration Cellular, Mononuclear Cell | (10)<br>6 (60%) | (0)        | (0)             | (0)       | (10)<br>6 (60%)    | (10)<br>3 (30%) |
| <b>HEMATOPOIETIC SYSTEM</b>                         |                 |            |                 |           |                    |                 |
| Lymph Node, Mandibular<br>Atrophy                   | (10)<br>1 (10%) | (10)       | (10)            | (10)      | (10)<br>2 (20%)    | (10)<br>7 (70%) |
| Hyperplasia, Lymphoid                               | 1 (10%)         | 1 (10%)    |                 |           |                    |                 |
| Lymph Node, Mesenteric<br>Atrophy                   | (10)<br>4 (40%) | (10)       | (10)            | (10)      | (10)<br>2 (20%)    | (10)<br>8 (80%) |
| Hyperplasia, Lymphoid                               |                 | 4 (40%)    | 3 (30%)         | 1 (10%)   |                    |                 |
| Spleen<br>Lymphoid Follicle, Hyperplasia            | (10)<br>2 (20%) | (10)       | (10)<br>1 (10%) | (10)      | (10)<br>1 (10%)    | (10)<br>1 (10%) |
| Thymus<br>Atrophy                                   | (10)            | (10)       | (10)            | (10)      | (10)               | (10)<br>6 (60%) |
| <b>INTEGUMENTARY SYSTEM</b>                         |                 |            |                 |           |                    |                 |
| None  |                 |            |                 |           |                    |                 |
| <b>MUSCULOSKELETAL SYSTEM</b>                       |                 |            |                 |           |                    |                 |
| None  |                 |            |                 |           |                    |                 |
| <b>NERVOUS SYSTEM</b>                               |                 |            |                 |           |                    |                 |
| Brain<br>Hydrocephalus                              | (10)            | (0)        | (0)             | (0)       | (10)<br>1 (10%)    | (10)            |
| <b>RESPIRATORY SYSTEM</b>                           |                 |            |                 |           |                    |                 |
| Lung  | (10)            | (0)        | (0)             | (0)       | (10)               | (10)            |
| Nose  | (10)            | (10)       | (10)            | (10)      | (10)               | (10)            |
| Foreign Body<br>Inflammation                        |                 |            | 1 (10%)         |           | 1 (10%)<br>1 (10%) | 1 (10%)         |
| Glands, Olfactory Epithelium, Hyperplasia           |                 |            |                 |           |                    | 3 (30%)         |
| Lamina Propria, Pigmentation, Histiocyte            |                 |            |                 |           |                    | 1 (10%)         |
| Nerve, Atrophy                                      |                 |            |                 | 5 (50%)   | 7 (70%)            | 5 (50%)         |
| Olfactory Epithelium, Atrophy                       |                 | 1 (10%)    |                 | 4 (40%)   | 4 (40%)            | 4 (40%)         |
| Olfactory Epithelium, Hyperplasia, Basal Cell       |                 |            |                 |           |                    | 3 (30%)         |
| Olfactory Epithelium, Metaplasia                    |                 |            |                 | 5 (50%)   | 5 (50%)            | 5 (50%)         |

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Green tea extract

CAS Number: GREENTEAEXTR

Date Report Requested: 04/15/2009

Time Report Requested: 08:55:24

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

Lab: BAT

| B6C3F1 MICE MALE                                | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|---|---------|------------|-----------|-----------|-----------|------------|
| Olfactory Epithelium, Necrosis                  |         |            | 1 (10%)   |           | 1 (10%)   | 3 (30%)    |
| Olfactory Epithelium, Pigmentation              |         |            |           |           |           | 1 (10%)    |
| Respiratory Epithelium, Hyaline Droplet         |         |            |           |           | 1 (10%)   | 3 (30%)    |
| Respiratory Epithelium, Hyperplasia             |         |            |           |           |           | 3 (30%)    |
| Respiratory Epithelium, Metaplasia,<br>Squamous |         |            |           |           |           | 1 (10%)    |
| Respiratory Epithelium, Necrosis                |         |            |           |           | 1 (10%)   | 1 (10%)    |
| <b>SPECIAL SENSES SYSTEM</b>                    |         |            |           |           |           |            |
| None  |         |            |           |           |           |            |
| <b>URINARY SYSTEM</b>                           |         |            |           |           |           |            |
| Kidney  | (10)    | (0)        | (0)       | (0)       | (10)      | (10)       |
| Nephropathy                                     | 5 (50%) |            |           |           | 4 (40%)   | 4 (40%)    |
| Urinary Bladder                                 | (10)    | (0)        | (0)       | (0)       | (10)      | (10)       |
| Infiltration Cellular, Lymphocyte               | 1 (10%) |            |           |           | 2 (20%)   |            |

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

Test Type: 90-DAY

Green tea extract

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Species/Strain: MICE/B6C3F1

Lab: BAT

| B6C3F1 MICE FEMALE                      | 0 mg/kg   | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|---|-----------|------------|-----------|-----------|-----------|------------|
| <b>Disposition Summary</b>              |           |            |           |           |           |            |
| 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         |
| <b>ALIMENTARY SYSTEM</b>                |           |            |           |           |           |            |
| Esophagus                               | (10)      | (0)        | (0)       | (0)       | (0)       | (10)       |
| Muscularis, Degeneration                | 1 (10%)   |            |           |           |           | 1 (10%)    |
| Intestine Large, Cecum                  | (10)      | (0)        | (0)       | (0)       | (0)       | (10)       |
| Peyer's Patch, Atrophy                  |           |            |           |           |           | 1 (10%)    |
| Intestine Small, Ileum                  | (10)      | (0)        | (0)       | (0)       | (0)       | (10)       |
| Peyer's Patch, Atrophy                  |           |            |           |           |           | 2 (20%)    |
| Liver                                   | (10)      | (10)       | (10)      | (10)      | (10)      | (10)       |
| Depletion Glycogen                      |           |            |           | 1 (10%)   | 4 (40%)   | 7 (70%)    |
| Fatty Change                            |           |            |           |           |           | 1 (10%)    |
| Infiltration Cellular, Mixed Cell       | 10 (100%) | 9 (90%)    | 10 (100%) | 10 (100%) | 10 (100%) | 3 (30%)    |
| Inflammation, Chronic                   |           |            |           |           |           | 3 (30%)    |
| Karyomegaly                             |           |            |           |           |           | 5 (50%)    |
| Mitosis                                 |           |            |           |           |           | 2 (20%)    |
| Pigmentation                            |           |            |           |           |           | 2 (20%)    |
| Centrilobular, Necrosis                 |           |            |           |           |           | 7 (70%)    |
| <b>CARDIOVASCULAR SYSTEM</b>            |           |            |           |           |           |            |
| Heart                                   | (10)      | (10)       | (10)      | (10)      | (10)      | (10)       |
| Myocardium, Hemorrhage                  |           |            |           |           |           | 1 (10%)    |
| Myocardium, Necrosis                    |           |            |           |           |           | 1 (10%)    |
| <b>ENDOCRINE SYSTEM</b>                 |           |            |           |           |           |            |
| Adrenal Cortex                          | (10)      | (0)        | (0)       | (0)       | (0)       | (10)       |
| Subcapsular, Hyperplasia                | 10 (100%) |            |           |           |           | 8 (80%)    |
| Thyroid Gland                           | (10)      | (0)        | (0)       | (0)       | (0)       | (10)       |
| Infiltration Cellular, Mononuclear Cell | 1 (10%)   |            |           |           |           |            |

| B6C3F1 MICE FEMALE             | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|--------------------------------|---------|------------|-----------|-----------|-----------|------------|
| <b>GENERAL BODY SYSTEM</b>     |         |            |           |           |           |            |
| None                           |         |            |           |           |           |            |
| <b>GENITAL SYSTEM</b>          |         |            |           |           |           |            |
| None                           |         |            |           |           |           |            |
| <b>HEMATOPOIETIC SYSTEM</b>    |         |            |           |           |           |            |
| Lymph Node, Mandibular Atrophy | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Hemorrhage                     |         | 1 (10%)    |           | 2 (20%)   | 2 (20%)   | 4 (40%)    |
| Hyperplasia, Lymphoid          |         | 1 (10%)    |           |           |           |            |
| Lymph Node, Mesenteric Atrophy | (10)    | (10)       | (10)      | (10)      | (10)      | (9)        |
| Hyperplasia, Lymphoid          | 2 (20%) |            |           |           | 2 (20%)   | 3 (33%)    |
| Spleen                         | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Atrophy, Lymphoid              |         |            |           | 1 (10%)   | 4 (40%)   | 4 (40%)    |
| Lymphoid Follicle, Hyperplasia |         |            |           |           | 1 (10%)   |            |
| Thymus                         | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Atrophy                        |         |            |           |           |           | 4 (40%)    |
| Necrosis                       |         |            |           |           |           | 2 (20%)    |
| <b>INTEGUMENTARY SYSTEM</b>    |         |            |           |           |           |            |
| None                           |         |            |           |           |           |            |
| <b>MUSCULOSKELETAL SYSTEM</b>  |         |            |           |           |           |            |
| None                           |         |            |           |           |           |            |
| <b>NERVOUS SYSTEM</b>          |         |            |           |           |           |            |
| None                           |         |            |           |           |           |            |
| <b>RESPIRATORY SYSTEM</b>      |         |            |           |           |           |            |
| Nose                           | (10)    | (10)       | (10)      | (10)      | (10)      | (10)       |
| Inflammation                   |         | 1 (10%)    | 1 (10%)   |           |           | 1 (10%)    |

| B6C3F1 MICE FEMALE                            | 0 mg/kg | 62.5 mg/kg | 125 mg/kg | 250 mg/kg | 500 mg/kg | 1000 mg/kg |
|---|---------|------------|-----------|-----------|-----------|------------|
| Glands, Olfactory Epithelium, Hyperplasia     |         |            |           |           |           | 1 (10%)    |
| Nasopharyngeal Duct, Degeneration             |         |            |           |           |           | 1 (10%)    |
| Nerve, Atrophy                                |         |            | 1 (10%)   | 1 (10%)   | 7 (70%)   | 5 (50%)    |
| Olfactory Epithelium, Atrophy                 |         |            | 1 (10%)   |           | 4 (40%)   | 4 (40%)    |
| Olfactory Epithelium, Hyperplasia, Basal Cell |         |            |           |           |           | 1 (10%)    |
| Olfactory Epithelium, Metaplasia              |         |            | 1 (10%)   | 1 (10%)   | 7 (70%)   | 6 (60%)    |
| Olfactory Epithelium, Necrosis                |         |            |           |           | 1 (10%)   | 4 (40%)    |
| Respiratory Epithelium, Hyaline Droplet       |         |            |           | 1 (10%)   | 4 (40%)   |            |
| Respiratory Epithelium, Hyperplasia           |         |            |           |           |           | 2 (20%)    |
| Respiratory Epithelium, Metaplasia, Squamous  |         |            |           |           |           | 1 (10%)    |
| Respiratory Epithelium, Necrosis              |         |            |           |           |           | 1 (10%)    |
| <b>SPECIAL SENSES SYSTEM</b>                  |         |            |           |           |           |            |
| None  |         |            |           |           |           |            |
| <b>URINARY SYSTEM</b>                         |         |            |           |           |           |            |
| Kidney  | (10)    | (0)        | (0)       | (0)       | (0)       | (10)       |
| Nephropathy                                   | 2 (20%) |            |           |           |           | 2 (20%)    |

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