

**Experiment Number:** 20725 - 02  
**Test Type:** 90-DAY  
**Route:** RESPIRATORY EXPOSURE WHOLE BODY  
**Species/Strain:** MICE/B6C3F1

**P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE(a)**  
2,3-Butanedione  
**CAS Number:** 431-03-8

**Date Report Requested:** 04/29/2016  
**Time Report Requested:** 14:39:21  
**First Dose M/F:** 07/28/08 / 07/28/08  
**Lab:** BNW

F1\_Rev.1\_M3

**NTP Study Number:** C20725  
**Lock Date:** 02/27/2009  
**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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First Dose M/F: 07/28/08 / 07/28/08

Lab: BNW

| B6C3F1 MICE MALE                  | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm | 50 ppm | 100 ppm |
|-----------------------------------|---------|----------|----------|--------|--------|---------|
| <b>Disposition Summary</b>        |         |          |          |        |        |         |
| 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      |
| <b>ALIMENTARY SYSTEM</b>          |         |          |          |        |        |         |
| Esophagus                         | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Gallbladder                       | (8)     | (0)      | (0)      | (0)    | (0)    | (8)     |
| 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)      | (0)      | (0)    | (0)    | (10)    |
| Inflammation, Chronic Active      | 2 (20%) |          |          |        |        | 4 (40%) |
| Pancreas                          | (10)    | (0)      | (0)      | (0)    | (0)    | (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)    |
| <b>CARDIOVASCULAR SYSTEM</b>      |         |          |          |        |        |         |
| Blood Vessel                      | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Heart                             | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| <b>ENDOCRINE SYSTEM</b>           |         |          |          |        |        |         |
| Adrenal Cortex                    | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Accessory Adrenal Cortical Nodule | 1 (10%) |          |          |        |        |         |
| Adrenal Medulla                   | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |

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

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| B6C3F1 MICE MALE   | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm | 50 ppm | 100 ppm |
|--------------------|---------|----------|----------|--------|--------|---------|
| Islets, Pancreatic | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Parathyroid Gland  | (3)     | (0)      | (0)      | (0)    | (0)    | (7)     |
| Pituitary Gland    | (10)    | (0)      | (0)      | (0)    | (0)    | (9)     |
| Thyroid Gland      | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |

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GENERAL BODY SYSTEM

None

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GENITAL SYSTEM

|                              |      |     |     |     |     |         |
|------------------------------|------|-----|-----|-----|-----|---------|
| Epididymis                   | (10) | (0) | (0) | (0) | (0) | (10)    |
| Preputial Gland              | (10) | (0) | (0) | (0) | (0) | (10)    |
| Inflammation, Chronic Active |      |     |     |     |     | 1 (10%) |
| Prostate                     | (10) | (0) | (0) | (0) | (0) | (10)    |
| Seminal Vesicle              | (10) | (0) | (0) | (0) | (0) | (10)    |
| Testes                       | (10) | (0) | (0) | (0) | (0) | (10)    |

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HEMATOPOIETIC SYSTEM

|                         |      |     |     |     |     |      |
|-------------------------|------|-----|-----|-----|-----|------|
| Bone Marrow             | (10) | (0) | (0) | (0) | (0) | (10) |
| Lymph Node, Bronchial   | (9)  | (0) | (0) | (0) | (0) | (9)  |
| Lymph Node, Mandibular  | (7)  | (0) | (0) | (0) | (0) | (7)  |
| Lymph Node, Mediastinal | (6)  | (0) | (0) | (0) | (0) | (3)  |
| 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

|      |      |     |     |     |     |      |
|------|------|-----|-----|-----|-----|------|
| Skin | (10) | (0) | (0) | (0) | (0) | (10) |
|------|------|-----|-----|-----|-----|------|

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

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Species/Strain: MICE/B6C3F1

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First Dose M/F: 07/28/08 / 07/28/08

Lab: BNW

| B6C3F1 MICE MALE                                      | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm  | 50 ppm    | 100 ppm   |
|---|---------|----------|----------|---------|-----------|-----------|
| <b>MUSCULOSKELETAL SYSTEM</b>                         |         |          |          |         |           |           |
| Bone  | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>NERVOUS SYSTEM</b>                                 |         |          |          |         |           |           |
| Brain   | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>RESPIRATORY SYSTEM</b>                             |         |          |          |         |           |           |
| Larynx  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Inflammation, Chronic Active Epithelium, Necrosis     | 1 (10%) | 1 (10%)  | 3 (30%)  | 3 (30%) | 8 (80%)   | 10 (100%) |
| Respiratory Epithelium, Hyperplasia                   |         |          | 2 (20%)  | 1 (10%) | 9 (90%)   | 8 (80%)   |
| Respiratory Epithelium, Hyperplasia, Atypical         |         |          |          | 2 (20%) | 8 (80%)   | 8 (80%)   |
| Respiratory Epithelium, Metaplasia, Atypical Squamous |         |          |          |         | 7 (70%)   | 10 (100%) |
| Respiratory Epithelium, Metaplasia, Squamous          |         |          |          | 1 (10%) | 3 (30%)   |           |
| Respiratory Epithelium, Regeneration                  |         |          |          |         | 5 (50%)   |           |
| Squamous Epithelium, Hyperplasia                      |         |          |          | 3 (30%) | 3 (30%)   | 5 (50%)   |
| Squamous Epithelium, Hyperplasia, Atypical            |         |          |          |         | 7 (70%)   | 5 (50%)   |
| Lung  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Bronchus, Infiltration Cellular, Polymorphonuclear    |         |          |          |         |           | 10 (100%) |
| Bronchus, Inflammation, Chronic                       | 1 (10%) |          |          |         | 7 (70%)   | 10 (100%) |
| Bronchus, Epithelium, Degeneration                    |         |          |          |         |           | 1 (10%)   |
| Bronchus, Epithelium, Hyperplasia                     |         |          |          |         |           | 1 (10%)   |
| Bronchus, Epithelium, Hyperplasia, Atypical           |         |          |          |         | 2 (20%)   | 9 (90%)   |
| Bronchus, Epithelium, Metaplasia, Atypical Squamous   |         |          |          |         |           | 10 (100%) |
| Bronchus, Epithelium, Regeneration                    |         |          |          |         | 1 (10%)   | 9 (90%)   |
| Nose  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Inflammation, Suppurative                             |         |          |          |         | 10 (100%) | 10 (100%) |
| Inflammation, Chronic                                 |         | 1 (10%)  |          |         |           |           |
| Olfactory Epithelium, Atrophy                         |         |          |          |         | 10 (100%) | 10 (100%) |

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

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| B6C3F1 MICE MALE                              | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm  | 50 ppm    | 100 ppm   |
|---|---------|----------|----------|---------|-----------|-----------|
| Olfactory Epithelium, Metaplasia, Respiratory |         |          |          |         | 6 (60%)   | 7 (70%)   |
| Respiratory Epithelium, Degeneration          |         |          |          | 1 (10%) |           |           |
| Respiratory Epithelium, Metaplasia, Squamous  |         |          |          | 1 (10%) | 10 (100%) | 10 (100%) |
| Respiratory Epithelium, Necrosis              |         |          |          | 8 (80%) | 10 (100%) | 10 (100%) |
| Respiratory Epithelium, Regeneration          |         |          |          |         | 10 (100%) | 10 (100%) |
| Septum, Perforation                           |         |          |          |         |           | 2 (20%)   |
| Turbinate, Atrophy                            |         |          |          |         | 10 (100%) | 10 (100%) |
| Turbinate, Necrosis                           |         |          |          |         | 3 (30%)   | 5 (50%)   |
| Trachea                                       | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Inflammation, Chronic Active                  |         |          |          |         |           | 7 (70%)   |
| Epithelium, Degeneration                      |         |          |          | 1 (10%) | 3 (30%)   | 8 (80%)   |
| Epithelium, Hyperplasia                       |         |          |          |         | 2 (20%)   | 9 (90%)   |
| Epithelium, Metaplasia, Atypical Squamous     |         |          |          |         |           | 10 (100%) |
| Epithelium, Regeneration                      |         |          |          |         | 7 (70%)   |           |
| <b>SPECIAL SENSES SYSTEM</b>                  |         |          |          |         |           |           |
| Eye   | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| Harderian Gland                               | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>URINARY SYSTEM</b>                         |         |          |          |         |           |           |
| Kidney  | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| Renal Tubule, Regeneration                    | 1 (10%) |          |          |         |           |           |
| Urinary Bladder                               | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |

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

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First Dose M/F: 07/28/08 / 07/28/08

Lab: BNW

| B6C3F1 MICE FEMALE               | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm   | 50 ppm | 100 ppm |
|----------------------------------|---------|----------|----------|----------|--------|---------|
| <b>Disposition Summary</b>       |         |          |          |          |        |         |
| 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      |
| <b>ALIMENTARY SYSTEM</b>         |         |          |          |          |        |         |
| Esophagus                        | (10)    | (0)      | (0)      | (0)      | (0)    | (10)    |
| Gallbladder                      | (9)     | (0)      | (0)      | (0)      | (0)    | (6)     |
| Inflammation, Suppurative        | 1 (11%) |          |          |          |        |         |
| 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)      | (1)      | (0)    | (10)    |
| Diverticulum                     |         |          |          | 1 (100%) |        |         |
| Liver                            | (10)    | (0)      | (0)      | (0)      | (0)    | (10)    |
| Inflammation, Chronic Active     | 5 (50%) |          |          |          |        | 8 (80%) |
| Pancreas                         | (10)    | (0)      | (0)      | (0)      | (0)    | (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)    |
| <b>CARDIOVASCULAR SYSTEM</b>     |         |          |          |          |        |         |
| Blood Vessel                     | (10)    | (0)      | (0)      | (0)      | (0)    | (10)    |
| Heart                            | (10)    | (0)      | (0)      | (0)      | (0)    | (10)    |
| <b>ENDOCRINE SYSTEM</b>          |         |          |          |          |        |         |
| Adrenal Cortex                   | (10)    | (0)      | (0)      | (0)      | (0)    | (10)    |

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

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Species/Strain: MICE/B6C3F1

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| B6C3F1 MICE FEMALE           | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm | 50 ppm | 100 ppm |
|------------------------------|---------|----------|----------|--------|--------|---------|
| Adrenal Medulla              | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Islets, Pancreatic           | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Parathyroid Gland            | (5)     | (0)      | (0)      | (0)    | (0)    | (7)     |
| Pituitary Gland              | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Thyroid Gland                | (10)    | (0)      | (0)      | (0)    | (0)    | (8)     |
| <b>GENERAL BODY SYSTEM</b>   |         |          |          |        |        |         |
| None                         |         |          |          |        |        |         |
| <b>GENITAL SYSTEM</b>        |         |          |          |        |        |         |
| Clitoral Gland               | (10)    | (0)      | (0)      | (0)    | (0)    | (6)     |
| Inflammation, Chronic Active |         |          |          |        |        | 2 (33%) |
| Ovary                        | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Uterus                       | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| <b>HEMATOPOIETIC SYSTEM</b>  |         |          |          |        |        |         |
| Bone Marrow                  | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Lymph Node, Bronchial        | (9)     | (0)      | (0)      | (0)    | (0)    | (9)     |
| Lymph Node, Mandibular       | (9)     | (0)      | (0)      | (0)    | (0)    | (9)     |
| Lymph Node, Mediastinal      | (3)     | (0)      | (0)      | (0)    | (0)    | (1)     |
| Lymph Node, Mesenteric       | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Spleen                       | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Thymus                       | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| <b>INTEGUMENTARY SYSTEM</b>  |         |          |          |        |        |         |
| Mammary Gland                | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |
| Skin                         | (10)    | (0)      | (0)      | (0)    | (0)    | (10)    |

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| B6C3F1 MICE FEMALE                                    | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm  | 50 ppm    | 100 ppm   |
|---|---------|----------|----------|---------|-----------|-----------|
| <b>MUSCULOSKELETAL SYSTEM</b>                         |         |          |          |         |           |           |
| Bone  | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>NERVOUS SYSTEM</b>                                 |         |          |          |         |           |           |
| Brain   | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>RESPIRATORY SYSTEM</b>                             |         |          |          |         |           |           |
| Larynx  | (10)    | (10)     | (10)     | (10)    | (9)       | (10)      |
| Inflammation, Chronic Active                          |         | 3 (30%)  | 1 (10%)  | 4 (40%) | 4 (44%)   | 10 (100%) |
| Epithelium, Necrosis                                  |         |          |          | 1 (10%) | 5 (56%)   | 9 (90%)   |
| Respiratory Epithelium, Hyperplasia                   |         |          |          | 4 (40%) | 8 (89%)   | 9 (90%)   |
| Respiratory Epithelium, Metaplasia, Atypical Squamous |         |          |          |         |           | 10 (100%) |
| Respiratory Epithelium, Metaplasia, Squamous          |         |          |          | 1 (10%) | 9 (100%)  |           |
| Respiratory Epithelium, Regeneration                  |         |          |          | 2 (20%) | 8 (89%)   |           |
| Squamous Epithelium, Hyperplasia                      |         |          |          | 2 (20%) | 4 (44%)   | 1 (10%)   |
| Squamous Epithelium, Hyperplasia, Atypical            |         |          |          | 2 (20%) | 3 (33%)   | 9 (90%)   |
| Lung  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Metaplasia, Osseous                                   |         |          |          | 1 (10%) |           |           |
| Bronchus, Infiltration Cellular, Polymorphonuclear    |         |          |          |         |           | 8 (80%)   |
| Bronchus, Inflammation, Chronic                       | 1 (10%) |          |          |         | 5 (50%)   | 8 (80%)   |
| Bronchus, Epithelium, Hyperplasia, Atypical           |         |          |          |         |           | 7 (70%)   |
| Bronchus, Epithelium, Metaplasia, Atypical Squamous   |         |          |          |         |           | 7 (70%)   |
| Bronchus, Epithelium, Regeneration                    |         |          |          |         | 6 (60%)   | 7 (70%)   |
| Nose  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Inflammation, Suppurative                             |         |          |          | 1 (10%) | 10 (100%) | 10 (100%) |
| Olfactory Epithelium, Accumulation, Hyaline Droplet   |         |          |          |         | 1 (10%)   | 1 (10%)   |
| Olfactory Epithelium, Atrophy                         |         |          |          |         | 10 (100%) | 10 (100%) |
| Olfactory Epithelium, Metaplasia, Respiratory         |         |          |          |         | 8 (80%)   | 9 (90%)   |

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

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 Lab: BNW

| B6C3F1 MICE FEMALE   | CONTROL | 6.25 ppm | 12.5 ppm | 25 ppm  | 50 ppm    | 100 ppm   |
|--|---------|----------|----------|---------|-----------|-----------|
| Olfactory Epithelium, Necrosis                                     |         |          |          | 1 (10%) |           |           |
| Respiratory Epithelium, Accumulation, Hyaline Droplet              |         |          |          |         |           | 2 (20%)   |
| Respiratory Epithelium, Degeneration                               |         |          |          | 2 (20%) |           |           |
| Respiratory Epithelium, Metaplasia, Squamous                       |         |          |          |         | 10 (100%) | 10 (100%) |
| Respiratory Epithelium, Necrosis                                   |         |          |          | 4 (40%) | 10 (100%) | 10 (100%) |
| Respiratory Epithelium, Regeneration                               |         |          |          |         | 9 (90%)   | 10 (100%) |
| Septum, Necrosis   |         |          |          |         |           | 1 (10%)   |
| Turbinate, Atrophy   |         |          |          |         | 10 (100%) | 10 (100%) |
| Turbinate, Necrosis  |         |          |          |         | 4 (40%)   | 8 (80%)   |
| Trachea  | (10)    | (10)     | (10)     | (10)    | (10)      | (10)      |
| Inflammation, Chronic Active Epithelium, Degeneration              |         |          |          |         |           | 7 (70%)   |
| Epithelium, Hyperplasia  |         |          |          |         | 3 (30%)   | 8 (80%)   |
| Epithelium, Metaplasia, Atypical Squamous Epithelium, Regeneration |         |          |          |         | 2 (20%)   | 9 (90%)   |
|  |         |          |          |         | 7 (70%)   | 10 (100%) |
| <b>SPECIAL SENSES SYSTEM</b>                                       |         |          |          |         |           |           |
| Eye  | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| Cornea, Epithelium, Cellular Alteration, Focal                     |         |          |          |         |           | 1 (10%)   |
| Harderian Gland  | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| <b>URINARY SYSTEM</b>  |         |          |          |         |           |           |
| Kidney   | (10)    | (0)      | (0)      | (0)     | (0)       | (10)      |
| Renal Tubule, Casts Protein  |         |          |          |         |           | 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