

**Experiment Number:** 97011-23  
**Test Type:** 26-WEEK  
**Route:** SKIN APPLICATION  
**Species/Strain:** Mouse/FVB/N

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS  
ABRIDGED) (a)**

**Test Compound:** Transgenic model evaluation (Melphalan)

**CAS Number:** 148-82-3

**Date Report Requested:** 10/20/2014

**Time Report Requested:** 04:54:09

**First Dose M/F:** NA / NA

**Lab:** MBA

**C Number:** C97011C  
**Lock Date:** 07/21/2000  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date:** NONE

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| <b>FVB/N Mouse MALE</b>                 | <b>VEHICLE CONTROL</b> | <b>4.0</b> | <b>MG/KG</b> |
|---|------------------------|------------|--------------|
| <b>Disposition Summary</b>              |                        |            |              |
| <b>Animals Initially In Study</b>       | <b>15</b>              |            | <b>15</b>    |
| <b>Early Deaths</b>                     |                        |            |              |
| <b>Moribund Sacrifice</b>               |                        |            | <b>1</b>     |
| <b>Natural Death</b>                    | <b>1</b>               |            | <b>4</b>     |
| <b>Survivors</b>                        |                        |            |              |
| <b>Terminal Sacrifice</b>               | <b>14</b>              |            | <b>10</b>    |
| <b>Animals Examined Microscopically</b> | <b>15</b>              |            | <b>15</b>    |

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**ALIMENTARY SYSTEM**

|                           |      |      |
|---------------------------|------|------|
| Intestine Large, Cecum    | (14) | (13) |
| Intestine Large, Colon    | (14) | (13) |
| Intestine Large, Rectum   | (14) | (13) |
| Intestine Small, Duodenum | (14) | (13) |
| Intestine Small, Ileum    | (14) | (12) |
| Intestine Small, Jejunum  | (14) | (12) |
| Liver                     | (15) | (15) |
| Pancreas                  | (0)  | (1)  |
| Stomach, Forestomach      | (14) | (15) |
| Stomach, Glandular        | (14) | (15) |
| Tooth                     | (0)  | (7)  |

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**CARDIOVASCULAR SYSTEM**

|       |      |      |
|-------|------|------|
| Heart | (15) | (15) |
|-------|------|------|

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**ENDOCRINE SYSTEM**

|                 |      |      |
|-----------------|------|------|
| Adrenal Cortex  | (14) | (15) |
| Adrenal Medulla | (14) | (15) |
| Pituitary Gland | (13) | (13) |

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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| FVB/N Mouse MALE                       | VEHICLE CONTROL | 4.0     | MG/KG |
|--|-----------------|---------|-------|
| Thyroid Gland                          | (14)            | (15)    |       |
| GENERAL BODY SYSTEM                    |                 |         |       |
| None                                   |                 |         |       |
| GENITAL SYSTEM                         |                 |         |       |
| Epididymis                             | (15)            | (15)    |       |
| Penis                                  | (0)             | (1)     |       |
| Testes                                 | (15)            | (15)    |       |
| HEMATOPOIETIC SYSTEM                   |                 |         |       |
| Bone Marrow                            | (14)            | (14)    |       |
| Lymph Node                             | (0)             | (1)     |       |
| Lymph Node, Mandibular                 | (15)            | (15)    |       |
| Lymph Node, Mediastinal                | (13)            | (11)    |       |
| Lymph Node, Mesenteric                 | (15)            | (13)    |       |
| Spleen                                 | (14)            | (15)    |       |
| Thymus                                 | (14)            | (14)    |       |
| INTEGUMENTARY SYSTEM                   |                 |         |       |
| Skin                                   | (15)            | (15)    |       |
| MUSCULOSKELETAL SYSTEM                 |                 |         |       |
| None                                   |                 |         |       |
| NERVOUS SYSTEM                         |                 |         |       |
| None                                   |                 |         |       |
| RESPIRATORY SYSTEM                     |                 |         |       |
| Lung                                   | (15)            | (15)    |       |
| Alveolar/Bronchiolar Adenoma           |                 | 4 (27%) |       |
| Alveolar/Bronchiolar Adenoma, Multiple |                 | 1 (7%)  |       |

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**First Dose M/F:** NA / NA

**Lab:** MBA

| <b>FVB/N Mouse MALE</b>        | <b>VEHICLE CONTROL</b> | <b>4.0 MG/KG</b> |
|--------------------------------|------------------------|------------------|
| Alveolar/Bronchiolar Carcinoma |                        | 1 (7%)           |
| <b>SPECIAL SENSES SYSTEM</b>   |                        |                  |
| Eye                            | (0)                    | (1)              |
| <b>URINARY SYSTEM</b>          |                        |                  |
| Kidney                         | (14)                   | (15)             |
| <b>SYSTEMIC LESIONS</b>        |                        |                  |
| Multiple Organ                 | *(15)                  | *(15)            |
| Lymphoma Malignant             |                        | 5 (33%)          |

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**Lab:** MBA

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| <b>FVB/N Mouse MALE</b>  | <b>VEHICLE CONTROL</b> | <b>4.0</b> | <b>MG/KG</b> |
|--|------------------------|------------|--------------|
| <b>Tumor Summary for MALE</b>  |                        |            |              |
| <b>Total Animals with Primary Neoplasms (b)</b>                          |                        |            | <b>9</b>     |
| <b>Total Primary Neoplasms</b>   |                        |            | <b>11</b>    |
| <b>Total Animals with Benign Neoplasms</b>                               |                        |            | <b>5</b>     |
| <b>Total Benign Neoplasms</b>  |                        |            | <b>5</b>     |
| <b>Total Animals with Malignant Neoplasms</b>                            |                        |            | <b>6</b>     |
| <b>Total Malignant Neoplasms</b>   |                        |            | <b>6</b>     |
| <b>Total Animals with Metastatic Neoplasms</b>                           |                        |            |              |
| <b>Total Metastatic Neoplasms</b>  |                        |            |              |
| <b>Total Animals with Malignant Neoplasms<br/>Uncertain Primary Site</b> |                        |            |              |
| <b>Total Animals with Neoplasms Uncertain -<br/>Benign or Malignant</b>  |                        |            |              |
| <b>Total Uncertain Neoplasms</b>   |                        |            |              |

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

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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 First Dose M/F: NA / NA  
 Lab: MBA

| FVB/N Mouse FEMALE               | VEHICLE CONTROL | 4.0 | MG/KG |
|----------------------------------|-----------------|-----|-------|
| <b>Disposition Summary</b>       |                 |     |       |
| Animals Initially In Study       | 15              |     | 15    |
| Early Deaths                     |                 |     |       |
| Survivors                        |                 |     |       |
| Terminal Sacrifice               | 15              |     | 15    |
| Animals Examined Microscopically | 15              |     | 15    |
| <b>ALIMENTARY SYSTEM</b>         |                 |     |       |
| Intestine Large, Cecum           | (15)            |     | (15)  |
| Intestine Large, Colon           | (15)            |     | (15)  |
| Intestine Large, Rectum          | (15)            |     | (15)  |
| Intestine Small, Duodenum        | (15)            |     | (15)  |
| Intestine Small, Ileum           | (15)            |     | (15)  |
| Intestine Small, Jejunum         | (15)            |     | (15)  |
| Liver                            | (15)            |     | (15)  |
| Stomach, Forestomach             | (15)            |     | (15)  |
| Stomach, Glandular               | (15)            |     | (15)  |
| <b>CARDIOVASCULAR SYSTEM</b>     |                 |     |       |
| Heart                            | (15)            |     | (15)  |
| <b>ENDOCRINE SYSTEM</b>          |                 |     |       |
| Adrenal Cortex                   | (15)            |     | (14)  |
| Adrenal Medulla                  | (15)            |     | (15)  |
| Pituitary Gland                  | (15)            |     | (15)  |
| Thyroid Gland                    | (15)            |     | (15)  |
| <b>GENERAL BODY SYSTEM</b>       |                 |     |       |
| None                             |                 |     |       |
| <b>GENITAL SYSTEM</b>            |                 |     |       |

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

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| FVB/N Mouse FEMALE                            | VEHICLE CONTROL | 4.0 | MG/KG   |
|---|-----------------|-----|---------|
| Ovary   | (15)            |     | (15)    |
| Uterus  | (15)            |     | (15)    |
| HEMATOPOIETIC SYSTEM                          |                 |     |         |
| Bone Marrow                                   | (15)            |     | (15)    |
| Lymph Node, Mandibular                        | (15)            |     | (15)    |
| Lymph Node, Mediastinal                       | (15)            |     | (15)    |
| Lymph Node, Mesenteric                        | (15)            |     | (15)    |
| Spleen  | (15)            |     | (15)    |
| Thymus  | (15)            |     | (15)    |
| INTEGUMENTARY SYSTEM                          |                 |     |         |
| Mammary Gland                                 | (15)            |     | (15)    |
| Skin  | (15)            |     | (15)    |
| MUSCULOSKELETAL SYSTEM                        |                 |     |         |
| None  |                 |     |         |
| NERVOUS SYSTEM                                |                 |     |         |
| None  |                 |     |         |
| RESPIRATORY SYSTEM                            |                 |     |         |
| Lung  | (15)            |     | (15)    |
| Alveolar/Bronchiolar Adenoma                  | 1 (7%)          |     | 2 (13%) |
| Alveolar/Bronchiolar Adenoma, Multiple        |                 |     | 2 (13%) |
| Carcinoma, Metastatic, Uncertain Primary Site |                 |     | 1 (7%)  |
| SPECIAL SENSES SYSTEM                         |                 |     |         |
| None  |                 |     |         |
| URINARY SYSTEM                                |                 |     |         |

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

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\* Number of animals with any tissue examined microscopically

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**Lab:** MBA

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| <b>FVB/N Mouse FEMALE</b> | <b>VEHICLE CONTROL</b> | <b>4.0</b> | <b>MG/KG</b> |
|---------------------------|------------------------|------------|--------------|
| Kidney                    | (15)                   | (15)       |              |

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

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\* Number of animals with any tissue examined microscopically



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| <b>FVB/N Mouse FEMALE</b>  | <b>VEHICLE CONTROL</b> | <b>4.0</b> | <b>MG/KG</b> |
|--|------------------------|------------|--------------|
| <b>Tumor Summary for FEMALE</b>  |                        |            |              |
| <b>Total Animals with Primary Neoplasms (b)</b>                          | <b>1</b>               |            | <b>4</b>     |
| <b>Total Primary Neoplasms</b>   | <b>1</b>               |            | <b>4</b>     |
| <b>Total Animals with Benign Neoplasms</b>                               | <b>1</b>               |            | <b>4</b>     |
| <b>Total Benign Neoplasms</b>  | <b>1</b>               |            | <b>4</b>     |
| <b>Total Animals with Malignant Neoplasms</b>                            |                        |            |              |
| <b>Total Malignant Neoplasms</b>   |                        |            |              |
| <b>Total Animals with Metastatic Neoplasms</b>                           |                        |            | <b>1</b>     |
| <b>Total Metastatic Neoplasms</b>  |                        |            | <b>1</b>     |
| <b>Total Animals with Malignant Neoplasms<br/>Uncertain Primary Site</b> |                        |            | <b>1</b>     |
| <b>Total Animals with Neoplasms Uncertain -<br/>Benign or Malignant</b>  |                        |            |              |
| <b>Total Uncertain Neoplasms</b>   |                        |            |              |

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

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically