

**Experiment Number:** 88073-04  
**Test Type:** 26-WEEK  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

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

**Test Compound:** 2',3'-Dideoxycytidine

**CAS Number:** 7481-89-2

**Date Report Requested:** 10/18/2014

**Time Report Requested:** 15:29:15

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

**Lab:** SRI

|                             |            |
|-----------------------------|------------|
| <b>C Number:</b>            | C88073C    |
| <b>Lock Date:</b>           | 07/25/1995 |
| <b>Cage Range:</b>          | All        |
| <b>Date Range:</b>          | All        |
| <b>Reasons For Removal:</b> | All        |
| <b>Removal Date Range:</b>  | All        |
| <b>Treatment Groups:</b>    | All        |
| <b>Study Gender:</b>        | Both       |
| <b>PWG Approval Date</b>    | NONE       |

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| B6C3F1 Mouse MALE                 | VEHICLE | 500 MG/KG/DY | 1000 MG/KG/DY | 1000 MG/KG/DY |
|-----------------------------------|---------|--------------|---------------|---------------|
| <b>Disposition Summary</b>        |         |              |               |               |
| Animals Initially In Study        | 50      | 50           | 50            | 50            |
| Early Deaths                      |         |              |               |               |
| Moribund Sacrifice                |         | 1            |               |               |
| Survivors                         |         |              |               |               |
| Terminal Sacrifice                | 50      | 49           | 50            | 50            |
| Animals Examined Microscopically  | 50      | 50           | 50            | 50            |
| <b>ALIMENTARY SYSTEM</b>          |         |              |               |               |
| Liver                             | (50)    | (50)         | (50)          | (50)          |
| Basophilic Focus                  |         |              | 1 (2%)        | 1 (2%)        |
| Inflammation, Chronic Active      | 4 (8%)  | 1 (2%)       | 2 (4%)        | 2 (4%)        |
| Mixed Cell Focus                  |         |              |               | 1 (2%)        |
| Necrosis, Focal                   | 9 (18%) | 3 (6%)       | 4 (8%)        | 8 (16%)       |
| <b>CARDIOVASCULAR SYSTEM</b>      |         |              |               |               |
| None                              |         |              |               |               |
| <b>ENDOCRINE SYSTEM</b>           |         |              |               |               |
| Adrenal Cortex                    | (49)    | (50)         | (49)          | (49)          |
| Accessory Adrenal Cortical Nodule | 1 (2%)  | 1 (2%)       | 1 (2%)        | 2 (4%)        |
| Hypertrophy, Focal                | 3 (6%)  |              |               |               |
| Adrenal Medulla                   | (49)    | (50)         | (49)          | (49)          |
| <b>GENERAL BODY SYSTEM</b>        |         |              |               |               |
| None                              |         |              |               |               |
| <b>GENITAL SYSTEM</b>             |         |              |               |               |
| None                              |         |              |               |               |
| <b>HEMATOPOIETIC SYSTEM</b>       |         |              |               |               |
| Bone Marrow                       | (50)    | (50)         | (50)          | (50)          |
| Hyperplasia                       |         |              | 2 (4%)        |               |

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

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| B6C3F1 Mouse MALE                | VEHICLE | 500 MG/KG/DY   | 1000 MG/KG/DY | 1000 MG/KG/DY |
|----------------------------------|---------|----------------|---------------|---------------|
| Lymph Node                       | (0)     | (0)            | (1)           | (0)           |
| Lymph Node, Mesenteric Atrophy   | (49)    | (50)<br>1 (2%) | (50)          | (50)          |
| Hematopoietic Cell Proliferation |         |                | 1 (2%)        |               |
| Spleen                           | (50)    | (50)           | (50)          | (50)          |
| Hematopoietic Cell Proliferation |         | 2 (4%)         | 4 (8%)        | 9 (18%)       |
| Thymus                           | (49)    | (50)           | (49)          | (50)          |
| Atrophy                          |         | 2 (4%)         | 8 (16%)       |               |
| Hyperplasia                      |         | 3 (6%)         | 4 (8%)        | 3 (6%)        |
| <b>INTEGUMENTARY SYSTEM</b>      |         |                |               |               |
| Skin                             | (0)     | (0)            | (0)           | (1)           |
| <b>MUSCULOSKELETAL SYSTEM</b>    |         |                |               |               |
| None                             |         |                |               |               |
| <b>NERVOUS SYSTEM</b>            |         |                |               |               |
| None                             |         |                |               |               |
| <b>RESPIRATORY SYSTEM</b>        |         |                |               |               |
| Lung                             | (50)    | (50)           | (50)          | (50)          |
| Alveolar Epith, Hyperplasia      |         |                |               | 1 (2%)        |
| Hemorrhage                       | 7 (14%) |                | 2 (4%)        | 1 (2%)        |
| Metaplasia, Osseous              |         |                | 1 (2%)        |               |
| <b>SPECIAL SENSES SYSTEM</b>     |         |                |               |               |
| None                             |         |                |               |               |
| <b>URINARY SYSTEM</b>            |         |                |               |               |
| Kidney                           | (0)     | (0)            | (1)           | (0)           |

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

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

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 Lab: SRI

| B6C3F1 Mouse FEMALE               | VEHICLE | 500 MG/KG/DY | 1000 MG/KG/DY | 1000 MG/KG/DY |
|-----------------------------------|---------|--------------|---------------|---------------|
| <b>Disposition Summary</b>        |         |              |               |               |
| Animals Initially In Study        | 50      | 50           | 50            | 50            |
| Early Deaths                      |         |              |               |               |
| Moribund Sacrifice                |         |              | 3             | 4             |
| Natural Death                     |         |              |               | 1             |
| Survivors                         |         |              |               |               |
| Moribund Sacrifice                |         |              |               | 1             |
| Terminal Sacrifice                | 50      | 50           | 47            | 44            |
| Animals Examined Microscopically  | 50      | 50           | 50            | 50            |
| <b>ALIMENTARY SYSTEM</b>          |         |              |               |               |
| Liver                             | (50)    | (50)         | (50)          | (50)          |
| Inflammation, Chronic Active      | 2 (4%)  |              |               |               |
| Mixed Cell Focus                  |         |              | 1 (2%)        |               |
| Necrosis, Focal                   | 1 (2%)  | 1 (2%)       |               | 1 (2%)        |
| Mesentery                         | (0)     | (0)          | (0)           | (1)           |
| Fat, Necrosis                     |         |              |               | 1 (100%)      |
| Pancreas                          | (0)     | (0)          | (0)           | (1)           |
| <b>CARDIOVASCULAR SYSTEM</b>      |         |              |               |               |
| None                              |         |              |               |               |
| <b>ENDOCRINE SYSTEM</b>           |         |              |               |               |
| Adrenal Cortex                    | (49)    | (50)         | (50)          | (50)          |
| Accessory Adrenal Cortical Nodule | 2 (4%)  | 2 (4%)       | 2 (4%)        | 2 (4%)        |
| Hyperplasia, Diffuse              |         |              |               | 1 (2%)        |
| Hyperplasia, Focal                |         |              | 1 (2%)        |               |
| Adrenal Medulla                   | (48)    | (50)         | (50)          | (50)          |
| <b>GENERAL BODY SYSTEM</b>        |         |              |               |               |
| None                              |         |              |               |               |

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Test Compound: 2',3'-Dideoxycytidine

CAS Number: 7481-89-2

Date Report Requested: 10/18/2014

Time Report Requested: 15:29:16

First Dose M/F: NA / NA

Lab: SRI

| B6C3F1 Mouse FEMALE                         | VEHICLE  | 500 MG/KG/DY | 1000 MG/KG/DY | 1000 MG/KG/DY |
|---|----------|--------------|---------------|---------------|
| <b>GENITAL SYSTEM</b>                       |          |              |               |               |
| Ovary                                       | (50)     | (50)         | (50)          | (50)          |
| Amyloid Deposition                          |          |              | 1 (2%)        |               |
| Cyst  |          | 3 (6%)       | 1 (2%)        | 2 (4%)        |
| Uterus                                      | (7)      | (7)          | (6)           | (1)           |
| Hyperplasia, Cystic                         | 7 (100%) | 7 (100%)     | 4 (67%)       |               |
| <b>HEMATOPOIETIC SYSTEM</b>                 |          |              |               |               |
| Bone Marrow                                 | (50)     | (50)         | (50)          | (50)          |
| Hyperplasia                                 |          | 1 (2%)       |               |               |
| Lymph Node                                  | (1)      | (0)          | (3)           | (2)           |
| Inguinal, Infiltration Cellular, Histiocyte | 1 (100%) |              |               |               |
| Lymph Node, Mandibular                      | (0)      | (0)          | (2)           | (4)           |
| Lymph Node, Mesenteric                      | (50)     | (50)         | (50)          | (49)          |
| Spleen                                      | (50)     | (50)         | (50)          | (50)          |
| Hematopoietic Cell Proliferation            | 12 (24%) | 9 (18%)      | 18 (36%)      | 3 (6%)        |
| Pigmentation                                |          |              | 1 (2%)        |               |
| Thymus                                      | (50)     | (50)         | (50)          | (49)          |
| Atrophy                                     |          | 6 (12%)      | 10 (20%)      | 1 (2%)        |
| Hyperplasia                                 |          |              | 1 (2%)        |               |
| <b>INTEGUMENTARY SYSTEM</b>                 |          |              |               |               |
| Skin  | (0)      | (2)          | (3)           | (2)           |
| Epidermis, Hyperplasia                      |          |              | 2 (67%)       | 2 (100%)      |
| Inflammation, Chronic Active                |          |              | 1 (33%)       |               |
| <b>MUSCULOSKELETAL SYSTEM</b>               |          |              |               |               |
| None  |          |              |               |               |
| <b>NERVOUS SYSTEM</b>                       |          |              |               |               |
| Brain                                       | (0)      | (0)          | (0)           | (1)           |
| Hemorrhage                                  |          |              |               | 1 (100%)      |

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

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| <b>B6C3F1 Mouse FEMALE</b>   | <b>VEHICLE</b> | <b>500</b> | <b>MG/KG/DY</b> | <b>1000</b> | <b>MG/KG/DY</b> | <b>1000</b> | <b>MG/KG/DY</b> |
|------------------------------|----------------|------------|-----------------|-------------|-----------------|-------------|-----------------|
| <b>RESPIRATORY SYSTEM</b>    |                |            |                 |             |                 |             |                 |
| Lung                         | (50)           | (50)       |                 | (50)        |                 | (50)        |                 |
| Hemorrhage                   | 3 (6%)         |            |                 |             |                 | 1 (2%)      |                 |
| Inflammation, Chronic Active | 1 (2%)         |            |                 |             |                 |             |                 |
| <b>SPECIAL SENSES SYSTEM</b> |                |            |                 |             |                 |             |                 |
| None                         |                |            |                 |             |                 |             |                 |
| <b>URINARY SYSTEM</b>        |                |            |                 |             |                 |             |                 |
| Kidney                       | (0)            | (0)        |                 | (2)         |                 | (4)         |                 |

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