

# NTP Historical Controls Report

All Routes And Vehicles

MICE

May 2009

# REPORT DESCRIPTION

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This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

**Male**

M1  
M2  
M3  
M4  
M5

**Female**

F1  
F2  
F3  
F4  
F5

the data would be shown as:

| <b>Male</b> |    |    | <b>Female</b> |    |    |
|-------------|----|----|---------------|----|----|
| M1          | M2 | M3 | F1            | F2 | F3 |
| M4          | M5 |    | F4            | F5 |    |

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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 Report Date:04/29/2009

**Study Summary**

| Laboratory Name              | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical   |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--|
| <b>Male</b>                  |              |                  |                         |                                      |                                       |                                 |  |
| Southern Research Institute  | 059902408    | 12/16/02         | 729                     | 50 (1)                               | 36(687)                               | 53.8                            | Androstenedione  |
| Southern Research Institute  | 059903706    | 06/30/03         | 729                     | 50 (1)                               | 40(701)                               | 53.9                            | alpha/beta Thujone mixture                             |
| Battelle Columbus Laboratory | 059902806    | 10/03/02         | 728                     | 50 (1)                               | 37(682)                               | 53.5                            | bis(2-Chloroethoxy)methane                             |
| Battelle Northwest           | 052001106    | 07/21/03         | 729                     | 50 (5)                               | 37(689)                               | 53.4                            | 1-Bromopropane   |
| Southern Research Institute  | 059902704    | 07/29/02         | 729                     | 50 (1)                               | 46(715)                               | 50.0                            | Chromium picolinate monohydrate                        |
| Battelle Columbus Laboratory | 050517406    | N/A              | N/A                     | 0 (0)                                | 0(0)                                  | N/A                             | Cresols  |
| Battelle Northwest           | 059601106    | 06/11/01         | 729                     | 50 (5)                               | 38(709)                               | 53.9                            | Cumene   |
| Battelle Columbus Laboratory | 059700308    | 06/25/02         | 730                     | 50 (1)                               | 34(702)                               | 54.2                            | 1,2-Dibromo-2,4-dicyanobutane                          |
| Battelle Northwest           | 059901706    | 08/18/03         | 729                     | 50 (5)                               | 31(686)                               | 53.8                            | Diethylamine   |
| Southern Research Institute  | 059302008    | 05/08/00         | 729                     | 50 (1)                               | 39(710)                               | 52.6                            | Diisopropylcarbodiimide                                |
| Battelle Columbus Laboratory | 058812307    | 10/04/01         | 728                     | 50 (1)                               | 39(698)                               | 52.9                            | Formamide  |
| Battelle Columbus Laboratory | 052000506    | 02/10/04         | 730                     | 50 (1)                               | 32(691)                               | 51.1                            | Ginseng  |
| Southern Research Institute  | 059900706    | 05/12/03         | 729                     | 50 (1)                               | 43(715)                               | 48.3                            | Goldenseal root powder                                 |
| Battelle Columbus Laboratory | 059501106    | 08/09/01         | 728                     | 50 (1)                               | 40(702)                               | 52.3                            | 5-(Hydroxymethyl)-2-furfural                           |
| Battelle Columbus Laboratory | 058810504    | 05/09/02         | 728                     | 50 (1)                               | 39(688)                               | 56.7                            | Isoeugenol   |
| Battelle Columbus Laboratory | 052000706    | 08/24/04         | 730                     | 50 (1)                               | 34(689)                               | 56.4                            | Kava kava extract                                      |
| Battelle Northwest           | 059700602    | 06/05/00         | 729                     | 50 (5)                               | 40(709)                               | 53.2                            | Methyl isobutyl ketone                                 |
| Southern Research Institute  | 059100508    | 07/10/00         | 729                     | 50 (1)                               | 35(693)                               | 53.6                            | Methylene blue trihydrate                              |
| Southern Research Institute  | 059201306    | 02/03/00         | 729                     | 50 (1)                               | 45(717)                               | 46.1                            | 4-Methylimidazole                                      |
| Battelle Northwest           | 058800604    | 07/30/01         | 729                     | 50 (5)                               | 35(698)                               | 54.9                            | alpha-Methylstyrene                                    |
| Southern Research Institute  | 052000804    | 03/25/03         | 729                     | 50 (1)                               | 45(712)                               | 49.8                            | Milk thistle extract                                   |
| Battelle Columbus Laboratory | 059902304    | 04/11/02         | 728                     | 50 (1)                               | 34(692)                               | 56.2                            | beta-Myrcene   |
| Battelle Northwest           | 059700806    | 09/17/01         | 729                     | 50 (5)                               | 37(694)                               | 53.5                            | Propargyl alcohol                                      |
| Battelle Columbus Laboratory | 059902006    | 04/15/03         | 730                     | 50 (1)                               | 38(691)                               | 56.6                            | Pulegone   |
| Southern Research Institute  | 052011406    | 09/04/02         | 729                     | 50 (1)                               | 33(700)                               | 55.6                            | Sodium dichromate dihydrate (VI)                       |
| Battelle Columbus Laboratory | 058814807    | 02/04/03         | 728                     | 50 (1)                               | 35(702)                               | 52.7                            | 3,3',4,4'-Tetrachloroazobenzene                        |
| Battelle Northwest           | 059302506    | 06/23/03         | 729                     | 50 (5)                               | 36(695)                               | 52.9                            | Tetralin   |
| Southern Research Institute  | 059601906    | 10/10/01         | 729                     | 50 (1)                               | 38(696)                               | 54.1                            | Water disinfection byproducts (Bromochloroacetic acid) |
| Southern Research Institute  | 059601706    | 02/23/00         | 729                     | 49 (1)                               | 31(685)                               | 52.5                            | Water disinfection byproducts (Dibromoacetic acid)     |
| Southern Research Institute  | 059601506    | 08/22/01         | 729                     | 50 (1)                               | 40(697)                               | 54.0                            | Water disinfection byproducts (Dibromoacetonitrile)    |

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 4  
 Report Date:04/29/2009

| Laboratory Name              | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical   |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--|
| Female                       |              |                  |                         |                                      |                                       |                                 |  |
| Southern Research Institute  | 059902408    | 12/16/02         | 733                     | 50 (5)                               | 35(690)                               | 65.3                            | Androstenedione  |
| Southern Research Institute  | 059903706    | 06/30/03         | 731                     | 50 (5)                               | 37(668)                               | 64.7                            | alpha/beta Thujone mixture                             |
| Battelle Columbus Laboratory | 059902806    | 10/02/02         | 727                     | 50 (1)                               | 31(692)                               | 60.8                            | bis(2-Chloroethoxy)methane                             |
| Battelle Northwest           | 052001106    | 07/21/03         | 731                     | 50 (5)                               | 36(698)                               | 61.2                            | 1-Bromopropane   |
| Southern Research Institute  | 059902704    | 07/29/02         | 732                     | 50 (5)                               | 45(698)                               | 50.3                            | Chromium picolinate monohydrate                        |
| Battelle Columbus Laboratory | 050517406    | 08/20/02         | 728                     | 50 (5)                               | 41(696)                               | 51.8                            | Cresols  |
| Battelle Northwest           | 059601106    | 06/11/01         | 731                     | 50 (5)                               | 37(685)                               | 60.7                            | Cumene   |
| Battelle Columbus Laboratory | 059700308    | 06/24/02         | 729                     | 50 (1)                               | 33(693)                               | 60.9                            | 1,2-Dibromo-2,4-dicyanobutane                          |
| Battelle Northwest           | 059901706    | 08/18/03         | 731                     | 50 (5)                               | 32(684)                               | 60.7                            | Diethylamine   |
| Southern Research Institute  | 059302008    | 05/08/00         | 732                     | 50 (1)                               | 33(674)                               | 65.7                            | Diisopropylcarbodiimide                                |
| Battelle Columbus Laboratory | 058812307    | 10/03/01         | 727                     | 50 (5)                               | 38(692)                               | 64.7                            | Formamide  |
| Battelle Columbus Laboratory | 052000506    | 02/09/04         | 729                     | 50 (5)                               | 38(711)                               | 63.9                            | Ginseng  |
| Southern Research Institute  | 059900706    | 05/12/03         | 732                     | 50 (5)                               | 44(718)                               | 51.9                            | Goldenseal root powder                                 |
| Battelle Columbus Laboratory | 059501106    | 08/08/01         | 727                     | 50 (5)                               | 39(694)                               | 64.4                            | 5-(Hydroxymethyl)-2-furfural                           |
| Battelle Columbus Laboratory | 058810504    | 05/08/02         | 727                     | 49 (5)                               | 34(679)                               | 65.0                            | Isoeugenol   |
| Battelle Columbus Laboratory | 052000706    | 08/23/04         | 729                     | 50 (5)                               | 38(695)                               | 66.2                            | Kava kava extract                                      |
| Battelle Northwest           | 059700602    | 06/05/00         | 731                     | 50 (5)                               | 35(695)                               | 60.3                            | Methyl isobutyl ketone                                 |
| Southern Research Institute  | 059100508    | 07/10/00         | 732                     | 50 (5)                               | 29(695)                               | 63.5                            | Methylene blue trihydrate                              |
| Southern Research Institute  | 059201306    | 02/03/00         | 734                     | 50 (5)                               | 42(706)                               | 45.6                            | 4-Methylimidazole                                      |
| Battelle Northwest           | 058800604    | 07/30/01         | 731                     | 50 (5)                               | 39(701)                               | 58.6                            | alpha-Methylstyrene                                    |
| Southern Research Institute  | 052000804    | 03/25/03         | 732                     | 50 (5)                               | 40(714)                               | 51.0                            | Milk thistle extract                                   |
| Battelle Columbus Laboratory | 059902304    | 04/10/02         | 727                     | 50 (5)                               | 39(705)                               | 64.1                            | beta-Myrcene   |
| Battelle Northwest           | 059700806    | 09/17/01         | 731                     | 50 (5)                               | 39(699)                               | 58.3                            | Propargyl alcohol                                      |
| Battelle Columbus Laboratory | 059902006    | 04/14/03         | 729                     | 49 (5)                               | 35(705)                               | 64.9                            | Pulegone   |
| Southern Research Institute  | 052011406    | 09/04/02         | 735                     | 50 (5)                               | 35(701)                               | 64.3                            | Sodium dichromate dihydrate (VI)                       |
| Battelle Columbus Laboratory | 058814807    | 02/03/03         | 731                     | 50 (5)                               | 35(675)                               | 63.2                            | 3,3',4,4'-Tetrachloroazobenzene                        |
| Battelle Northwest           | 059302506    | 06/23/03         | 731                     | 50 (5)                               | 31(663)                               | 62.1                            | Tetralin   |
| Southern Research Institute  | 059601906    | 10/10/01         | 734                     | 50 (5)                               | 36(693)                               | 63.0                            | Water disinfection byproducts (Bromochloroacetic acid) |
| Southern Research Institute  | 059601706    | 02/23/00         | 734                     | 50 (5)                               | 38(708)                               | 64.3                            | Water disinfection byproducts (Dibromoacetic acid)     |
| Southern Research Institute  | 059601506    | 08/22/01         | 731                     | 50 (5)                               | 35(705)                               | 60.9                            | Water disinfection byproducts (Dibromoacetonitrile)    |

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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 5  
 Report Date:04/29/2009

|                                    |       | Male               |             |             |       | Female            |             |             |  |
|------------------------------------|-------|--------------------|-------------|-------------|-------|-------------------|-------------|-------------|--|
| <b>#All Organs:</b>                |       |                    |             |             |       |                   |             |             |  |
| <b>Benign Tumors</b>               |       |                    |             |             |       |                   |             |             |  |
|                                    |       | 38/50 (76%)        | 32/50 (64%) | 41/50 (82%) |       | 27/50 (54%)       | 22/50 (44%) | 27/50 (54%) |  |
|                                    |       | 36/50 (72%)        | 28/50 (56%) |             |       | 22/50 (44%)       | 16/50 (32%) | 16/50 (32%) |  |
|                                    |       | 43/50 (86%)        | 40/50 (80%) | 33/50 (66%) |       | 34/50 (68%)       | 39/50 (78%) | 25/50 (50%) |  |
|                                    |       | 29/50 (58%)        | 31/50 (62%) | 38/50 (76%) |       | 35/50 (70%)       | 17/50 (34%) | 33/50 (66%) |  |
|                                    |       | 28/50 (56%)        | 42/50 (84%) | 33/50 (66%) |       | 17/50 (34%)       | 26/50 (52%) | 20/49 (41%) |  |
|                                    |       | 34/50 (68%)        | 27/50 (54%) | 37/50 (74%) |       | 26/50 (52%)       | 29/50 (58%) | 25/50 (50%) |  |
|                                    |       | 26/50 (52%)        | 35/50 (70%) | 21/50 (42%) |       | 18/50 (36%)       | 26/50 (52%) | 18/50 (36%) |  |
|                                    |       | 33/50 (66%)        | 28/50 (56%) | 30/50 (60%) |       | 21/50 (42%)       | 26/50 (52%) | 27/49 (55%) |  |
|                                    |       | 42/50 (84%)        | 30/50 (60%) | 42/50 (84%) |       | 27/50 (54%)       | 24/50 (48%) | 24/50 (48%) |  |
|                                    |       | 41/50 (82%)        | 25/49 (51%) | 32/50 (64%) |       | 32/50 (64%)       | 29/50 (58%) | 29/50 (58%) |  |
| <b>Overall Incidence</b>           | Total | 975/1449 (67.29%)  | Mean 67.28% | SD 11.88%   | Total | 757/1498 (50.53%) | Mean 50.53% | SD 11.76%   |  |
| .....                              |       |                    |             |             |       |                   |             |             |  |
| <b>#All Organs:</b>                |       |                    |             |             |       |                   |             |             |  |
| <b>Malignant Tumors</b>            |       |                    |             |             |       |                   |             |             |  |
|                                    |       | 37/50 (74%)        | 30/50 (60%) | 26/50 (52%) |       | 27/50 (54%)       | 19/50 (38%) | 31/50 (62%) |  |
|                                    |       | 30/50 (60%)        | 24/50 (48%) |             |       | 33/50 (66%)       | 22/50 (44%) | 20/50 (40%) |  |
|                                    |       | 27/50 (54%)        | 27/50 (54%) | 36/50 (72%) |       | 26/50 (52%)       | 31/50 (62%) | 23/50 (46%) |  |
|                                    |       | 27/50 (54%)        | 28/50 (56%) | 26/50 (52%) |       | 26/50 (52%)       | 26/50 (52%) | 15/50 (30%) |  |
|                                    |       | 20/50 (40%)        | 26/50 (52%) | 20/50 (40%) |       | 13/50 (26%)       | 16/50 (32%) | 21/49 (43%) |  |
|                                    |       | 32/50 (64%)        | 29/50 (58%) | 26/50 (52%) |       | 19/50 (38%)       | 30/50 (60%) | 26/50 (52%) |  |
|                                    |       | 15/50 (30%)        | 19/50 (38%) | 29/50 (58%) |       | 20/50 (40%)       | 29/50 (58%) | 19/50 (38%) |  |
|                                    |       | 30/50 (60%)        | 22/50 (44%) | 19/50 (38%) |       | 14/50 (28%)       | 23/50 (46%) | 20/49 (41%) |  |
|                                    |       | 31/50 (62%)        | 28/50 (56%) | 26/50 (52%) |       | 22/50 (44%)       | 13/50 (26%) | 27/50 (54%) |  |
|                                    |       | 36/50 (72%)        | 23/49 (47%) | 29/50 (58%) |       | 38/50 (76%)       | 36/50 (72%) | 31/50 (62%) |  |
| <b>Overall Incidence</b>           | Total | 778/1449 (53.69%)  | Mean 53.69% | SD 10.45%   | Total | 716/1498 (47.8%)  | Mean 47.79% | SD 13.32%   |  |
| .....                              |       |                    |             |             |       |                   |             |             |  |
| <b>#All Organs:</b>                |       |                    |             |             |       |                   |             |             |  |
| <b>Malignant and Benign Tumors</b> |       |                    |             |             |       |                   |             |             |  |
|                                    |       | 47/50 (94%)        | 45/50 (90%) | 48/50 (96%) |       | 40/50 (80%)       | 35/50 (70%) | 44/50 (88%) |  |
|                                    |       | 47/50 (94%)        | 40/50 (80%) |             |       | 42/50 (84%)       | 31/50 (62%) | 29/50 (58%) |  |
|                                    |       | 48/50 (96%)        | 45/50 (90%) | 48/50 (96%) |       | 42/50 (84%)       | 46/50 (92%) | 41/50 (82%) |  |
|                                    |       | 42/50 (84%)        | 41/50 (82%) | 46/50 (92%) |       | 47/50 (94%)       | 36/50 (72%) | 42/50 (84%) |  |
|                                    |       | 38/50 (76%)        | 49/50 (98%) | 43/50 (86%) |       | 26/50 (52%)       | 34/50 (68%) | 34/49 (69%) |  |
|                                    |       | 47/50 (94%)        | 45/50 (90%) | 46/50 (92%) |       | 39/50 (78%)       | 42/50 (84%) | 39/50 (78%) |  |
|                                    |       | 34/50 (68%)        | 43/50 (86%) | 39/50 (78%) |       | 29/50 (58%)       | 40/50 (80%) | 32/50 (64%) |  |
|                                    |       | 43/50 (86%)        | 38/50 (76%) | 38/50 (76%) |       | 30/50 (60%)       | 37/50 (74%) | 40/49 (82%) |  |
|                                    |       | 49/50 (98%)        | 41/50 (82%) | 47/50 (94%) |       | 36/50 (72%)       | 29/50 (58%) | 40/50 (80%) |  |
|                                    |       | 47/50 (94%)        | 37/49 (76%) | 41/50 (82%) |       | 43/50 (86%)       | 42/50 (84%) | 44/50 (88%) |  |
| <b>Overall Incidence</b>           | Total | 1262/1449 (87.09%) | Mean 87.09% | SD 8.19%    | Total | 1131/1498 (75.5%) | Mean 75.5%  | SD 11.34%   |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

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 Species: MICE  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

Page: 6  
 Report Date:04/29/2009

|                          |              | Male           |           |           |  |                 |            | Female    |           |           |  |  |  |
|--------------------------|--------------|----------------|-----------|-----------|--|-----------------|------------|-----------|-----------|-----------|--|--|--|
| <b>#All Organs:</b>      |              |                |           |           |  |                 |            |           |           |           |  |  |  |
| <b>Hemangioma</b>        |              |                |           |           |  |                 |            |           |           |           |  |  |  |
|                          |              | 1/50 (2%)      | 0/50 (0%) | 2/50 (4%) |  | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) |  |  |  |
|                          |              | 0/50 (0%)      | 0/50 (0%) |           |  | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |  |  |  |
|                          |              | 1/50 (2%)      | 0/50 (0%) | 0/50 (0%) |  | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |  |  |  |
|                          |              | 1/50 (2%)      | 2/50 (4%) | 1/50 (2%) |  | 2/50 (4%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |  |  |  |
|                          |              | 0/50 (0%)      | 0/50 (0%) | 0/50 (0%) |  | 0/50 (0%)       | 2/50 (4%)  | 2/50 (4%) | 2/50 (4%) | 0/49 (0%) |  |  |  |
|                          |              | 2/50 (4%)      | 1/50 (2%) | 0/50 (0%) |  | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |  |  |  |
|                          |              | 0/50 (0%)      | 0/50 (0%) | 2/50 (4%) |  | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) |  |  |  |
|                          |              | 0/50 (0%)      | 0/50 (0%) | 0/50 (0%) |  | 2/50 (4%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) |  |  |  |
|                          |              | 0/50 (0%)      | 0/50 (0%) | 1/50 (2%) |  | 1/50 (2%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |  |  |  |
|                          |              | 1/50 (2%)      | 0/49 (0%) | 1/50 (2%) |  | 2/50 (4%)       | 3/50 (6%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |  |  |  |
| <b>Overall Incidence</b> | <b>Total</b> | 16/1449 (1.1%) | Mean 1.1% | SD 1.47%  |  | 20/1498 (1.34%) | Mean 1.33% | SD 1.69%  |           |           |  |  |  |

|                          |              |                 |            |            |  |                 |            |            |  |            |  |
|--------------------------|--------------|-----------------|------------|------------|--|-----------------|------------|------------|--|------------|--|
| <b>#All Organs:</b>      |              |                 |            |            |  |                 |            |            |  |            |  |
| <b>Hemangiosarcoma</b>   |              |                 |            |            |  |                 |            |            |  |            |  |
|                          |              | 5/50 (10%)      | 4/50 (8%)  | 5/50 (10%) |  | 1/50 (2%)       | 1/50 (2%)  | 7/50 (14%) |  |            |  |
|                          |              | 2/50 (4%)       | 2/50 (4%)  |            |  | 4/50 (8%)       | 3/50 (6%)  | 1/50 (2%)  |  | 1/50 (2%)  |  |
|                          |              | 0/50 (0%)       | 6/50 (12%) | 7/50 (14%) |  | 1/50 (2%)       | 1/50 (2%)  | 5/50 (10%) |  | 5/50 (10%) |  |
|                          |              | 0/50 (0%)       | 3/50 (6%)  | 4/50 (8%)  |  | 4/50 (8%)       | 2/50 (4%)  | 0/50 (0%)  |  | 0/50 (0%)  |  |
|                          |              | 2/50 (4%)       | 2/50 (4%)  | 3/50 (6%)  |  | 1/50 (2%)       | 5/50 (10%) | 1/49 (2%)  |  | 1/49 (2%)  |  |
|                          |              | 6/50 (12%)      | 3/50 (6%)  | 6/50 (12%) |  | 1/50 (2%)       | 3/50 (6%)  | 3/50 (6%)  |  | 3/50 (6%)  |  |
|                          |              | 1/50 (2%)       | 4/50 (8%)  | 3/50 (6%)  |  | 3/50 (6%)       | 4/50 (8%)  | 2/50 (4%)  |  | 2/50 (4%)  |  |
|                          |              | 7/50 (14%)      | 2/50 (4%)  | 3/50 (6%)  |  | 1/50 (2%)       | 2/50 (4%)  | 3/49 (6%)  |  | 3/49 (6%)  |  |
|                          |              | 4/50 (8%)       | 3/50 (6%)  | 4/50 (8%)  |  | 2/50 (4%)       | 0/50 (0%)  | 2/50 (4%)  |  | 2/50 (4%)  |  |
|                          |              | 3/50 (6%)       | 4/49 (8%)  | 1/50 (2%)  |  | 1/50 (2%)       | 1/50 (2%)  | 3/50 (6%)  |  | 3/50 (6%)  |  |
| <b>Overall Incidence</b> | <b>Total</b> | 99/1449 (6.83%) | Mean 6.83% | SD 3.76%   |  | 68/1498 (4.54%) | Mean 4.54% | SD 3.28%   |  |            |  |

|                                      |              |                 |            |            |  |                 |            |            |  |            |  |
|--------------------------------------|--------------|-----------------|------------|------------|--|-----------------|------------|------------|--|------------|--|
| <b>#All Organs:</b>                  |              |                 |            |            |  |                 |            |            |  |            |  |
| <b>Hemangiosarcoma or Hemangioma</b> |              |                 |            |            |  |                 |            |            |  |            |  |
|                                      |              | 5/50 (10%)      | 4/50 (8%)  | 7/50 (14%) |  | 2/50 (4%)       | 1/50 (2%)  | 8/50 (16%) |  |            |  |
|                                      |              | 2/50 (4%)       | 2/50 (4%)  |            |  | 4/50 (8%)       | 3/50 (6%)  | 1/50 (2%)  |  | 1/50 (2%)  |  |
|                                      |              | 1/50 (2%)       | 6/50 (12%) | 7/50 (14%) |  | 1/50 (2%)       | 1/50 (2%)  | 5/50 (10%) |  | 5/50 (10%) |  |
|                                      |              | 1/50 (2%)       | 5/50 (10%) | 5/50 (10%) |  | 6/50 (12%)      | 2/50 (4%)  | 1/50 (2%)  |  | 1/50 (2%)  |  |
|                                      |              | 2/50 (4%)       | 2/50 (4%)  | 3/50 (6%)  |  | 1/50 (2%)       | 7/50 (14%) | 1/49 (2%)  |  | 1/49 (2%)  |  |
|                                      |              | 8/50 (16%)      | 4/50 (8%)  | 6/50 (12%) |  | 1/50 (2%)       | 3/50 (6%)  | 4/50 (8%)  |  | 4/50 (8%)  |  |
|                                      |              | 1/50 (2%)       | 4/50 (8%)  | 4/50 (8%)  |  | 3/50 (6%)       | 5/50 (10%) | 3/50 (6%)  |  | 3/50 (6%)  |  |
|                                      |              | 7/50 (14%)      | 2/50 (4%)  | 3/50 (6%)  |  | 3/50 (6%)       | 2/50 (4%)  | 4/49 (8%)  |  | 4/49 (8%)  |  |
|                                      |              | 4/50 (8%)       | 3/50 (6%)  | 5/50 (10%) |  | 3/50 (6%)       | 1/50 (2%)  | 2/50 (4%)  |  | 2/50 (4%)  |  |
|                                      |              | 4/50 (8%)       | 4/49 (8%)  | 2/50 (4%)  |  | 3/50 (6%)       | 4/50 (8%)  | 3/50 (6%)  |  | 3/50 (6%)  |  |
| <b>Overall Incidence</b>             | <b>Total</b> | 113/1449 (7.8%) | Mean 7.8%  | SD 3.94%   |  | 88/1498 (5.87%) | Mean 5.87% | SD 3.75%   |  |            |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                            |       | Male           |            |           |           | Female          |            |          |  |
|----------------------------|-------|----------------|------------|-----------|-----------|-----------------|------------|----------|--|
| <b>#All Organs:</b>        |       |                |            |           |           |                 |            |          |  |
| <b>Histiocytic Sarcoma</b> |       |                |            |           |           |                 |            |          |  |
|                            |       | 0/50 (0%)      | 1/50 (2%)  | 1/50 (2%) | 2/50 (4%) | 2/50 (4%)       | 3/50 (6%)  |          |  |
|                            |       | 0/50 (0%)      | 0/50 (0%)  |           | 1/50 (2%) | 1/50 (2%)       | 2/50 (4%)  |          |  |
|                            |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 1/50 (2%)       | 1/50 (2%)  |          |  |
|                            |       | 1/50 (2%)      | 0/50 (0%)  | 1/50 (2%) | 3/50 (6%) | 2/50 (4%)       | 0/50 (0%)  |          |  |
|                            |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |          |  |
|                            |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 3/50 (6%) | 3/50 (6%)       | 2/50 (4%)  |          |  |
|                            |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 1/50 (2%)       | 1/50 (2%)  |          |  |
|                            |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 3/49 (6%)  |          |  |
|                            |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 2/50 (4%) | 1/50 (2%)       | 2/50 (4%)  |          |  |
|                            |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 4/50 (8%)  |          |  |
| <b>Overall Incidence</b>   | Total | 7/1449 (0.48%) | Mean 0.48% | SD 0.87%  | Total     | 43/1498 (2.87%) | Mean 2.87% | SD 2.28% |  |

|  |       |                 |            |            |             |                   |             |          |  |
|--|-------|-----------------|------------|------------|-------------|-------------------|-------------|----------|--|
| <b>#All Organs:</b>  |       |                 |            |            |             |                   |             |          |  |
| <b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b> |       |                 |            |            |             |                   |             |          |  |
|  |       | 4/50 (8%)       | 4/50 (8%)  | 0/50 (0%)  | 14/50 (28%) | 6/50 (12%)        | 9/50 (18%)  |          |  |
|  |       | 2/50 (4%)       | 2/50 (4%)  |            | 17/50 (34%) | 5/50 (10%)        | 7/50 (14%)  |          |  |
|  |       | 2/50 (4%)       | 1/50 (2%)  | 2/50 (4%)  | 7/50 (14%)  | 14/50 (28%)       | 8/50 (16%)  |          |  |
|  |       | 2/50 (4%)       | 2/50 (4%)  | 4/50 (8%)  | 10/50 (20%) | 10/50 (20%)       | 9/50 (18%)  |          |  |
|  |       | 1/50 (2%)       | 2/50 (4%)  | 0/50 (0%)  | 6/50 (12%)  | 8/50 (16%)        | 11/49 (22%) |          |  |
|  |       | 2/50 (4%)       | 1/50 (2%)  | 2/50 (4%)  | 6/50 (12%)  | 13/50 (26%)       | 6/50 (12%)  |          |  |
|  |       | 3/50 (6%)       | 0/50 (0%)  | 6/50 (12%) | 7/50 (14%)  | 15/50 (30%)       | 11/50 (22%) |          |  |
|  |       | 1/50 (2%)       | 1/50 (2%)  | 1/50 (2%)  | 7/50 (14%)  | 13/50 (26%)       | 6/49 (12%)  |          |  |
|  |       | 2/50 (4%)       | 1/50 (2%)  | 2/50 (4%)  | 7/50 (14%)  | 2/50 (4%)         | 12/50 (24%) |          |  |
|  |       | 2/50 (4%)       | 0/49 (0%)  | 0/50 (0%)  | 18/50 (36%) | 27/50 (54%)       | 9/50 (18%)  |          |  |
| <b>Overall Incidence</b>   | Total | 52/1449 (3.59%) | Mean 3.59% | SD 2.8%    | Total       | 300/1498 (20.03%) | Mean 20.02% | SD 9.88% |  |

|   |       |                |            |           |           |             |           |       |  |
|---|-------|----------------|------------|-----------|-----------|-------------|-----------|-------|--|
| <b>#All Organs:</b>                         |       |                |            |           |           |             |           |       |  |
| <b>Mesothelioma: Benign, Malignant, NOS</b> |       |                |            |           |           |             |           |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  |           | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/49 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/49 (0%) |       |  |
|   |       | 2/50 (4%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |
| <b>Overall Incidence</b>                    | Total | 3/1449 (0.21%) | Mean 0.21% | SD 0.82%  | Total     | 0/1498 (0%) | Mean 0%   | SD 0% |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied





Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                    |       | Male            |            |            |           | Female         |            |           |           |
|------------------------------------|-------|-----------------|------------|------------|-----------|----------------|------------|-----------|-----------|
| <b>#All Organs:</b>                |       |                 |            |            |           |                |            |           |           |
| <b>Osteosarcoma or Osteoma</b>     |       |                 |            |            |           |                |            |           |           |
|                                    |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)      | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/49 (2%) |
|                                    |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |
|                                    |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 5/1449 (0.35%)  | Mean 0.34% | SD 0.77%   | Total     | 8/1498 (0.53%) | Mean 0.53% | SD 1.04%  |           |
| .....                              |       |                 |            |            |           |                |            |           |           |
| <b>*Adrenal Cortex:</b>            |       |                 |            |            |           |                |            |           |           |
| <b>Adenoma</b>                     |       |                 |            |            |           |                |            |           |           |
|                                    |       | 1/50 (2%)       | 2/50 (4%)  | 6/49 (12%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 4/49 (8%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 1/50 (2%)       | 6/50 (12%) | 6/50 (12%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 1/50 (2%) |
|                                    |       | 5/50 (10%)      | 2/50 (4%)  | 1/50 (2%)  | 0/50 (0%) | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 2/50 (4%)       | 5/49 (10%) | 3/50 (6%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) |
|                                    |       | 0/50 (0%)       | 2/50 (4%)  | 5/48 (10%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 4/50 (8%)       | 0/50 (0%)  | 1/50 (2%)  | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 2/50 (4%)       | 1/49 (2%)  | 1/50 (2%)  | 1/50 (2%) | 0/49 (0%)      | 1/49 (2%)  | 0/49 (0%) | 1/49 (2%) |
|                                    |       | 7/49 (14%)      | 3/50 (6%)  | 2/49 (4%)  | 0/49 (0%) | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 9/50 (18%)      | 3/49 (6%)  | 6/50 (12%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 90/1441 (6.25%) | Mean 6.26% | SD 4.81%   | Total     | 5/1492 (0.34%) | Mean 0.33% | SD 0.76%  |           |
| .....                              |       |                 |            |            |           |                |            |           |           |
| <b>*Adrenal Cortex:</b>            |       |                 |            |            |           |                |            |           |           |
| <b>Plasma Cell Tumor Malignant</b> |       |                 |            |            |           |                |            |           |           |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%)  | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/49 (0%)       | 0/50 (0%)  | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 0/1441 (0%)     | Mean 0%    | SD 0%      | Total     | 1/1492 (0.07%) | Mean 0.07% | SD 0.37%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                 |       | Male   |         |            |          |       |         | Female  |            |          |      |      |      |
|---------------------------------|-------|--------|---------|------------|----------|-------|---------|---------|------------|----------|------|------|------|
| <b>*Adrenal Cortex:</b>         |       |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>Sarcoma</b>                  |       |        |         |            |          |       |         |         |            |          |      |      |      |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/49  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     |       |         | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/49     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/48 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/48  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/49     | (0%) | 0/49 | (0%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     | 0/49  | (0%)    | 0/49    | (0%)       | 0/49     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
| <b>Overall Incidence</b>        | Total | 0/1441 | (0%)    | Mean 0%    | SD 0%    | Total | 1/1492  | (0.07%) | Mean 0.07% | SD 0.37% |      |      |      |
| .....                           |       |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>*Adrenal Medulla:</b>        |       |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>Pheochromocytoma Benign</b>  |       |        |         |            |          |       |         |         |            |          |      |      |      |
|                                 |       | 0/49   | (0%)    | 0/49       | (0%)     | 0/49  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 1/50   | (2%)    | 0/49       | (0%)     |       |         | 3/50    | (6%)       | 0/49     | (0%) | 0/49 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 2/50     | (4%) | 0/50 | (0%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/49    | (0%)       | 0/50     | (0%) | 1/50 | (2%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/48 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/48  | (0%)    | 0/50    | (0%)       | 2/50     | (4%) | 1/50 | (2%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 1/49  | (2%)    | 0/50    | (0%)       | 2/50     | (4%) | 0/49 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/47       | (0%)     | 1/50  | (2%)    | 0/50    | (0%)       | 1/48     | (2%) | 1/49 | (2%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     | 1/47  | (2%)    | 0/49    | (0%)       | 0/49     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 1/49  | (2%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
| <b>Overall Incidence</b>        | Total | 5/1432 | (0.35%) | Mean 0.35% | SD 0.79% | Total | 14/1489 | (0.94%) | Mean 0.94% | SD 1.64% |      |      |      |
| .....                           |       |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>*Adrenal Medulla:</b>        |       |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>Pheochromocytoma Complex</b> |       |        |         |            |          |       |         |         |            |          |      |      |      |
|                                 |       | 0/49   | (0%)    | 0/49       | (0%)     | 0/49  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     |       |         | 0/50    | (0%)       | 0/49     | (0%) | 0/49 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/49    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/48 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/48  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/50       | (0%)     | 0/49  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/47       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/48     | (0%) | 0/49 | (0%) |
|                                 |       | 0/49   | (0%)    | 0/50       | (0%)     | 0/47  | (0%)    | 0/49    | (0%)       | 0/49     | (0%) | 0/50 | (0%) |
|                                 |       | 0/50   | (0%)    | 0/49       | (0%)     | 0/49  | (0%)    | 1/50    | (2%)       | 0/50     | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b>        | Total | 0/1432 | (0%)    | Mean 0%    | SD 0%    | Total | 1/1489  | (0.07%) | Mean 0.07% | SD 0.37% |      |      |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

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|  |       | Male           |            |           |           | Female          |            |           |           |
|--|-------|----------------|------------|-----------|-----------|-----------------|------------|-----------|-----------|
| <b>*Adrenal Medulla:</b>                                 |       |                |            |           |           |                 |            |           |           |
| <b>Pheochromocytoma Malignant</b>                        |       |                |            |           |           |                 |            |           |           |
|  |       | 0/49 (0%)      | 1/49 (2%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/49 (0%)  |           | 1/50 (2%) | 1/49 (2%)       | 1/49 (2%)  | 1/49 (2%) | 1/49 (2%) |
|  |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) |
|  |       | 0/50 (0%)      | 1/50 (2%)  | 0/48 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/47 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/48 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/47 (0%) | 0/49 (0%) | 1/49 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 1/49 (2%)  | 0/49 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                 | Total | 5/1432 (0.35%) | Mean 0.35% | SD 0.78%  | Total     | 6/1489 (0.4%)   | Mean 0.4%  | SD 0.82%  |           |
| .....  |       |                |            |           |           |                 |            |           |           |
| <b>*Adrenal Medulla:</b>                                 |       |                |            |           |           |                 |            |           |           |
| <b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b> |       |                |            |           |           |                 |            |           |           |
|  |       | 0/49 (0%)      | 1/49 (2%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 1/50 (2%)      | 0/49 (0%)  |           | 4/50 (8%) | 1/49 (2%)       | 1/49 (2%)  | 1/49 (2%) | 1/49 (2%) |
|  |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 2/50 (4%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/48 (0%)  | 0/48 (0%) | 0/48 (0%) |
|  |       | 0/50 (0%)      | 1/50 (2%)  | 0/48 (0%) | 0/50 (0%) | 2/50 (4%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 1/49 (2%) | 1/50 (2%) | 2/50 (4%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/47 (0%)  | 1/50 (2%) | 0/50 (0%) | 1/48 (2%)       | 1/49 (2%)  | 1/49 (2%) | 1/49 (2%) |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 1/47 (2%) | 0/49 (0%) | 1/49 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 1/49 (2%)  | 1/49 (2%) | 2/50 (4%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                 | Total | 10/1432 (0.7%) | Mean 0.7%  | SD 0.98%  | Total     | 21/1489 (1.41%) | Mean 1.41% | SD 1.91%  |           |
| .....  |       |                |            |           |           |                 |            |           |           |
| <b>*Bone Marrow:</b>                                     |       |                |            |           |           |                 |            |           |           |
| <b>Hemangioma</b>  |       |                |            |           |           |                 |            |           |           |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/48 (0%)      | 0/50 (0%)  |           | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/49 (0%)       | 0/48 (0%)  | 0/48 (0%) | 0/48 (0%) |
|  |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/47 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                 | Total | 1/1442 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1493 (0%)     | Mean 0%    | SD 0%     |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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 Vehicle: ALL VEHICLES

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|                                    |       | Male            |            |           |       | Female         |            |           |           |  |  |
|------------------------------------|-------|-----------------|------------|-----------|-------|----------------|------------|-----------|-----------|--|--|
| <b>*Bone Marrow:</b>               |       |                 |            |           |       |                |            |           |           |  |  |
| <b>Hemangiosarcoma</b>             |       |                 |            |           |       |                |            |           |           |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) |       | 0/50 (0%)      | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) |  |  |
|                                    |       | 0/48 (0%)       | 0/50 (0%)  |           |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 1/50 (2%)  | 2/50 (4%) |       | 0/49 (0%)      | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%) |  |  |
|                                    |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 1/49 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/49 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/48 (0%) |  |  |
|                                    |       | 2/50 (4%)       | 0/50 (0%)  | 1/50 (2%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 1/50 (2%)       | 0/50 (0%)  | 1/49 (2%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 2/50 (4%)  | 1/49 (2%) | 1/49 (2%) |  |  |
|                                    |       | 1/49 (2%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |  |  |
|                                    |       | 1/50 (2%)       | 0/47 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
| <b>Overall Incidence</b>           | Total | 11/1442 (0.76%) | Mean 0.76% | SD 1.25%  | Total | 8/1493 (0.54%) | Mean 0.54% | SD 1.05%  |           |  |  |
| .....                              |       |                 |            |           |       |                |            |           |           |  |  |
| <b>*Bone Marrow:</b>               |       |                 |            |           |       |                |            |           |           |  |  |
| <b>Plasma Cell Tumor Malignant</b> |       |                 |            |           |       |                |            |           |           |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/48 (0%)       | 0/50 (0%)  |           |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/49 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/48 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |  |  |
|                                    |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/47 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
| <b>Overall Incidence</b>           | Total | 0/1442 (0%)     | Mean 0%    | SD 0%     | Total | 1/1493 (0.07%) | Mean 0.07% | SD 0.37%  |           |  |  |
| .....                              |       |                 |            |           |       |                |            |           |           |  |  |
| <b>#Bone:</b>                      |       |                 |            |           |       |                |            |           |           |  |  |
| <b>Hemangiosarcoma</b>             |       |                 |            |           |       |                |            |           |           |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  |           |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
|                                    |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |  |  |
|                                    |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |  |  |
| <b>Overall Incidence</b>           | Total | 1/1449 (0.07%)  | Mean 0.07% | SD 0.37%  | Total | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
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**Toxicology Data Management System**  
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|                                |       | Male           |            |           |           | Female         |            |           |           |
|--------------------------------|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Bone:</b>                  |       |                |            |           |           |                |            |           |           |
| <b>Osteoma</b>                 |       |                |            |           |           |                |            |           |           |
|                                |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>       | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |
| .....                          |       |                |            |           |           |                |            |           |           |
| <b>#Bone:</b>                  |       |                |            |           |           |                |            |           |           |
| <b>Osteosarcoma</b>            |       |                |            |           |           |                |            |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)      | 2/50 (4%)  |           |           |
|                                |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/49 (2%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  |           |           |
|                                |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
| <b>Overall Incidence</b>       | Total | 3/1449 (0.21%) | Mean 0.21% | SD 0.62%  | Total     | 7/1498 (0.47%) | Mean 0.47% | SD 1.01%  |           |
| .....                          |       |                |            |           |           |                |            |           |           |
| <b>#Bone:</b>                  |       |                |            |           |           |                |            |           |           |
| <b>Osteosarcoma or Osteoma</b> |       |                |            |           |           |                |            |           |           |
|                                |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)      | 2/50 (4%)  |           |           |
|                                |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/49 (2%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  |           |           |
|                                |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  |           |           |
|                                |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  |           |           |
|                                |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
|                                |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |           |           |
| <b>Overall Incidence</b>       | Total | 4/1449 (0.28%) | Mean 0.28% | SD 0.7%   | Total     | 8/1498 (0.53%) | Mean 0.53% | SD 1.04%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                             |       | Male           |            |           |           | Female      |           |           |           |
|-----------------------------|-------|----------------|------------|-----------|-----------|-------------|-----------|-----------|-----------|
| <b>#Bone:</b>               |       |                |            |           |           |             |           |           |           |
| <b>Sarcoma</b>              |       |                |            |           |           |             |           |           |           |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>    | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1498 (0%) | Mean 0%   | SD 0%     |           |
| .....                       |       |                |            |           |           |             |           |           |           |
| <b>*Brain:</b>              |       |                |            |           |           |             |           |           |           |
| <b>Meningioma Benign</b>    |       |                |            |           |           |             |           |           |           |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>    | Total | 1/1448 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1497 (0%) | Mean 0%   | SD 0%     |           |
| .....                       |       |                |            |           |           |             |           |           |           |
| <b>*Brain:</b>              |       |                |            |           |           |             |           |           |           |
| <b>Meningioma Malignant</b> |       |                |            |           |           |             |           |           |           |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|                             |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                             |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>    | Total | 1/1448 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1497 (0%) | Mean 0%   | SD 0%     |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male           |            |           |           | Female         |            |          |  |  |
|--|-------|----------------|------------|-----------|-----------|----------------|------------|----------|--|--|
| <b>*Clitoral/Preputial Gland: Carcinoma</b>            |       |                |            |           |           |                |            |          |  |  |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/47 (0%) | 0/48 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  |           | 0/46 (0%) | 0/44 (0%)      | 1/49 (2%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/41 (0%) | 0/50 (0%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/46 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/45 (0%)      | 0/48 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/43 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/42 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/49 (2%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/48 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/43 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
| <b>Overall Incidence</b>                               | Total | 0/1443 (0%)    | Mean 0%    | SD 0%     | Total     | 2/1419 (0.14%) | Mean 0.14% | SD 0.52% |  |  |
| .....  |       |                |            |           |           |                |            |          |  |  |
| <b>*Clitoral/Preputial Gland: Carcinoma or Adenoma</b> |       |                |            |           |           |                |            |          |  |  |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/47 (0%) | 0/48 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  |           | 0/46 (0%) | 0/44 (0%)      | 1/49 (2%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/41 (0%) | 0/50 (0%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/46 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/45 (0%)      | 0/48 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/43 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/42 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/49 (2%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/48 (0%)      | 0/49 (0%)  | 1/49 (2%) | 0/43 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
| <b>Overall Incidence</b>                               | Total | 2/1443 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 2/1419 (0.14%) | Mean 0.14% | SD 0.52% |  |  |
| .....  |       |                |            |           |           |                |            |          |  |  |
| <b>*Clitoral/Preputial Gland: Hemangioma</b>           |       |                |            |           |           |                |            |          |  |  |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/47 (0%) | 0/48 (0%)      | 1/50 (2%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  |           | 0/46 (0%) | 0/44 (0%)      | 0/49 (0%)  |          |  |  |
|  |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/41 (0%) | 0/50 (0%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/46 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/45 (0%)      | 0/48 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/43 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/42 (0%)      | 0/47 (0%)  |          |  |  |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)      | 0/46 (0%)  |          |  |  |
|  |       | 0/48 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/43 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
| <b>Overall Incidence</b>                               | Total | 0/1443 (0%)    | Mean 0%    | SD 0%     | Total     | 1/1419 (0.07%) | Mean 0.07% | SD 0.37% |  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male           |            |           |           | Female      |           |       |  |  |
|---|-------|----------------|------------|-----------|-----------|-------------|-----------|-------|--|--|
| <b>*Clitoral/Preputial Gland:<br/>Hemangiosarcoma</b> |       |                |            |           |           |             |           |       |  |  |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/47 (0%) | 0/48 (0%)   | 0/50 (0%) |       |  |  |
|   |       | 0/49 (0%)      | 0/50 (0%)  |           | 0/46 (0%) | 0/44 (0%)   | 0/49 (0%) |       |  |  |
|   |       | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/41 (0%) | 0/50 (0%)   | 0/46 (0%) |       |  |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/46 (0%) | 0/50 (0%)   | 0/50 (0%) |       |  |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/47 (0%) |       |  |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/45 (0%)   | 0/48 (0%) |       |  |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/43 (0%)   | 0/47 (0%) |       |  |  |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/42 (0%)   | 0/47 (0%) |       |  |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)   | 0/46 (0%) |       |  |  |
|   |       | 0/48 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/43 (0%) | 0/50 (0%)   | 0/47 (0%) |       |  |  |
| <b>Overall Incidence</b>                              | Total | 1/1443 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1419 (0%) | Mean 0%   | SD 0% |  |  |

|   |       |             |           |           |           |                |            |          |  |  |
|---|-------|-------------|-----------|-----------|-----------|----------------|------------|----------|--|--|
| <b>*Clitoral/Preputial Gland:<br/>Squamous Cell Carcinoma</b> |       |             |           |           |           |                |            |          |  |  |
|   |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | 0/48 (0%)      | 0/50 (0%)  |          |  |  |
|   |       | 0/49 (0%)   | 0/50 (0%) |           | 0/46 (0%) | 0/44 (0%)      | 0/49 (0%)  |          |  |  |
|   |       | 0/49 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/41 (0%) | 0/50 (0%)      | 0/46 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/46 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/45 (0%)      | 0/48 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/43 (2%)      | 0/47 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/42 (0%)      | 0/47 (0%)  |          |  |  |
|   |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)      | 0/46 (0%)  |          |  |  |
|   |       | 0/48 (0%)   | 0/49 (0%) | 0/49 (0%) | 0/43 (0%) | 0/50 (0%)      | 0/47 (0%)  |          |  |  |
| <b>Overall Incidence</b>                                      | Total | 0/1443 (0%) | Mean 0%   | SD 0%     | Total     | 1/1419 (0.07%) | Mean 0.08% | SD 0.42% |  |  |

|  |       |             |           |           |           |                |            |          |  |  |
|--|-------|-------------|-----------|-----------|-----------|----------------|------------|----------|--|--|
| <b>#Esophagus:<br/>Squamous Cell Carcinoma</b> |       |             |           |           |           |                |            |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) |           | 1/50 (2%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
|  |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  |          |  |  |
| <b>Overall Incidence</b>                       | Total | 0/1449 (0%) | Mean 0%   | SD 0%     | Total     | 1/1498 (0.07%) | Mean 0.07% | SD 0.37% |  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |              | Male              |             |             |  |            | Female            |             |           |           |           |
|--------------------------|--------------|-------------------|-------------|-------------|--|------------|-------------------|-------------|-----------|-----------|-----------|
| <b>#Eye:</b>             |              |                   |             |             |  |            |                   |             |           |           |           |
| <b>Sarcoma</b>           |              |                   |             |             |  |            |                   |             |           |           |           |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 1/50 (2%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   |             |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 1/50 (2%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|                          |              | 0/50 (0%)         | 0/49 (0%)   | 0/50 (0%)   |  | 0/50 (0%)  | 0/50 (0%)         | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b> | <b>Total</b> | 2/1449 (0.14%)    | Mean 0.14%  | SD 0.52%    |  | Total      | 0/1498 (0%)       | Mean 0%     | SD 0%     |           |           |
| .....                    |              |                   |             |             |  |            |                   |             |           |           |           |
| <b>#Harderian Gland:</b> |              |                   |             |             |  |            |                   |             |           |           |           |
| <b>Adenoma</b>           |              |                   |             |             |  |            |                   |             |           |           |           |
|                          |              | 7/50 (14%)        | 8/50 (16%)  | 10/50 (20%) |  | 9/50 (18%) | 5/50 (10%)        | 3/50 (6%)   |           |           |           |
|                          |              | 7/50 (14%)        | 5/50 (10%)  |             |  | 3/50 (6%)  | 7/50 (14%)        | 6/50 (12%)  |           |           |           |
|                          |              | 8/50 (16%)        | 7/50 (14%)  | 4/50 (8%)   |  | 8/50 (16%) | 6/50 (12%)        | 3/50 (6%)   |           |           |           |
|                          |              | 9/50 (18%)        | 6/50 (12%)  | 11/50 (22%) |  | 9/50 (18%) | 4/50 (8%)         | 7/50 (14%)  |           |           |           |
|                          |              | 7/50 (14%)        | 11/50 (22%) | 8/50 (16%)  |  | 5/50 (10%) | 7/50 (14%)        | 3/49 (6%)   |           |           |           |
|                          |              | 5/50 (10%)        | 5/50 (10%)  | 8/50 (16%)  |  | 5/50 (10%) | 6/50 (12%)        | 4/50 (8%)   |           |           |           |
|                          |              | 4/50 (8%)         | 10/50 (20%) | 5/50 (10%)  |  | 6/50 (12%) | 3/50 (6%)         | 6/50 (12%)  |           |           |           |
|                          |              | 9/50 (18%)        | 3/50 (6%)   | 6/50 (12%)  |  | 4/50 (8%)  | 4/50 (8%)         | 7/49 (14%)  |           |           |           |
|                          |              | 6/50 (12%)        | 6/50 (12%)  | 2/50 (4%)   |  | 4/50 (8%)  | 14/50 (28%)       | 1/50 (2%)   |           |           |           |
|                          |              | 5/50 (10%)        | 3/49 (6%)   | 5/50 (10%)  |  | 1/50 (2%)  | 9/50 (18%)        | 6/50 (12%)  |           |           |           |
| <b>Overall Incidence</b> | <b>Total</b> | 190/1449 (13.11%) | Mean 13.11% | SD 4.76%    |  | Total      | 165/1498 (11.01%) | Mean 11.01% | SD 5.38%  |           |           |
| .....                    |              |                   |             |             |  |            |                   |             |           |           |           |
| <b>#Harderian Gland:</b> |              |                   |             |             |  |            |                   |             |           |           |           |
| <b>Carcinoma</b>         |              |                   |             |             |  |            |                   |             |           |           |           |
|                          |              | 2/50 (4%)         | 2/50 (4%)   | 2/50 (4%)   |  | 1/50 (2%)  | 1/50 (2%)         | 0/50 (0%)   |           |           |           |
|                          |              | 3/50 (6%)         | 1/50 (2%)   |             |  | 2/50 (4%)  | 2/50 (4%)         | 1/50 (2%)   |           |           |           |
|                          |              | 4/50 (8%)         | 0/50 (0%)   | 4/50 (8%)   |  | 5/50 (10%) | 2/50 (4%)         | 2/50 (4%)   |           |           |           |
|                          |              | 2/50 (4%)         | 2/50 (4%)   | 1/50 (2%)   |  | 1/50 (2%)  | 4/50 (8%)         | 0/50 (0%)   |           |           |           |
|                          |              | 2/50 (4%)         | 3/50 (6%)   | 4/50 (8%)   |  | 2/50 (4%)  | 0/50 (0%)         | 1/49 (2%)   |           |           |           |
|                          |              | 0/50 (0%)         | 2/50 (4%)   | 3/50 (6%)   |  | 0/50 (0%)  | 1/50 (2%)         | 0/50 (0%)   |           |           |           |
|                          |              | 1/50 (2%)         | 1/50 (2%)   | 0/50 (0%)   |  | 1/50 (2%)  | 1/50 (2%)         | 2/50 (4%)   |           |           |           |
|                          |              | 1/50 (2%)         | 3/50 (6%)   | 1/50 (2%)   |  | 0/50 (0%)  | 0/50 (0%)         | 1/49 (2%)   |           |           |           |
|                          |              | 0/50 (0%)         | 0/50 (0%)   | 3/50 (6%)   |  | 1/50 (2%)  | 0/50 (0%)         | 1/50 (2%)   |           |           |           |
|                          |              | 0/50 (0%)         | 0/49 (0%)   | 0/50 (0%)   |  | 2/50 (4%)  | 1/50 (2%)         | 2/50 (4%)   |           |           |           |
| <b>Overall Incidence</b> | <b>Total</b> | 47/1449 (3.24%)   | Mean 3.24%  | SD 2.69%    |  | Total      | 37/1498 (2.47%)   | Mean 2.47%  | SD 2.33%  |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied





Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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 Vehicle: ALL VEHICLES

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|  |              | Male           |            |           |              | Female      |           |           |           |           |           |
|--|--------------|----------------|------------|-----------|--------------|-------------|-----------|-----------|-----------|-----------|-----------|
| <b>#Intestine Large: Cecum: Carcinoma or Adenoma</b> |              |                |            |           |              |             |           |           |           |           |           |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|  |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |              | 1/50 (2%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                             | <b>Total</b> | 4/1449 (0.28%) | Mean 0.28% | SD 0.7%   | <b>Total</b> | 0/1498 (0%) | Mean 0%   | SD 0%     |           |           |           |

|   |              |             |           |           |              |                |            |           |           |           |           |
|---|--------------|-------------|-----------|-----------|--------------|----------------|------------|-----------|-----------|-----------|-----------|
| <b>#Intestine Large: Cecum: Leiomyoma</b> |              |             |           |           |              |                |            |           |           |           |           |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                  | <b>Total</b> | 0/1449 (0%) | Mean 0%   | SD 0%     | <b>Total</b> | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |           |           |

|   |              |             |           |           |              |                |            |           |           |           |           |
|---|--------------|-------------|-----------|-----------|--------------|----------------|------------|-----------|-----------|-----------|-----------|
| <b>#Intestine Large: Colon/Rectum: Leiomyosarcoma</b> |              |             |           |           |              |                |            |           |           |           |           |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|   |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |              | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| <b>Overall Incidence</b>                              | <b>Total</b> | 0/1449 (0%) | Mean 0%   | SD 0%     | <b>Total</b> | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
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**Toxicology Data Management System**  
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|                                    |              | Male   |         |      |       | Female |       |       |        |         |      |       |    |       |
|------------------------------------|--------------|--------|---------|------|-------|--------|-------|-------|--------|---------|------|-------|----|-------|
| <b>#Intestine Small: Duodenum:</b> |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
| <b>Adenoma</b>                     |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 1/50 | (2%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 1/50  | (2%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 1/50   | (2%)    | 1/50 | (2%)  | 0/50   | (0%)  | 1/50  | (2%)   | 1/50    | (2%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 3/50   | (6%)    | 0/49 | (0%)  | 1/50   | (2%)  | 1/50  | (2%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>           | <b>Total</b> | 9/1449 | (0.62%) | Mean | 0.62% | SD     | 1.32% | Total | 4/1498 | (0.27%) | Mean | 0.27% | SD | 0.69% |
| .....                              |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
| <b>#Intestine Small: Duodenum:</b> |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
| <b>Carcinoma</b>                   |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
|                                    |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 2/50 | (4%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 1/50   | (2%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>           | <b>Total</b> | 4/1449 | (0.28%) | Mean | 0.28% | SD     | 0.88% | Total | 1/1498 | (0.07%) | Mean | 0.07% | SD | 0.37% |
| .....                              |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
| <b>#Intestine Small: Duodenum:</b> |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
| <b>Leiomyosarcoma</b>              |              |        |         |      |       |        |       |       |        |         |      |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                                    |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>           | <b>Total</b> | 0/1449 | (0%)    | Mean | 0%    | SD     | 0%    | Total | 1/1498 | (0.07%) | Mean | 0.07% | SD | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                    |       | Male           |            |           |           | Female         |            |           |           |
|------------------------------------|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Intestine Small: Duodenum:</b> |       |                |            |           |           |                |            |           |           |
| <b>Polyp Adenomatous</b>           |       |                |            |           |           |                |            |           |           |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 1/50 (2%)      | 0/50 (0%)  |           |           | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |
| .....                              |       |                |            |           |           |                |            |           |           |
| <b>#Intestine Small: Ileum:</b>    |       |                |            |           |           |                |            |           |           |
| <b>Carcinoma</b>                   |       |                |            |           |           |                |            |           |           |
|                                    |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 1/50 (2%)  |           |           | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 0/1498 (0%)    | Mean 0%    | SD 0%     |           |
| .....                              |       |                |            |           |           |                |            |           |           |
| <b>#Intestine Small: Ileum:</b>    |       |                |            |           |           |                |            |           |           |
| <b>Hemangiosarcoma</b>             |       |                |            |           |           |                |            |           |           |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  |           |           | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1498 (0%)    | Mean 0%    | SD 0%     |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied





Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male   |         |      |       | Female |       |       |        |      |      |    |    |    |
|---|-------|--------|---------|------|-------|--------|-------|-------|--------|------|------|----|----|----|
| <b>#Intestine Small: Jejunum:<br/>Hemangiosarcoma</b> |       |        |         |      |       |        |       |       |        |      |      |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 1/50   | (2%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
| <b>Overall Incidence</b>                              | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD     | 0.37% | Total | 0/1498 | (0%) | Mean | 0% | SD | 0% |

|  |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|--|-------|--------|---------|------|-------|------|-------|-------|--------|---------|------|-------|----|-------|
| <b>#Intestine Small: Jejunum:<br/>Leiomyosarcoma</b> |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|  |       | 0/50   | (0%)    | 1/50 | (2%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (2%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>                             | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total | 1/1498 | (0.07%) | Mean | 0.07% | SD | 0.37% |

|   |       |        |         |      |       |      |       |       |        |      |      |    |    |    |
|---|-------|--------|---------|------|-------|------|-------|-------|--------|------|------|----|----|----|
| <b>#Intestine Small: Jejunum:<br/>Polyp Adenomatous</b> |       |        |         |      |       |      |       |       |        |      |      |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|   |       | 0/50   | (0%)    | 1/49 | (2%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
| <b>Overall Incidence</b>                                | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD   | 0.38% | Total | 0/1498 | (0%) | Mean | 0% | SD | 0% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male            |            |           |           |           | Female          |            |           |           |           |
|---|-------|-----------------|------------|-----------|-----------|-----------|-----------------|------------|-----------|-----------|-----------|
| <b>#Intestine Small: Site Unspecified: Adenoma</b>              |       |                 |            |           |           |           |                 |            |           |           |           |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|   |       | 2/50 (4%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | 1/50 (2%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 3/50 (6%)       | 0/49 (0%)  | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 11/1449 (0.76%) | Mean 0.76% | SD 1.46%  |           | Total     | 5/1498 (0.33%)  | Mean 0.33% | SD 0.92%  |           |           |
| .....   |       |                 |            |           |           |           |                 |            |           |           |           |
| <b>#Intestine Small: Site Unspecified: Carcinoma</b>            |       |                 |            |           |           |           |                 |            |           |           |           |
|   |       | 3/50 (6%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 4/50 (8%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 2/50 (4%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 2/50 (4%)       | 0/49 (0%)  | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 23/1449 (1.59%) | Mean 1.59% | SD 2.23%  |           | Total     | 5/1498 (0.33%)  | Mean 0.33% | SD 0.76%  |           |           |
| .....   |       |                 |            |           |           |           |                 |            |           |           |           |
| <b>#Intestine Small: Site Unspecified: Carcinoma or Adenoma</b> |       |                 |            |           |           |           |                 |            |           |           |           |
|   |       | 3/50 (6%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 4/50 (8%)       | 3/50 (6%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 2/50 (4%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 3/50 (6%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | 1/50 (2%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 5/50 (10%)      | 0/49 (0%)  | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 33/1449 (2.28%) | Mean 2.28% | SD 2.76%  |           | Total     | 10/1498 (0.67%) | Mean 0.67% | SD 1.21%  |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

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 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male           |            |           |           | Female      |           |           |           |
|--|-------|----------------|------------|-----------|-----------|-------------|-----------|-----------|-----------|
| <b>#Intestine Small: Site Unspecified: Hemangiosarcoma</b> |       |                |            |           |           |             |           |           |           |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                   | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 0/1498 (0%) | Mean 0%   | SD 0%     |           |

|   |       |                |            |           |           |                |            |           |           |
|---|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b> |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                  | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |

|  |       |                |            |           |           |                |            |           |           |
|--|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Intestine Small: Site Unspecified: Polyp Adenomatous</b> |       |                |            |           |           |                |            |           |           |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) |
|  |       | 0/50 (0%)      | 1/49 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                     | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                             |              | Male            |            |           |  |           | Female          |            |          |  |  |
|-----------------------------|--------------|-----------------|------------|-----------|--|-----------|-----------------|------------|----------|--|--|
| <b>*Islets, Pancreatic:</b> |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>Adenoma</b>              |              |                 |            |           |  |           |                 |            |          |  |  |
|                             |              | 2/50 (4%)       | 4/50 (8%)  | 0/50 (0%) |  | 0/49 (0%) | 1/48 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/48 (0%)       | 1/50 (2%)  |           |  | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/50 (0%)  | 2/50 (4%) |  | 1/49 (2%) | 1/50 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 1/49 (2%)       | 0/50 (0%)  | 1/50 (2%) |  | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  |          |  |  |
|                             |              | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 1/48 (2%) | 0/50 (0%)       | 0/47 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 1/49 (2%)  | 0/50 (0%) |  | 1/50 (2%) | 0/50 (0%)       | 1/46 (2%)  |          |  |  |
|                             |              | 0/49 (0%)       | 0/50 (0%)  | 0/49 (0%) |  | 0/49 (0%) | 0/49 (0%)       | 0/49 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 1/49 (2%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |          |  |  |
|                             |              | 3/49 (6%)       | 0/50 (0%)  | 2/49 (4%) |  | 1/49 (2%) | 1/49 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 1/50 (2%)       | 0/46 (0%)  | 1/50 (2%) |  | 1/49 (2%) | 1/49 (2%)       | 1/49 (2%)  |          |  |  |
| <b>Overall Incidence</b>    | <b>Total</b> | 20/1436 (1.39%) | Mean 1.39% | SD 2.09%  |  | Total     | 13/1478 (0.88%) | Mean 0.89% | SD 1.03% |  |  |
| .....                       |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>*Islets, Pancreatic:</b> |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>Carcinoma</b>            |              |                 |            |           |  |           |                 |            |          |  |  |
|                             |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/49 (0%) | 0/48 (0%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/48 (0%)       | 0/50 (0%)  |           |  | 0/50 (0%) | 2/50 (4%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/49 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/49 (0%)       | 0/50 (0%)  | 1/50 (2%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/48 (0%) | 0/50 (0%)       | 0/47 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/46 (0%)  |          |  |  |
|                             |              | 0/49 (0%)       | 1/50 (2%)  | 0/49 (0%) |  | 0/49 (0%) | 0/49 (0%)       | 0/49 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 1/50 (2%)       | 0/49 (0%)  |          |  |  |
|                             |              | 0/49 (0%)       | 2/50 (4%)  | 0/49 (0%) |  | 0/49 (0%) | 1/49 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/46 (0%)  | 0/50 (0%) |  | 0/49 (0%) | 0/49 (0%)       | 0/49 (0%)  |          |  |  |
| <b>Overall Incidence</b>    | <b>Total</b> | 4/1436 (0.28%)  | Mean 0.28% | SD 0.88%  |  | Total     | 4/1478 (0.27%)  | Mean 0.27% | SD 0.87% |  |  |
| .....                       |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>*Islets, Pancreatic:</b> |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>Carcinoma or Adenoma</b> |              |                 |            |           |  |           |                 |            |          |  |  |
|                             |              | 2/50 (4%)       | 4/50 (8%)  | 0/50 (0%) |  | 0/49 (0%) | 1/48 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 0/48 (0%)       | 1/50 (2%)  |           |  | 0/50 (0%) | 2/50 (4%)       | 1/50 (2%)  |          |  |  |
|                             |              | 0/50 (0%)       | 0/50 (0%)  | 2/50 (4%) |  | 1/49 (2%) | 1/50 (2%)       | 0/50 (0%)  |          |  |  |
|                             |              | 1/49 (2%)       | 0/50 (0%)  | 2/50 (4%) |  | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  |          |  |  |
|                             |              | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 1/48 (2%) | 0/50 (0%)       | 0/47 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 1/49 (2%)  | 0/50 (0%) |  | 1/50 (2%) | 0/50 (0%)       | 1/46 (2%)  |          |  |  |
|                             |              | 0/49 (0%)       | 1/50 (2%)  | 0/49 (0%) |  | 0/49 (0%) | 0/49 (0%)       | 0/49 (0%)  |          |  |  |
|                             |              | 0/50 (0%)       | 1/49 (2%)  | 0/50 (0%) |  | 0/50 (0%) | 1/50 (2%)       | 0/49 (0%)  |          |  |  |
|                             |              | 3/49 (6%)       | 2/50 (4%)  | 2/49 (4%) |  | 1/49 (2%) | 2/49 (4%)       | 0/50 (0%)  |          |  |  |
|                             |              | 1/50 (2%)       | 0/46 (0%)  | 1/50 (2%) |  | 1/49 (2%) | 1/49 (2%)       | 1/49 (2%)  |          |  |  |
| <b>Overall Incidence</b>    | <b>Total</b> | 24/1436 (1.67%) | Mean 1.67% | SD 2.16%  |  | Total     | 17/1478 (1.15%) | Mean 1.15% | SD 1.27% |  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male            |            |           |           |           | Female         |            |           |           |           |
|--|-------|-----------------|------------|-----------|-----------|-----------|----------------|------------|-----------|-----------|-----------|
| <b>*Kidney: Renal Tubule: Adenoma</b>              |       |                 |            |           |           |           |                |            |           |           |           |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/48 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) |
|  |       | 1/50 (2%)       | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/48 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 1/50 (2%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 4/50 (8%)       | 1/49 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                           | Total | 11/1443 (0.76%) | Mean 0.76% | SD 1.73%  |           | Total     | 1/1489 (0.07%) | Mean 0.07% | SD 0.37%  |           |           |
| .....  |       |                 |            |           |           |           |                |            |           |           |           |
| <b>*Kidney: Renal Tubule: Carcinoma</b>            |       |                 |            |           |           |           |                |            |           |           |           |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/48 (0%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/48 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                           | Total | 3/1443 (0.21%)  | Mean 0.21% | SD 0.62%  |           | Total     | 0/1489 (0%)    | Mean 0%    | SD 0%     |           |           |
| .....  |       |                 |            |           |           |           |                |            |           |           |           |
| <b>*Kidney: Renal Tubule: Carcinoma or Adenoma</b> |       |                 |            |           |           |           |                |            |           |           |           |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/49 (0%)       | 3/50 (6%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/48 (0%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) |
|  |       | 1/50 (2%)       | 0/50 (0%)  | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/48 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 1/50 (2%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) |
|  |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|  |       | 4/50 (8%)       | 1/49 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                           | Total | 14/1443 (0.97%) | Mean 0.97% | SD 1.9%   |           | Total     | 1/1489 (0.07%) | Mean 0.07% | SD 0.37%  |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

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|   |       | Male   |         |      |       |      |       | Female |        |         |      |       |      |       |
|---|-------|--------|---------|------|-------|------|-------|--------|--------|---------|------|-------|------|-------|
| <b>*Kidney: Renal Tubule: Hemangioma</b>                  |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/49   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/48   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/47  | (0%) |       |
|   |       | 1/50   | (2%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/48  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>                                  | Total | 1/1443 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total  | 0/1489 | (0%)    | Mean | 0%    | SD   | 0%    |
| .....   |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>*Kidney: Renal Tubule: Hemangiosarcoma</b>             |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/49   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/48   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/47  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/48  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|   |       | 0/50   | (0%)    | 1/50 | (2%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>                                  | Total | 1/1443 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total  | 0/1489 | (0%)    | Mean | 0%    | SD   | 0%    |
| .....   |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>*Kidney: Renal Tubule: Plasma Cell Tumor Malignant</b> |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 1/50    | (2%) | 0/50  | (0%) |       |
|   |       | 0/49   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/48   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/47  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/48  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|   |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>                                  | Total | 0/1443 | (0%)    | Mean | 0%    | SD   | 0%    | Total  | 1/1489 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                           |              | Male   |         |      |       | Female |       |       |        |      |      |    |    |    |
|---------------------------|--------------|--------|---------|------|-------|--------|-------|-------|--------|------|------|----|----|----|
| <b>*Liver:</b>            |              |        |         |      |       |        |       |       |        |      |      |    |    |    |
| <b>Cholangiocarcinoma</b> |              |        |         |      |       |        |       |       |        |      |      |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/49 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)  | 0/49  | (0%)   | 0/50 | (0%) |    |    |    |
|                           |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50 | (0%) |    |    |    |
| <b>Overall Incidence</b>  | <b>Total</b> | 1/1447 | (0.07%) | Mean | 0.07% | SD     | 0.37% | Total | 0/1495 | (0%) | Mean | 0% | SD | 0% |

|                             |              |        |      |      |      |      |      |       |        |         |      |       |    |       |
|-----------------------------|--------------|--------|------|------|------|------|------|-------|--------|---------|------|-------|----|-------|
| <b>*Liver:</b>              |              |        |      |      |      |      |      |       |        |         |      |       |    |       |
| <b>Fibrous Histiocytoma</b> |              |        |      |      |      |      |      |       |        |         |      |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 1/50    | (2%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/49  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |              | 0/50   | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
| <b>Overall Incidence</b>    | <b>Total</b> | 0/1447 | (0%) | Mean | 0%   | SD   | 0%   | Total | 1/1495 | (0.07%) | Mean | 0.07% | SD | 0.37% |

|                          |              |        |         |      |       |      |      |       |        |        |      |      |    |       |
|--------------------------|--------------|--------|---------|------|-------|------|------|-------|--------|--------|------|------|----|-------|
| <b>*Liver:</b>           |              |        |         |      |       |      |      |       |        |        |      |      |    |       |
| <b>Hemangioma</b>        |              |        |         |      |       |      |      |       |        |        |      |      |    |       |
|                          |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/50   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/50   | (0%) |      |    |       |
|                          |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/50   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/50   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/49   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 1/50 | (2%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/50   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 1/50   | (2%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%) | 0/50  | (0%)   | 0/49   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%) | 1/49  | (2%)   | 0/49   | (0%) |      |    |       |
|                          |              | 0/50   | (0%)    | 0/49 | (0%)  | 1/50 | (2%) | 0/50  | (0%)   | 1/49   | (2%) |      |    |       |
| <b>Overall Incidence</b> | <b>Total</b> | 4/1447 | (0.28%) | Mean | 0.28% | SD   | 0.7% | Total | 3/1495 | (0.2%) | Mean | 0.2% | SD | 0.62% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
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**Toxicology Data Management System**  
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|                          |              | Male           |           |           |              | Female       |           |          |  |
|--------------------------|--------------|----------------|-----------|-----------|--------------|--------------|-----------|----------|--|
| <b>*Liver:</b>           |              |                |           |           |              |              |           |          |  |
| <b>Hemangiosarcoma</b>   |              |                |           |           |              |              |           |          |  |
|                          |              | 3/50 (6%)      | 2/50 (4%) | 1/50 (2%) | 0/50 (0%)    | 1/50 (2%)    | 2/50 (4%) |          |  |
|                          |              | 1/50 (2%)      | 2/50 (4%) |           | 0/50 (0%)    | 0/50 (0%)    | 0/50 (0%) |          |  |
|                          |              | 0/50 (0%)      | 1/50 (2%) | 2/50 (4%) | 0/50 (0%)    | 1/50 (2%)    | 1/50 (2%) |          |  |
|                          |              | 0/50 (0%)      | 1/50 (2%) | 2/50 (4%) | 1/50 (2%)    | 0/50 (0%)    | 0/50 (0%) |          |  |
|                          |              | 0/50 (0%)      | 1/50 (2%) | 1/50 (2%) | 0/50 (0%)    | 0/50 (0%)    | 0/49 (0%) |          |  |
|                          |              | 5/50 (10%)     | 2/50 (4%) | 2/50 (4%) | 1/50 (2%)    | 1/50 (2%)    | 0/50 (0%) |          |  |
|                          |              | 0/50 (0%)      | 4/50 (8%) | 0/50 (0%) | 0/50 (0%)    | 1/50 (2%)    | 0/50 (0%) |          |  |
|                          |              | 5/50 (10%)     | 1/49 (2%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)    | 0/49 (0%) |          |  |
|                          |              | 1/50 (2%)      | 1/50 (2%) | 1/49 (2%) | 1/49 (2%)    | 0/49 (0%)    | 2/50 (4%) |          |  |
|                          |              | 2/50 (4%)      | 1/49 (2%) | 0/50 (0%) | 0/50 (0%)    | 1/49 (2%)    | 2/50 (4%) |          |  |
| <b>Overall Incidence</b> | <b>Total</b> | 42/1447 (2.9%) | Mean 2.9% | SD 2.75%  | <b>Total</b> | 15/1495 (1%) | Mean 1%   | SD 1.37% |  |

|                          |              |                 |            |           |              |                |            |         |  |
|--------------------------|--------------|-----------------|------------|-----------|--------------|----------------|------------|---------|--|
| <b>*Liver:</b>           |              |                 |            |           |              |                |            |         |  |
| <b>Hepatoblastoma</b>    |              |                 |            |           |              |                |            |         |  |
|                          |              | 3/50 (6%)       | 3/50 (6%)  | 2/50 (4%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  |         |  |
|                          |              | 1/50 (2%)       | 0/50 (0%)  |           | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  |         |  |
|                          |              | 1/50 (2%)       | 2/50 (4%)  | 1/50 (2%) | 0/50 (0%)    | 1/50 (2%)      | 0/50 (0%)  |         |  |
|                          |              | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  |         |  |
|                          |              | 1/50 (2%)       | 1/50 (2%)  | 3/50 (6%) | 0/50 (0%)    | 1/50 (2%)      | 0/49 (0%)  |         |  |
|                          |              | 0/50 (0%)       | 0/50 (0%)  | 2/50 (4%) | 0/50 (0%)    | 1/50 (2%)      | 0/50 (0%)  |         |  |
|                          |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  |         |  |
|                          |              | 4/50 (8%)       | 0/49 (0%)  | 1/50 (2%) | 0/50 (0%)    | 0/50 (0%)      | 0/49 (0%)  |         |  |
|                          |              | 17/50 (34%)     | 2/50 (4%)  | 0/49 (0%) | 0/49 (0%)    | 0/49 (0%)      | 0/50 (0%)  |         |  |
|                          |              | 4/50 (8%)       | 0/49 (0%)  | 1/50 (2%) | 0/50 (0%)    | 1/49 (2%)      | 0/50 (0%)  |         |  |
| <b>Overall Incidence</b> | <b>Total</b> | 51/1447 (3.52%) | Mean 3.52% | SD 6.36%  | <b>Total</b> | 4/1495 (0.27%) | Mean 0.27% | SD 0.7% |  |

|                               |              |                  |             |             |              |                   |             |           |  |
|-------------------------------|--------------|------------------|-------------|-------------|--------------|-------------------|-------------|-----------|--|
| <b>*Liver:</b>                |              |                  |             |             |              |                   |             |           |  |
| <b>Hepatocellular Adenoma</b> |              |                  |             |             |              |                   |             |           |  |
|                               |              | 32/50 (64%)      | 24/50 (48%) | 33/50 (66%) | 14/50 (28%)  | 13/50 (26%)       | 22/50 (44%) |           |  |
|                               |              | 30/50 (60%)      | 21/50 (42%) |             | 19/50 (38%)  | 1/50 (2%)         | 4/50 (8%)   |           |  |
|                               |              | 34/50 (68%)      | 35/50 (70%) | 28/50 (56%) | 18/50 (36%)  | 31/50 (62%)       | 14/50 (28%) |           |  |
|                               |              | 18/50 (36%)      | 24/50 (48%) | 34/50 (68%) | 21/50 (42%)  | 6/50 (12%)        | 21/50 (42%) |           |  |
|                               |              | 22/50 (44%)      | 33/50 (66%) | 24/50 (48%) | 3/50 (6%)    | 14/50 (28%)       | 11/49 (22%) |           |  |
|                               |              | 27/50 (54%)      | 17/50 (34%) | 28/50 (56%) | 8/50 (16%)   | 13/50 (26%)       | 15/50 (30%) |           |  |
|                               |              | 17/50 (34%)      | 24/50 (48%) | 12/50 (24%) | 4/50 (8%)    | 10/50 (20%)       | 3/50 (6%)   |           |  |
|                               |              | 26/50 (52%)      | 21/49 (43%) | 22/50 (44%) | 6/50 (12%)   | 15/50 (30%)       | 13/49 (27%) |           |  |
|                               |              | 36/50 (72%)      | 22/50 (44%) | 33/49 (67%) | 14/49 (29%)  | 3/49 (6%)         | 14/50 (28%) |           |  |
|                               |              | 27/50 (54%)      | 18/49 (37%) | 29/50 (58%) | 27/50 (54%)  | 19/49 (39%)       | 19/50 (38%) |           |  |
| <b>Overall Incidence</b>      | <b>Total</b> | 751/1447 (51.9%) | Mean 51.89% | SD 12.69%   | <b>Total</b> | 395/1495 (26.42%) | Mean 26.41% | SD 14.94% |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
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|                                 |       | Male              |             |             |       | Female           |            |             |  |
|---------------------------------|-------|-------------------|-------------|-------------|-------|------------------|------------|-------------|--|
| <b>*Liver:</b>                  |       |                   |             |             |       |                  |            |             |  |
| <b>Hepatocellular Carcinoma</b> |       |                   |             |             |       |                  |            |             |  |
|                                 |       | 26/50 (52%)       | 16/50 (32%) | 14/50 (28%) |       | 5/50 (10%)       | 3/50 (6%)  | 3/50 (6%)   |  |
|                                 |       | 15/50 (30%)       | 15/50 (30%) |             |       | 5/50 (10%)       | 3/50 (6%)  | 1/50 (2%)   |  |
|                                 |       | 13/50 (26%)       | 17/50 (34%) | 20/50 (40%) |       | 10/50 (20%)      | 8/50 (16%) | 4/50 (8%)   |  |
|                                 |       | 20/50 (40%)       | 15/50 (30%) | 14/50 (28%) |       | 10/50 (20%)      | 4/50 (8%)  | 2/50 (4%)   |  |
|                                 |       | 8/50 (16%)        | 11/50 (22%) | 8/50 (16%)  |       | 3/50 (6%)        | 2/50 (4%)  | 3/49 (6%)   |  |
|                                 |       | 20/50 (40%)       | 12/50 (24%) | 13/50 (26%) |       | 3/50 (6%)        | 6/50 (12%) | 5/50 (10%)  |  |
|                                 |       | 10/50 (20%)       | 10/50 (20%) | 17/50 (34%) |       | 1/50 (2%)        | 3/50 (6%)  | 0/50 (0%)   |  |
|                                 |       | 14/50 (28%)       | 10/49 (20%) | 13/50 (26%) |       | 1/50 (2%)        | 4/50 (8%)  | 5/49 (10%)  |  |
|                                 |       | 14/50 (28%)       | 17/50 (34%) | 11/49 (22%) |       | 8/49 (16%)       | 2/49 (4%)  | 7/50 (14%)  |  |
|                                 |       | 19/50 (38%)       | 14/49 (29%) | 24/50 (48%) |       | 14/50 (28%)      | 3/49 (6%)  | 10/50 (20%) |  |
| <b>Overall Incidence</b>        | Total | 430/1447 (29.72%) | Mean 29.7%  | SD 8.72%    | Total | 138/1495 (9.23%) | Mean 9.23% | SD 6.54%    |  |

|   |       |                |             |             |       |                  |            |             |  |
|---|-------|----------------|-------------|-------------|-------|------------------|------------|-------------|--|
| <b>*Liver:</b>                                    |       |                |             |             |       |                  |            |             |  |
| <b>Hepatocellular Carcinoma or Hepatoblastoma</b> |       |                |             |             |       |                  |            |             |  |
|   |       | 27/50 (54%)    | 18/50 (36%) | 15/50 (30%) |       | 5/50 (10%)       | 3/50 (6%)  | 3/50 (6%)   |  |
|   |       | 16/50 (32%)    | 15/50 (30%) |             |       | 5/50 (10%)       | 3/50 (6%)  | 1/50 (2%)   |  |
|   |       | 14/50 (28%)    | 19/50 (38%) | 20/50 (40%) |       | 10/50 (20%)      | 9/50 (18%) | 4/50 (8%)   |  |
|   |       | 20/50 (40%)    | 16/50 (32%) | 14/50 (28%) |       | 10/50 (20%)      | 4/50 (8%)  | 2/50 (4%)   |  |
|   |       | 9/50 (18%)     | 12/50 (24%) | 11/50 (22%) |       | 3/50 (6%)        | 3/50 (6%)  | 3/49 (6%)   |  |
|   |       | 20/50 (40%)    | 12/50 (24%) | 15/50 (30%) |       | 3/50 (6%)        | 6/50 (12%) | 5/50 (10%)  |  |
|   |       | 10/50 (20%)    | 10/50 (20%) | 17/50 (34%) |       | 1/50 (2%)        | 3/50 (6%)  | 0/50 (0%)   |  |
|   |       | 16/50 (32%)    | 10/49 (20%) | 13/50 (26%) |       | 1/50 (2%)        | 4/50 (8%)  | 5/49 (10%)  |  |
|   |       | 25/50 (50%)    | 19/50 (38%) | 11/49 (22%) |       | 8/49 (16%)       | 2/49 (4%)  | 7/50 (14%)  |  |
|   |       | 21/50 (42%)    | 14/49 (29%) | 24/50 (48%) |       | 14/50 (28%)      | 4/49 (8%)  | 10/50 (20%) |  |
| <b>Overall Incidence</b>                          | Total | 463/1447 (32%) | Mean 31.98% | SD 9.41%    | Total | 141/1495 (9.43%) | Mean 9.43% | SD 6.55%    |  |

|   |       |                |             |             |       |                   |             |             |  |
|---|-------|----------------|-------------|-------------|-------|-------------------|-------------|-------------|--|
| <b>*Liver:</b>  |       |                |             |             |       |                   |             |             |  |
| <b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b> |       |                |             |             |       |                   |             |             |  |
|   |       | 41/50 (82%)    | 33/50 (66%) | 40/50 (80%) |       | 17/50 (34%)       | 15/50 (30%) | 22/50 (44%) |  |
|   |       | 38/50 (76%)    | 32/50 (64%) |             |       | 24/50 (48%)       | 4/50 (8%)   | 4/50 (8%)   |  |
|   |       | 40/50 (80%)    | 41/50 (82%) | 40/50 (80%) |       | 25/50 (50%)       | 32/50 (64%) | 16/50 (32%) |  |
|   |       | 35/50 (70%)    | 33/50 (66%) | 39/50 (78%) |       | 29/50 (58%)       | 9/50 (18%)  | 23/50 (46%) |  |
|   |       | 26/50 (52%)    | 39/50 (78%) | 28/50 (56%) |       | 6/50 (12%)        | 14/50 (28%) | 13/49 (27%) |  |
|   |       | 38/50 (76%)    | 27/50 (54%) | 37/50 (74%) |       | 10/50 (20%)       | 17/50 (34%) | 19/50 (38%) |  |
|   |       | 23/50 (46%)    | 28/50 (56%) | 26/50 (52%) |       | 5/50 (10%)        | 13/50 (26%) | 3/50 (6%)   |  |
|   |       | 33/50 (66%)    | 26/49 (53%) | 29/50 (58%) |       | 7/50 (14%)        | 17/50 (34%) | 17/49 (35%) |  |
|   |       | 42/50 (84%)    | 34/50 (68%) | 37/49 (76%) |       | 17/49 (35%)       | 4/49 (8%)   | 20/50 (40%) |  |
|   |       | 34/50 (68%)    | 28/49 (57%) | 37/50 (74%) |       | 31/50 (62%)       | 22/49 (45%) | 27/50 (54%) |  |
| <b>Overall Incidence</b>                                  | Total | 984/1447 (68%) | Mean 67.99% | SD 11.16%   | Total | 482/1495 (32.24%) | Mean 32.23% | SD 16.94%   |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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 Vehicle: ALL VEHICLES

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|  |              | Male              |             |             |              | Female            |             |             |  |
|--|--------------|-------------------|-------------|-------------|--------------|-------------------|-------------|-------------|--|
| <b>*Liver:</b>   |              |                   |             |             |              |                   |             |             |  |
| <b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b> |              |                   |             |             |              |                   |             |             |  |
|  |              | 41/50 (82%)       | 33/50 (66%) | 40/50 (80%) |              | 17/50 (34%)       | 15/50 (30%) | 22/50 (44%) |  |
|  |              | 38/50 (76%)       | 32/50 (64%) |             |              | 24/50 (48%)       | 4/50 (8%)   | 4/50 (8%)   |  |
|  |              | 41/50 (82%)       | 41/50 (82%) | 40/50 (80%) |              | 25/50 (50%)       | 32/50 (64%) | 16/50 (32%) |  |
|  |              | 35/50 (70%)       | 34/50 (68%) | 39/50 (78%) |              | 29/50 (58%)       | 9/50 (18%)  | 23/50 (46%) |  |
|  |              | 26/50 (52%)       | 39/50 (78%) | 30/50 (60%) |              | 6/50 (12%)        | 15/50 (30%) | 13/49 (27%) |  |
|  |              | 38/50 (76%)       | 27/50 (54%) | 38/50 (76%) |              | 10/50 (20%)       | 17/50 (34%) | 19/50 (38%) |  |
|  |              | 23/50 (46%)       | 28/50 (56%) | 26/50 (52%) |              | 5/50 (10%)        | 13/50 (26%) | 3/50 (6%)   |  |
|  |              | 34/50 (68%)       | 26/49 (53%) | 29/50 (58%) |              | 7/50 (14%)        | 17/50 (34%) | 17/49 (35%) |  |
|  |              | 46/50 (92%)       | 34/50 (68%) | 37/49 (76%) |              | 17/49 (35%)       | 4/49 (8%)   | 20/50 (40%) |  |
|  |              | 35/50 (70%)       | 28/49 (57%) | 37/50 (74%) |              | 31/50 (62%)       | 22/49 (45%) | 27/50 (54%) |  |
| <b>Overall Incidence</b>   | <b>Total</b> | 995/1447 (68.76%) | Mean 68.75% | SD 11.63%   | <b>Total</b> | 483/1495 (32.31%) | Mean 32.3%  | SD 16.93%   |  |

|                                 |              |                 |            |           |              |                |            |           |  |
|---------------------------------|--------------|-----------------|------------|-----------|--------------|----------------|------------|-----------|--|
| <b>*Liver:</b>                  |              |                 |            |           |              |                |            |           |  |
| <b>Hepatocholangiocarcinoma</b> |              |                 |            |           |              |                |            |           |  |
|                                 |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|                                 |              | 1/50 (2%)       | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|                                 |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|                                 |              | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|                                 |              | 1/50 (2%)       | 0/50 (0%)  | 2/50 (4%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|                                 |              | 4/50 (8%)       | 5/50 (10%) | 0/50 (0%) |              | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) |  |
|                                 |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|                                 |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|                                 |              | 0/50 (0%)       | 1/50 (2%)  | 0/49 (0%) |              | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) |  |
|                                 |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |  |
| <b>Overall Incidence</b>        | <b>Total</b> | 15/1447 (1.04%) | Mean 1.03% | SD 2.43%  | <b>Total</b> | 1/1495 (0.07%) | Mean 0.07% | SD 0.37%  |  |

|                          |              |                |            |           |              |             |           |           |  |
|--------------------------|--------------|----------------|------------|-----------|--------------|-------------|-----------|-----------|--|
| <b>*Liver:</b>           |              |                |            |           |              |             |           |           |  |
| <b>Hepatocholangioma</b> |              |                |            |           |              |             |           |           |  |
|                          |              | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/49 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/49 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |              | 0/49 (0%)   | 0/49 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) |  |
| <b>Overall Incidence</b> | <b>Total</b> | 1/1447 (0.07%) | Mean 0.07% | SD 0.37%  | <b>Total</b> | 0/1495 (0%) | Mean 0%   | SD 0%     |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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|                              |              | Male   |         |      |       |      |       | Female |        |      |      |      |      |    |
|------------------------------|--------------|--------|---------|------|-------|------|-------|--------|--------|------|------|------|------|----|
| <b>*Liver:</b>               |              |        |         |      |       |      |       |        |        |      |      |      |      |    |
| <b>Ito Cell Tumor Benign</b> |              |        |         |      |       |      |       |        |        |      |      |      |      |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 1/50 | (2%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/49 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50 | (0%) | 0/49 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49   | (0%)   | 0/49 | (0%) | 0/50 | (0%) |    |
|                              |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49 | (0%) | 0/50 | (0%) |    |
| <b>Overall Incidence</b>     | <b>Total</b> | 1/1447 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total  | 0/1495 | (0%) | Mean | 0%   | SD   | 0% |

|                                 |              |        |         |      |       |      |       |       |        |      |      |      |      |    |
|---------------------------------|--------------|--------|---------|------|-------|------|-------|-------|--------|------|------|------|------|----|
| <b>*Liver:</b>                  |              |        |         |      |       |      |       |       |        |      |      |      |      |    |
| <b>Ito Cell Tumor Malignant</b> |              |        |         |      |       |      |       |       |        |      |      |      |      |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  |      |       | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/49 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 1/50 | (2%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/50 | (0%) |    |
|                                 |              | 2/50   | (4%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50 | (0%) | 0/49 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49  | (0%)   | 0/49 | (0%) | 0/50 | (0%) |    |
|                                 |              | 0/50   | (0%)    | 0/49 | (0%)  | 2/50 | (4%)  | 0/50  | (0%)   | 0/49 | (0%) | 0/50 | (0%) |    |
| <b>Overall Incidence</b>        | <b>Total</b> | 5/1447 | (0.35%) | Mean | 0.34% | SD   | 1.08% | Total | 0/1495 | (0%) | Mean | 0%   | SD   | 0% |

|                                    |              |        |      |      |      |      |      |       |        |         |      |       |      |       |
|------------------------------------|--------------|--------|------|------|------|------|------|-------|--------|---------|------|-------|------|-------|
| <b>*Liver:</b>                     |              |        |      |      |      |      |      |       |        |         |      |       |      |       |
| <b>Plasma Cell Tumor Malignant</b> |              |        |      |      |      |      |      |       |        |         |      |       |      |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 1/50    | (2%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) |      |      | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/49  | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                                    |              | 0/50   | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/50  | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>           | <b>Total</b> | 0/1447 | (0%) | Mean | 0%   | SD   | 0%   | Total | 1/1495 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
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 Vehicle: ALL VEHICLES

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|                                     |              | Male     |          |             |          | Female       |         |         |            |          |       |
|-------------------------------------|--------------|----------|----------|-------------|----------|--------------|---------|---------|------------|----------|-------|
| <b>*Liver:</b>                      |              |          |          |             |          |              |         |         |            |          |       |
| <b>Sarcoma</b>                      |              |          |          |             |          |              |         |         |            |          |       |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 1/50    | (2%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/49        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/49         | (0%)    | 0/49    | (0%)       | 0/49     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/49        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/49     | (2%)  |
| <b>Overall Incidence</b>            | <b>Total</b> | 0/1447   | (0%)     | Mean 0%     | SD 0%    | <b>Total</b> | 2/1495  | (0.13%) | Mean 0.13% | SD 0.51% |       |
| .....                               |              |          |          |             |          |              |         |         |            |          |       |
| <b>*Lung:</b>                       |              |          |          |             |          |              |         |         |            |          |       |
| <b>Adenoma</b>                      |              |          |          |             |          |              |         |         |            |          |       |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/48     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
|                                     |              | 0/50     | (0%)     | 1/50        | (2%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%)  |
|                                     |              | 0/50     | (0%)     | 0/50        | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%)  |
|                                     |              | 0/50     | (0%)     | 1/49        | (2%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%)  |
| <b>Overall Incidence</b>            | <b>Total</b> | 2/1449   | (0.14%)  | Mean 0.14%  | SD 0.52% | <b>Total</b> | 0/1496  | (0%)    | Mean 0%    | SD 0%    |       |
| .....                               |              |          |          |             |          |              |         |         |            |          |       |
| <b>*Lung:</b>                       |              |          |          |             |          |              |         |         |            |          |       |
| <b>Alveolar/Bronchiolar Adenoma</b> |              |          |          |             |          |              |         |         |            |          |       |
|                                     |              | 7/50     | (14%)    | 7/50        | (14%)    | 6/50         | (12%)   | 0/50    | (0%)       | 3/50     | (6%)  |
|                                     |              | 6/50     | (12%)    | 13/50       | (26%)    | 1/50         | (2%)    | 1/50    | (2%)       | 5/50     | (10%) |
|                                     |              | 13/50    | (26%)    | 10/50       | (20%)    | 4/50         | (8%)    | 1/50    | (2%)       | 2/50     | (4%)  |
|                                     |              | 6/50     | (12%)    | 10/50       | (20%)    | 9/50         | (18%)   | 4/50    | (8%)       | 4/50     | (8%)  |
|                                     |              | 4/50     | (8%)     | 10/50       | (20%)    | 6/50         | (12%)   | 4/50    | (8%)       | 2/50     | (4%)  |
|                                     |              | 9/50     | (18%)    | 9/50        | (18%)    | 11/50        | (22%)   | 2/50    | (4%)       | 4/50     | (8%)  |
|                                     |              | 8/50     | (16%)    | 8/50        | (16%)    | 1/50         | (2%)    | 0/50    | (0%)       | 1/50     | (2%)  |
|                                     |              | 8/50     | (16%)    | 10/50       | (20%)    | 6/50         | (12%)   | 4/50    | (8%)       | 3/50     | (6%)  |
|                                     |              | 15/50    | (30%)    | 5/50        | (10%)    | 10/50        | (20%)   | 1/50    | (2%)       | 3/49     | (6%)  |
|                                     |              | 4/50     | (8%)     | 7/49        | (14%)    | 6/50         | (12%)   | 2/50    | (4%)       | 1/50     | (2%)  |
| <b>Overall Incidence</b>            | <b>Total</b> | 228/1449 | (15.73%) | Mean 15.73% | SD 6.13% | <b>Total</b> | 73/1496 | (4.88%) | Mean 4.88% | SD 3.36% |       |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                       |              | Male              |             |             |              | Female          |            |            |  |
|---------------------------------------|--------------|-------------------|-------------|-------------|--------------|-----------------|------------|------------|--|
| <b>*Lung:</b>                         |              |                   |             |             |              |                 |            |            |  |
| <b>Alveolar/Bronchiolar Carcinoma</b> |              |                   |             |             |              |                 |            |            |  |
|                                       |              | 11/50 (22%)       | 6/50 (12%)  | 5/50 (10%)  |              | 4/50 (8%)       | 1/50 (2%)  | 4/50 (8%)  |  |
|                                       |              | 8/50 (16%)        | 3/50 (6%)   |             |              | 0/50 (0%)       | 1/50 (2%)  | 2/50 (4%)  |  |
|                                       |              | 9/50 (18%)        | 6/50 (12%)  | 12/50 (24%) |              | 3/50 (6%)       | 3/50 (6%)  | 3/50 (6%)  |  |
|                                       |              | 2/50 (4%)         | 6/50 (12%)  | 3/50 (6%)   |              | 0/50 (0%)       | 2/50 (4%)  | 1/50 (2%)  |  |
|                                       |              | 6/50 (12%)        | 7/50 (14%)  | 2/50 (4%)   |              | 1/50 (2%)       | 1/50 (2%)  | 0/48 (0%)  |  |
|                                       |              | 2/50 (4%)         | 5/50 (10%)  | 1/50 (2%)   |              | 2/50 (4%)       | 0/50 (0%)  | 5/50 (10%) |  |
|                                       |              | 2/50 (4%)         | 5/50 (10%)  | 10/50 (20%) |              | 3/50 (6%)       | 1/50 (2%)  | 1/50 (2%)  |  |
|                                       |              | 5/50 (10%)        | 7/50 (14%)  | 3/50 (6%)   |              | 2/50 (4%)       | 2/50 (4%)  | 2/49 (4%)  |  |
|                                       |              | 3/50 (6%)         | 3/50 (6%)   | 11/50 (22%) |              | 2/50 (4%)       | 0/49 (0%)  | 0/50 (0%)  |  |
|                                       |              | 12/50 (24%)       | 5/49 (10%)  | 4/50 (8%)   |              | 6/50 (12%)      | 1/50 (2%)  | 6/50 (12%) |  |
| <b>Overall Incidence</b>              | <b>Total</b> | 164/1449 (11.32%) | Mean 11.32% | SD 6.46%    | <b>Total</b> | 59/1496 (3.94%) | Mean 3.94% | SD 3.42%   |  |

|   |              |                   |             |             |              |                  |            |            |  |
|---|--------------|-------------------|-------------|-------------|--------------|------------------|------------|------------|--|
| <b>*Lung:</b>   |              |                   |             |             |              |                  |            |            |  |
| <b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b> |              |                   |             |             |              |                  |            |            |  |
|   |              | 16/50 (32%)       | 13/50 (26%) | 11/50 (22%) |              | 4/50 (8%)        | 4/50 (8%)  | 5/50 (10%) |  |
|   |              | 13/50 (26%)       | 16/50 (32%) |             |              | 1/50 (2%)        | 2/50 (4%)  | 5/50 (10%) |  |
|   |              | 19/50 (38%)       | 15/50 (30%) | 15/50 (30%) |              | 4/50 (8%)        | 5/50 (10%) | 5/50 (10%) |  |
|   |              | 8/50 (16%)        | 16/50 (32%) | 12/50 (24%) |              | 4/50 (8%)        | 5/50 (10%) | 7/50 (14%) |  |
|   |              | 10/50 (20%)       | 16/50 (32%) | 7/50 (14%)  |              | 5/50 (10%)       | 3/50 (6%)  | 4/48 (8%)  |  |
|   |              | 11/50 (22%)       | 14/50 (28%) | 12/50 (24%) |              | 4/50 (8%)        | 4/50 (8%)  | 6/50 (12%) |  |
|   |              | 9/50 (18%)        | 13/50 (26%) | 11/50 (22%) |              | 3/50 (6%)        | 2/50 (4%)  | 2/50 (4%)  |  |
|   |              | 13/50 (26%)       | 17/50 (34%) | 9/50 (18%)  |              | 6/50 (12%)       | 5/50 (10%) | 3/49 (6%)  |  |
|   |              | 16/50 (32%)       | 7/50 (14%)  | 20/50 (40%) |              | 2/50 (4%)        | 3/49 (6%)  | 6/50 (12%) |  |
|   |              | 15/50 (30%)       | 12/49 (24%) | 10/50 (20%) |              | 8/50 (16%)       | 2/50 (4%)  | 9/50 (18%) |  |
| <b>Overall Incidence</b>  | <b>Total</b> | 376/1449 (25.95%) | Mean 25.95% | SD 6.77%    | <b>Total</b> | 128/1496 (8.56%) | Mean 8.55% | SD 3.7%    |  |

|                          |              |                |            |           |              |             |           |           |  |
|--------------------------|--------------|----------------|------------|-----------|--------------|-------------|-----------|-----------|--|
| <b>*Lung:</b>            |              |                |            |           |              |             |           |           |  |
| <b>Fibrosarcoma</b>      |              |                |            |           |              |             |           |           |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/48 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/49 (0%) |  |
|                          |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) |  |
|                          |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |  |
| <b>Overall Incidence</b> | <b>Total</b> | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | <b>Total</b> | 0/1496 (0%) | Mean 0%   | SD 0%     |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
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|                                    |              | Male   |         |            |          | Female       |        |         |            |          |      |
|------------------------------------|--------------|--------|---------|------------|----------|--------------|--------|---------|------------|----------|------|
| <b>*Lung:</b>                      |              |        |         |            |          |              |        |         |            |          |      |
| <b>Fibrous Histiocytoma</b>        |              |        |         |            |          |              |        |         |            |          |      |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 1/50    | (2%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/48     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>           | <b>Total</b> | 0/1449 | (0%)    | Mean 0%    | SD 0%    | <b>Total</b> | 1/1496 | (0.07%) | Mean 0.07% | SD 0.37% |      |
| .....                              |              |        |         |            |          |              |        |         |            |          |      |
| <b>*Lung:</b>                      |              |        |         |            |          |              |        |         |            |          |      |
| <b>Hemangiosarcoma</b>             |              |        |         |            |          |              |        |         |            |          |      |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/48     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 1/50   | (2%)    | 1/50       | (2%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|                                    |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>           | <b>Total</b> | 2/1449 | (0.14%) | Mean 0.14% | SD 0.52% | <b>Total</b> | 2/1496 | (0.13%) | Mean 0.13% | SD 0.51% |      |
| .....                              |              |        |         |            |          |              |        |         |            |          |      |
| <b>*Lung:</b>                      |              |        |         |            |          |              |        |         |            |          |      |
| <b>Plasma Cell Tumor Malignant</b> |              |        |         |            |          |              |        |         |            |          |      |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 1/50    | (2%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/48     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/49    | (0%)       | 0/50     | (0%) |
|                                    |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>           | <b>Total</b> | 0/1449 | (0%)    | Mean 0%    | SD 0%    | <b>Total</b> | 1/1496 | (0.07%) | Mean 0.07% | SD 0.37% |      |

.....  
 \*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied







Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

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 Vehicle: ALL VEHICLES

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|  |       | Male   |      |         |       | Female |        |         |            |          |      |
|--|-------|--------|------|---------|-------|--------|--------|---------|------------|----------|------|
| <b>#Lymph Node, Bronchial:<br/>Hemangiosarcoma</b>       |       |        |      |         |       |        |        |         |            |          |      |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/49    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>                                 | Total | 0/1449 | (0%) | Mean 0% | SD 0% | Total  | 1/1498 | (0.07%) | Mean 0.07% | SD 0.37% |      |
| .....  |       |        |      |         |       |        |        |         |            |          |      |
| <b>#Lymph Node, Mandibular:<br/>Fibrous Histiocytoma</b> |       |        |      |         |       |        |        |         |            |          |      |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/49    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>                                 | Total | 0/1449 | (0%) | Mean 0% | SD 0% | Total  | 1/1498 | (0.07%) | Mean 0.07% | SD 0.37% |      |
| .....  |       |        |      |         |       |        |        |         |            |          |      |
| <b>#Lymph Node, Mandibular:<br/>Hemangiosarcoma</b>      |       |        |      |         |       |        |        |         |            |          |      |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/49     | (0%) |
|  |       | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 1/50     | (2%) |
|  |       | 0/50   | (0%) | 0/49    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b>                                 | Total | 0/1449 | (0%) | Mean 0% | SD 0% | Total  | 2/1498 | (0.13%) | Mean 0.13% | SD 0.51% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male           |            |           |           | Female         |            |           |           |
|---|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Lymph Node, Mesenteric: Hemangioma</b>                  |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                    | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 0/1498 (0%)    | Mean 0%    | SD 0%     |           |
| .....   |       |                |            |           |           |                |            |           |           |
| <b>#Lymph Node, Mesenteric: Hemangiosarcoma</b>             |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                    | Total | 0/1449 (0%)    | Mean 0%    | SD 0%     | Total     | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |
| .....   |       |                |            |           |           |                |            |           |           |
| <b>#Lymph Node, Mesenteric: Plasma Cell Tumor Malignant</b> |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                                    | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total     | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |              | Male   |         |            |          | Female       |         |         |            |          |      |
|--------------------------|--------------|--------|---------|------------|----------|--------------|---------|---------|------------|----------|------|
| <b>#Mammary Gland:</b>   |              |        |         |            |          |              |         |         |            |          |      |
| <b>Adenocarcinoma</b>    |              |        |         |            |          |              |         |         |            |          |      |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/49     | (2%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b> | <b>Total</b> | 0/1449 | (0%)    | Mean 0%    | SD 0%    | <b>Total</b> | 1/1498  | (0.07%) | Mean 0.07% | SD 0.37% |      |
| .....                    |              |        |         |            |          |              |         |         |            |          |      |
| <b>#Mammary Gland:</b>   |              |        |         |            |          |              |         |         |            |          |      |
| <b>Adenoma</b>           |              |        |         |            |          |              |         |         |            |          |      |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/50     | (2%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/50     | (0%) |
| <b>Overall Incidence</b> | <b>Total</b> | 0/1449 | (0%)    | Mean 0%    | SD 0%    | <b>Total</b> | 1/1498  | (0.07%) | Mean 0.07% | SD 0.37% |      |
| .....                    |              |        |         |            |          |              |         |         |            |          |      |
| <b>#Mammary Gland:</b>   |              |        |         |            |          |              |         |         |            |          |      |
| <b>Carcinoma</b>         |              |        |         |            |          |              |         |         |            |          |      |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 1/50         | (2%)    | 1/50    | (2%)       | 2/50     | (4%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 2/50         | (4%)    | 1/50    | (2%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 4/50     | (8%) |
|                          |              | 1/50   | (2%)    | 0/50       | (0%)     | 0/50         | (0%)    | 1/50    | (2%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 0/49     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 1/50    | (2%)       | 2/50     | (4%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 1/50    | (2%)       | 0/50     | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/49     | (2%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/50     | (2%) |
|                          |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)    | 0/50    | (0%)       | 1/50     | (2%) |
| <b>Overall Incidence</b> | <b>Total</b> | 2/1449 | (0.14%) | Mean 0.14% | SD 0.52% | <b>Total</b> | 26/1498 | (1.74%) | Mean 1.73% | SD 1.87% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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 Vehicle: ALL VEHICLES

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|   |              | Male           |            |           |              | Female         |            |           |  |           |  |
|---|--------------|----------------|------------|-----------|--------------|----------------|------------|-----------|--|-----------|--|
| <b>#Mammary Gland:</b>                  |              |                |            |           |              |                |            |           |  |           |  |
| <b>Carcinoma or Adenoma</b>             |              |                |            |           |              |                |            |           |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |              | 1/50 (2%)      | 1/50 (2%)  | 2/50 (4%) |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 2/50 (4%)      | 1/50 (2%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)      | 0/50 (0%)  | 4/50 (8%) |  |           |  |
|   |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)      | 2/50 (4%)  | 1/50 (2%) |  | 1/50 (2%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) |  | 0/49 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 1/50 (2%)  | 2/50 (4%) |  | 2/50 (4%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)      | 1/50 (2%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/49 (2%) |  | 1/49 (2%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |  | 1/50 (2%) |  |
|   |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 2/50 (4%)      | 0/50 (0%)  | 1/50 (2%) |  | 1/50 (2%) |  |
| <b>Overall Incidence</b>                | <b>Total</b> | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | <b>Total</b> | 27/1498 (1.8%) | Mean 1.8%  | SD 1.85%  |  |           |  |
| .....                                   |              |                |            |           |              |                |            |           |  |           |  |
| <b>#Mammary Gland:</b>                  |              |                |            |           |              |                |            |           |  |           |  |
| <b>Fibroadenoma</b>                     |              |                |            |           |              |                |            |           |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  | 0/49 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  | 0/49 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                | <b>Total</b> | 0/1449 (0%)    | Mean 0%    | SD 0%     | <b>Total</b> | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |  |           |  |
| .....                                   |              |                |            |           |              |                |            |           |  |           |  |
| <b>#Mammary Gland:</b>                  |              |                |            |           |              |                |            |           |  |           |  |
| <b>Fibroma, Fibroadenoma or Adenoma</b> |              |                |            |           |              |                |            |           |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  | 0/49 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  | 0/49 (0%) |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
|   |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                | <b>Total</b> | 0/1449 (0%)    | Mean 0%    | SD 0%     | <b>Total</b> | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |  |           |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male           |            |           |       | Female          |            |            |  |           |  |
|---|-------|----------------|------------|-----------|-------|-----------------|------------|------------|--|-----------|--|
| <b>#Mammary Gland:</b>                              |       |                |            |           |       |                 |            |            |  |           |  |
| <b>Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b> |       |                |            |           |       |                 |            |            |  |           |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |       | 1/50 (2%)       | 1/50 (2%)  | 2/50 (4%)  |  |           |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  |           |       | 2/50 (4%)       | 1/50 (2%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)       | 0/50 (0%)  | 5/50 (10%) |  |           |  |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)       | 2/50 (4%)  | 1/50 (2%)  |  | 1/50 (2%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 1/50 (2%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 1/50 (2%)  | 2/50 (4%)  |  | 2/50 (4%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)       | 1/50 (2%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 1/49 (2%)  |  | 1/49 (2%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%)  |  | 1/50 (2%) |  |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |       | 2/50 (4%)       | 0/50 (0%)  | 1/50 (2%)  |  | 1/50 (2%) |  |
| <b>Overall Incidence</b>                            | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total | 28/1498 (1.87%) | Mean 1.87% | SD 2.1%    |  |           |  |
| .....   |       |                |            |           |       |                 |            |            |  |           |  |
| <b>#Mesentery:</b>                                  |       |                |            |           |       |                 |            |            |  |           |  |
| <b>Fibrosarcoma</b>                                 |       |                |            |           |       |                 |            |            |  |           |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  |           |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 3/50 (6%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                            | Total | 0/1449 (0%)    | Mean 0%    | SD 0%     | Total | 4/1498 (0.27%)  | Mean 0.27% | SD 1.14%   |  |           |  |
| .....   |       |                |            |           |       |                 |            |            |  |           |  |
| <b>#Mesentery:</b>                                  |       |                |            |           |       |                 |            |            |  |           |  |
| <b>Hemangioma</b>                                   |       |                |            |           |       |                 |            |            |  |           |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  |           |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)       | 0/50 (0%)  | 0/49 (0%)  |  | 0/49 (0%) |  |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%)  |  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                            | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total | 2/1498 (0.13%)  | Mean 0.13% | SD 0.51%   |  |           |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male           |            |           |           | Female         |            |           |           |
|---|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):<br/>Papilloma Squamous or Papilloma</b>                               |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 0/1449 (0%)    | Mean 0%    | SD 0%     | Total     | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |
| .....   |       |                |            |           |           |                |            |           |           |
| <b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):<br/>Squamous Cell Carcinoma</b>                                       |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |
| .....   |       |                |            |           |           |                |            |           |           |
| <b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):<br/>Squamous Cell Carcinoma, Papilloma Squamous, or<br/>Papilloma</b> |       |                |            |           |           |                |            |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 4/1498 (0.27%) | Mean 0.27% | SD 0.87%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                             | Male                  |       | Female     |       |          |       |
|-----------------------------|-----------------------|-------|------------|-------|----------|-------|
| <b>*Ovary:</b>              |                       |       |            |       |          |       |
| <b>Choriocarcinoma</b>      |                       |       |            |       |          |       |
|                             | 0/49                  | (0%)  | 1/48       | (2%)  | 0/50     | (0%)  |
|                             | 0/50                  | (0%)  | 0/48       | (0%)  | 0/50     | (0%)  |
|                             | 0/48                  | (0%)  | 0/50       | (0%)  | 0/49     | (0%)  |
|                             | 0/49                  | (0%)  | 0/50       | (0%)  | 0/50     | (0%)  |
|                             | 0/49                  | (0%)  | 0/50       | (0%)  | 0/48     | (0%)  |
|                             | 0/49                  | (0%)  | 0/49       | (0%)  | 0/47     | (0%)  |
|                             | 0/48                  | (0%)  | 0/48       | (0%)  | 0/46     | (0%)  |
|                             | 0/50                  | (0%)  | 0/49       | (0%)  | 0/49     | (0%)  |
|                             | 0/50                  | (0%)  | 0/49       | (0%)  | 0/50     | (0%)  |
|                             | 0/47                  | (0%)  | 0/49       | (0%)  | 1/50     | (2%)  |
| <b>Overall Incidence</b>    | Total 2/1468 (0.14%)  |       | Mean 0.14% |       | SD 0.52% |       |
| .....                       |                       |       |            |       |          |       |
| <b>*Ovary:</b>              |                       |       |            |       |          |       |
| <b>Cystadenoma</b>          |                       |       |            |       |          |       |
|                             | 4/49                  | (8%)  | 2/48       | (4%)  | 2/50     | (4%)  |
|                             | 3/50                  | (6%)  | 0/48       | (0%)  | 1/50     | (2%)  |
|                             | 5/48                  | (10%) | 3/50       | (6%)  | 3/49     | (6%)  |
|                             | 1/49                  | (2%)  | 1/50       | (2%)  | 7/50     | (14%) |
|                             | 3/49                  | (6%)  | 3/50       | (6%)  | 3/48     | (6%)  |
|                             | 5/49                  | (10%) | 0/49       | (0%)  | 2/47     | (4%)  |
|                             | 2/48                  | (4%)  | 2/48       | (4%)  | 1/46     | (2%)  |
|                             | 2/50                  | (4%)  | 6/49       | (12%) | 1/49     | (2%)  |
|                             | 1/50                  | (2%)  | 2/49       | (4%)  | 2/50     | (4%)  |
|                             | 2/47                  | (4%)  | 0/49       | (0%)  | 1/50     | (2%)  |
| <b>Overall Incidence</b>    | Total 70/1468 (4.77%) |       | Mean 4.76% |       | SD 3.47% |       |
| .....                       |                       |       |            |       |          |       |
| <b>*Ovary:</b>              |                       |       |            |       |          |       |
| <b>Fibrous Histiocytoma</b> |                       |       |            |       |          |       |
|                             | 0/49                  | (0%)  | 0/48       | (0%)  | 0/50     | (0%)  |
|                             | 0/50                  | (0%)  | 0/48       | (0%)  | 0/50     | (0%)  |
|                             | 0/48                  | (0%)  | 1/50       | (2%)  | 0/49     | (0%)  |
|                             | 0/49                  | (0%)  | 0/50       | (0%)  | 0/50     | (0%)  |
|                             | 0/49                  | (0%)  | 0/50       | (0%)  | 0/48     | (0%)  |
|                             | 0/49                  | (0%)  | 0/49       | (0%)  | 0/47     | (0%)  |
|                             | 0/48                  | (0%)  | 0/48       | (0%)  | 0/46     | (0%)  |
|                             | 0/50                  | (0%)  | 0/49       | (0%)  | 0/49     | (0%)  |
|                             | 0/50                  | (0%)  | 0/49       | (0%)  | 0/50     | (0%)  |
|                             | 0/47                  | (0%)  | 0/49       | (0%)  | 0/50     | (0%)  |
| <b>Overall Incidence</b>    | Total 1/1468 (0.07%)  |       | Mean 0.07% |       | SD 0.37% |       |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|   | Male                 |      | Female     |      |          |      |
|---|----------------------|------|------------|------|----------|------|
| <b>*Ovary:</b>                                      |                      |      |            |      |          |      |
| <b>Granulosa Cell Tumor Benign</b>                  |                      |      |            |      |          |      |
|   | 0/49                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 2/48       | (4%) | 0/50     | (0%) |
|   | 0/48                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 1/49                 | (2%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|   | 0/49                 | (0%) | 0/49       | (0%) | 0/47     | (0%) |
|   | 2/48                 | (4%) | 0/48       | (0%) | 0/46     | (0%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 1/49     | (2%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
|   | 0/47                 | (0%) | 0/49       | (0%) | 1/50     | (2%) |
| <b>Overall Incidence</b>                            | Total 7/1468 (0.48%) |      | Mean 0.48% |      | SD 1.18% |      |
| .....   |                      |      |            |      |          |      |
| <b>*Ovary:</b>                                      |                      |      |            |      |          |      |
| <b>Granulosa Cell Tumor Malignant</b>               |                      |      |            |      |          |      |
|   | 0/49                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 1/48       | (2%) | 0/50     | (0%) |
|   | 0/48                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 0/49                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|   | 0/49                 | (0%) | 0/49       | (0%) | 0/47     | (0%) |
|   | 0/48                 | (0%) | 0/48       | (0%) | 0/46     | (0%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 0/49     | (0%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
|   | 0/47                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>                            | Total 1/1468 (0.07%) |      | Mean 0.07% |      | SD 0.38% |      |
| .....   |                      |      |            |      |          |      |
| <b>*Ovary:</b>                                      |                      |      |            |      |          |      |
| <b>Granulosa Cell Tumor: Benign, Malignant, NOS</b> |                      |      |            |      |          |      |
|   | 0/49                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 3/48       | (6%) | 0/50     | (0%) |
|   | 0/48                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 1/49                 | (2%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|   | 0/49                 | (0%) | 0/49       | (0%) | 0/47     | (0%) |
|   | 2/48                 | (4%) | 0/48       | (0%) | 0/46     | (0%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 1/49     | (2%) |
|   | 0/50                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
|   | 0/47                 | (0%) | 0/49       | (0%) | 1/50     | (2%) |
| <b>Overall Incidence</b>                            | Total 8/1468 (0.54%) |      | Mean 0.55% |      | SD 1.43% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|                          | Male                 |      | Female              |      |
|--------------------------|----------------------|------|---------------------|------|
| <b>*Ovary:</b>           |                      |      |                     |      |
| <b>Hemangioma</b>        |                      |      |                     |      |
|                          | 0/49                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 0/48                | (0%) |
|                          | 0/48                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/50                | (0%) |
|                          | 0/48                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 0/49                | (2%) |
|                          | 0/50                 | (0%) | 1/49                | (2%) |
|                          | 0/47                 | (0%) | 0/49                | (0%) |
| <b>Overall Incidence</b> | Total 2/1468 (0.14%) |      | Mean 0.14% SD 0.52% |      |
| .....                    |                      |      |                     |      |
| <b>*Ovary:</b>           |                      |      |                     |      |
| <b>Hemangiosarcoma</b>   |                      |      |                     |      |
|                          | 0/49                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 0/48                | (0%) |
|                          | 0/48                 | (0%) | 0/50                | (0%) |
|                          | 1/49                 | (2%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/49                | (0%) |
|                          | 0/48                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 0/49                | (0%) |
|                          | 0/50                 | (0%) | 0/49                | (0%) |
|                          | 0/47                 | (0%) | 0/49                | (0%) |
| <b>Overall Incidence</b> | Total 4/1468 (0.27%) |      | Mean 0.28% SD 0.71% |      |
| .....                    |                      |      |                     |      |
| <b>*Ovary:</b>           |                      |      |                     |      |
| <b>Leiomyosarcoma</b>    |                      |      |                     |      |
|                          | 0/49                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 0/48                | (0%) |
|                          | 0/48                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/50                | (0%) |
|                          | 0/49                 | (0%) | 0/49                | (0%) |
|                          | 0/48                 | (0%) | 0/48                | (0%) |
|                          | 0/50                 | (0%) | 1/49                | (2%) |
|                          | 0/50                 | (0%) | 0/49                | (0%) |
|                          | 0/47                 | (0%) | 0/49                | (0%) |
| <b>Overall Incidence</b> | Total 1/1468 (0.07%) |      | Mean 0.07% SD 0.37% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|                                    | Male                 |      | Female     |      |          |      |
|------------------------------------|----------------------|------|------------|------|----------|------|
| <b>*Ovary:</b>                     |                      |      |            |      |          |      |
| <b>Luteoma</b>                     |                      |      |            |      |          |      |
|                                    | 0/49                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|                                    | 1/50                 | (2%) | 0/48       | (0%) | 0/50     | (0%) |
|                                    | 0/48                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|                                    | 1/49                 | (2%) | 0/49       | (0%) | 0/47     | (0%) |
|                                    | 0/48                 | (0%) | 0/48       | (0%) | 0/46     | (0%) |
|                                    | 1/50                 | (2%) | 0/49       | (0%) | 0/49     | (0%) |
|                                    | 0/50                 | (0%) | 0/49       | (0%) | 1/50     | (2%) |
|                                    | 0/47                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>           | Total 4/1468 (0.27%) |      | Mean 0.27% |      | SD 0.7%  |      |
| .....                              |                      |      |            |      |          |      |
| <b>*Ovary:</b>                     |                      |      |            |      |          |      |
| <b>Plasma Cell Tumor Malignant</b> |                      |      |            |      |          |      |
|                                    | 0/49                 | (0%) | 1/48       | (2%) | 0/50     | (0%) |
|                                    | 0/50                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|                                    | 0/48                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|                                    | 0/49                 | (0%) | 0/49       | (0%) | 0/47     | (0%) |
|                                    | 0/48                 | (0%) | 0/48       | (0%) | 0/46     | (0%) |
|                                    | 0/50                 | (0%) | 0/49       | (0%) | 0/49     | (0%) |
|                                    | 0/50                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
|                                    | 0/47                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>           | Total 1/1468 (0.07%) |      | Mean 0.07% |      | SD 0.38% |      |
| .....                              |                      |      |            |      |          |      |
| <b>*Ovary:</b>                     |                      |      |            |      |          |      |
| <b>Teratoma Benign</b>             |                      |      |            |      |          |      |
|                                    | 0/49                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|                                    | 0/50                 | (0%) | 0/48       | (0%) | 0/50     | (0%) |
|                                    | 1/48                 | (2%) | 0/50       | (0%) | 0/49     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                                    | 0/49                 | (0%) | 0/50       | (0%) | 0/48     | (0%) |
|                                    | 0/49                 | (0%) | 0/49       | (0%) | 0/47     | (0%) |
|                                    | 0/48                 | (0%) | 0/48       | (0%) | 0/46     | (0%) |
|                                    | 0/50                 | (0%) | 0/49       | (0%) | 0/49     | (0%) |
|                                    | 0/50                 | (0%) | 1/49       | (2%) | 1/50     | (2%) |
|                                    | 0/47                 | (0%) | 0/49       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>           | Total 3/1468 (0.2%)  |      | Mean 0.2%  |      | SD 0.62% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|                              |       | Male   |         |      |       | Female |         |       |        |      |       |    |    |
|------------------------------|-------|--------|---------|------|-------|--------|---------|-------|--------|------|-------|----|----|
| <b>*Ovary:</b>               |       |        |         |      |       |        |         |       |        |      |       |    |    |
| <b>Teratoma Malignant</b>    |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/48    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/48    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/48  | (0%)   | 0/50    | (0%)  | 0/49   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/50    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/50    | (0%)  | 0/48   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/49    | (0%)  | 0/47   | (0%) |       |    |    |
|                              |       |        |         |      | 0/48  | (0%)   | 0/48    | (0%)  | 0/46   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/49    | (0%)  | 0/49   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/49    | (0%)  | 1/50   | (2%) |       |    |    |
|                              |       |        |         |      | 0/47  | (0%)   | 0/49    | (0%)  | 0/50   | (0%) |       |    |    |
| <b>Overall Incidence</b>     |       |        |         |      | Total | 1/1468 | (0.07%) | Mean  | 0.07%  | SD   | 0.37% |    |    |
| .....                        |       |        |         |      |       |        |         |       |        |      |       |    |    |
| <b>*Ovary:</b>               |       |        |         |      |       |        |         |       |        |      |       |    |    |
| <b>Tubulostromal Adenoma</b> |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/48    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/48    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/48  | (0%)   | 0/50    | (0%)  | 0/49   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/50    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/50    | (0%)  | 0/48   | (0%) |       |    |    |
|                              |       |        |         |      | 0/49  | (0%)   | 0/49    | (0%)  | 0/47   | (0%) |       |    |    |
|                              |       |        |         |      | 0/48  | (0%)   | 0/48    | (0%)  | 0/46   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/49    | (0%)  | 0/49   | (0%) |       |    |    |
|                              |       |        |         |      | 0/50  | (0%)   | 0/49    | (0%)  | 0/50   | (0%) |       |    |    |
|                              |       |        |         |      | 0/47  | (0%)   | 0/49    | (0%)  | 1/50   | (2%) |       |    |    |
| <b>Overall Incidence</b>     |       |        |         |      | Total | 1/1468 | (0.07%) | Mean  | 0.07%  | SD   | 0.37% |    |    |
| .....                        |       |        |         |      |       |        |         |       |        |      |       |    |    |
| <b>*Pancreas:</b>            |       |        |         |      |       |        |         |       |        |      |       |    |    |
| <b>Adenoma</b>               |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       |        |         |      |       |        |         |       |        |      |       |    |    |
|                              |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)    | 0/49  | (0%)   | 0/48 | (0%)  |    |    |
|                              |       | 0/48   | (0%)    | 0/50 | (0%)  |        |         | 0/50  | (0%)   | 0/50 | (0%)  |    |    |
|                              |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)    | 0/49  | (0%)   | 0/50 | (0%)  |    |    |
|                              |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)    | 0/50  | (0%)   | 0/49 | (0%)  |    |    |
|                              |       | 1/49   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)    | 0/48  | (0%)   | 0/49 | (0%)  |    |    |
|                              |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/48   | (0%)    | 0/49  | (0%)   | 0/50 | (0%)  |    |    |
|                              |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)    | 0/49  | (0%)   | 0/49 | (0%)  |    |    |
|                              |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)    | 0/50  | (0%)   | 0/49 | (0%)  |    |    |
|                              |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)    | 0/48  | (0%)   | 0/49 | (0%)  |    |    |
|                              |       | 0/50   | (0%)    | 0/46 | (0%)  | 0/50   | (0%)    | 0/49  | (0%)   | 0/49 | (0%)  |    |    |
| <b>Overall Incidence</b>     | Total | 1/1434 | (0.07%) | Mean | 0.07% | SD     | 0.38%   | Total | 0/1474 | (0%) | Mean  | 0% |    |
|                              |       |        |         |      |       |        |         |       |        |      |       | SD | 0% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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 Report Date:04/29/2009

|                          |              | Male   |         |      |       |      | Female |              |        |         |      |       |      |       |
|--------------------------|--------------|--------|---------|------|-------|------|--------|--------------|--------|---------|------|-------|------|-------|
| <b>*Pancreas:</b>        |              |        |         |      |       |      |        |              |        |         |      |       |      |       |
| <b>Carcinoma</b>         |              |        |         |      |       |      |        |              |        |         |      |       |      |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)   | 0/49         | (0%)   | 0/48    | (0%) | 0/50  | (0%) |       |
|                          |              | 1/48   | (2%)    | 0/50 | (0%)  |      |        | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)   | 0/49         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)   | 0/50         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)   | 0/48         | (0%)   | 0/49    | (0%) | 0/47  | (0%) |       |
|                          |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/48 | (0%)   | 0/49         | (0%)   | 0/50    | (0%) | 0/46  | (0%) |       |
|                          |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)   | 0/49         | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)   | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)   | 0/48         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50   | (0%)    | 0/46 | (0%)  | 0/50 | (0%)   | 1/49         | (2%)   | 0/49    | (0%) | 0/49  | (0%) |       |
| <b>Overall Incidence</b> | <b>Total</b> | 1/1434 | (0.07%) | Mean | 0.07% | SD   | 0.39%  | <b>Total</b> | 1/1474 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

|                             |              |        |         |      |       |      |       |              |        |         |      |       |      |       |
|-----------------------------|--------------|--------|---------|------|-------|------|-------|--------------|--------|---------|------|-------|------|-------|
| <b>*Pancreas:</b>           |              |        |         |      |       |      |       |              |        |         |      |       |      |       |
| <b>Carcinoma or Adenoma</b> |              |        |         |      |       |      |       |              |        |         |      |       |      |       |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49         | (0%)   | 0/48    | (0%) | 0/50  | (0%) |       |
|                             |              | 1/48   | (2%)    | 0/50 | (0%)  |      |       | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                             |              | 1/49   | (2%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/48         | (0%)   | 0/49    | (0%) | 0/47  | (0%) |       |
|                             |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/48 | (0%)  | 0/49         | (0%)   | 0/50    | (0%) | 0/46  | (0%) |       |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49         | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|                             |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/48         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                             |              | 0/50   | (0%)    | 0/46 | (0%)  | 0/50 | (0%)  | 1/49         | (2%)   | 0/49    | (0%) | 0/49  | (0%) |       |
| <b>Overall Incidence</b>    | <b>Total</b> | 2/1434 | (0.14%) | Mean | 0.14% | SD   | 0.53% | <b>Total</b> | 1/1474 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

|   |              |        |         |      |       |      |       |              |         |         |       |       |       |       |
|---|--------------|--------|---------|------|-------|------|-------|--------------|---------|---------|-------|-------|-------|-------|
| <b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b> |              |        |         |      |       |      |       |              |         |         |       |       |       |       |
| <b>Adenoma</b>  |              |        |         |      |       |      |       |              |         |         |       |       |       |       |
|   |              | 0/50   | (0%)    | 0/48 | (0%)  | 1/50 | (2%)  | 1/49         | (2%)    | 2/49    | (4%)  | 4/49  | (8%)  |       |
|   |              | 1/46   | (2%)    | 0/48 | (0%)  |      |       | 5/46         | (11%)   | 1/47    | (2%)  | 2/50  | (4%)  |       |
|   |              | 1/48   | (2%)    | 0/50 | (0%)  | 0/50 | (0%)  | 8/50         | (16%)   | 5/50    | (10%) | 10/50 | (20%) |       |
|   |              | 0/48   | (0%)    | 1/50 | (2%)  | 1/50 | (2%)  | 4/48         | (8%)    | 3/50    | (6%)  | 1/50  | (2%)  |       |
|   |              | 0/50   | (0%)    | 0/48 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 2/49    | (4%)  | 4/47  | (9%)  |       |
|   |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 2/50         | (4%)    | 7/50    | (14%) | 1/46  | (2%)  |       |
|   |              | 0/49   | (0%)    | 0/48 | (0%)  | 0/48 | (0%)  | 5/49         | (10%)   | 4/50    | (8%)  | 2/49  | (4%)  |       |
|   |              | 0/49   | (0%)    | 0/47 | (0%)  | 0/50 | (0%)  | 1/50         | (2%)    | 4/50    | (8%)  | 2/49  | (4%)  |       |
|   |              | 0/49   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 3/48         | (6%)    | 1/49    | (2%)  | 6/49  | (12%) |       |
|   |              | 1/50   | (2%)    | 0/45 | (0%)  | 0/49 | (0%)  | 4/48         | (8%)    | 2/47    | (4%)  | 2/48  | (4%)  |       |
| <b>Overall Incidence</b>                                    | <b>Total</b> | 6/1418 | (0.42%) | Mean | 0.42% | SD   | 0.84% | <b>Total</b> | 98/1466 | (6.68%) | Mean  | 6.67% | SD    | 4.66% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |              | Male           |            |           |              | Female           |             |             |             |             |             |
|---|--------------|----------------|------------|-----------|--------------|------------------|-------------|-------------|-------------|-------------|-------------|
| <b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b> |              |                |            |           |              |                  |             |             |             |             |             |
| <b>Carcinoma</b>  |              |                |            |           |              |                  |             |             |             |             |             |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) | 0/49 (0%)    | 0/49 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/46 (0%)      | 0/48 (0%)  | 0/50 (0%) | 1/46 (2%)    | 0/47 (0%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/48 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/48 (0%)      | 1/50 (2%)  | 0/50 (0%) | 1/48 (2%)    | 0/50 (0%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/49 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/47 (0%)   | 0/47 (0%)   |
|   |              | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/46 (0%)   | 0/46 (0%)   |
|   |              | 0/49 (0%)      | 0/48 (0%)  | 0/48 (0%) | 0/49 (0%)    | 0/50 (0%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/49 (0%)      | 0/47 (0%)  | 0/50 (0%) | 0/50 (0%)    | 1/50 (2%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/48 (0%)    | 0/49 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/50 (0%)      | 0/45 (0%)  | 0/49 (0%) | 0/48 (0%)    | 0/47 (0%)        | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   |
| <b>Overall Incidence</b>                                    | <b>Total</b> | 1/1418 (0.07%) | Mean 0.07% | SD 0.37%  | <b>Total</b> | 3/1466 (0.2%)    | Mean 0.21%  | SD 0.64%    |             |             |             |
| .....   |              |                |            |           |              |                  |             |             |             |             |             |
| <b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b> |              |                |            |           |              |                  |             |             |             |             |             |
| <b>Carcinoma or Adenoma</b>                                 |              |                |            |           |              |                  |             |             |             |             |             |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 1/50 (2%) | 1/49 (2%)    | 2/49 (4%)        | 4/49 (8%)   | 4/49 (8%)   | 4/49 (8%)   | 2/50 (4%)   | 2/50 (4%)   |
|   |              | 1/46 (2%)      | 0/48 (0%)  | 0/50 (0%) | 6/46 (13%)   | 1/47 (2%)        | 2/50 (4%)   | 2/50 (4%)   | 2/50 (4%)   | 10/50 (20%) | 10/50 (20%) |
|   |              | 1/48 (2%)      | 0/50 (0%)  | 0/50 (0%) | 8/50 (16%)   | 5/50 (10%)       | 10/50 (20%) | 10/50 (20%) | 10/50 (20%) | 1/50 (2%)   | 1/50 (2%)   |
|   |              | 0/48 (0%)      | 2/50 (4%)  | 1/50 (2%) | 5/48 (10%)   | 3/50 (6%)        | 1/50 (2%)   | 1/50 (2%)   | 1/50 (2%)   | 4/47 (9%)   | 4/47 (9%)   |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%)    | 2/49 (4%)        | 4/47 (9%)   | 4/47 (9%)   | 4/47 (9%)   | 1/46 (2%)   | 1/46 (2%)   |
|   |              | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 2/50 (4%)    | 7/50 (14%)       | 1/46 (2%)   | 1/46 (2%)   | 1/46 (2%)   | 2/49 (4%)   | 2/49 (4%)   |
|   |              | 0/49 (0%)      | 0/48 (0%)  | 0/48 (0%) | 5/49 (10%)   | 4/50 (8%)        | 2/49 (4%)   | 2/49 (4%)   | 2/49 (4%)   | 2/49 (4%)   | 2/49 (4%)   |
|   |              | 0/49 (0%)      | 0/47 (0%)  | 0/50 (0%) | 1/50 (2%)    | 5/50 (10%)       | 2/49 (4%)   | 2/49 (4%)   | 2/49 (4%)   | 6/49 (12%)  | 6/49 (12%)  |
|   |              | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) | 3/48 (6%)    | 1/49 (2%)        | 6/49 (12%)  | 6/49 (12%)  | 6/49 (12%)  | 2/48 (4%)   | 2/48 (4%)   |
|   |              | 1/50 (2%)      | 0/45 (0%)  | 0/49 (0%) | 4/48 (8%)    | 2/47 (4%)        | 2/48 (4%)   | 2/48 (4%)   | 2/48 (4%)   | 2/48 (4%)   | 2/48 (4%)   |
| <b>Overall Incidence</b>                                    | <b>Total</b> | 7/1418 (0.49%) | Mean 0.49% | SD 1.04%  | <b>Total</b> | 101/1466 (6.89%) | Mean 6.88%  | SD 4.82%    |             |             |             |
| .....   |              |                |            |           |              |                  |             |             |             |             |             |
| <b>*Pituitary Gland: Pars Intermedia:</b>                   |              |                |            |           |              |                  |             |             |             |             |             |
| <b>Adenoma</b>  |              |                |            |           |              |                  |             |             |             |             |             |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 1/50 (2%) | 0/49 (0%)    | 0/49 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/46 (0%)      | 0/48 (0%)  | 0/50 (0%) | 0/46 (0%)    | 1/47 (2%)        | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   | 0/50 (0%)   |
|   |              | 0/48 (0%)      | 0/50 (0%)  | 0/50 (0%) | 2/50 (4%)    | 1/50 (2%)        | 2/50 (4%)   | 2/50 (4%)   | 2/50 (4%)   | 1/50 (2%)   | 1/50 (2%)   |
|   |              | 0/48 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/48 (0%)    | 1/50 (2%)        | 1/50 (2%)   | 1/50 (2%)   | 1/50 (2%)   | 0/47 (0%)   | 0/47 (0%)   |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%)    | 2/49 (4%)        | 0/47 (0%)   | 0/47 (0%)   | 0/47 (0%)   | 1/46 (2%)   | 1/46 (2%)   |
|   |              | 1/49 (2%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%)    | 0/50 (0%)        | 1/46 (2%)   | 1/46 (2%)   | 1/46 (2%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/49 (0%)      | 1/48 (2%)  | 0/48 (0%) | 0/49 (0%)    | 0/50 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/49 (0%)      | 0/47 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   |
|   |              | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/48 (0%)    | 0/50 (0%)        | 0/49 (0%)   | 0/49 (0%)   | 0/49 (0%)   | 1/49 (2%)   | 1/49 (2%)   |
|   |              | 1/50 (2%)      | 0/45 (0%)  | 0/49 (0%) | 0/48 (0%)    | 1/47 (2%)        | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   | 0/48 (0%)   |
| <b>Overall Incidence</b>                                    | <b>Total</b> | 4/1418 (0.28%) | Mean 0.28% | SD 0.71%  | <b>Total</b> | 14/1466 (0.95%)  | Mean 0.95%  | SD 1.38%    |             |             |             |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |              | Male           |            |           |              | Female          |            |           |  |
|---|--------------|----------------|------------|-----------|--------------|-----------------|------------|-----------|--|
| <b>*Pituitary Gland: Pars Intermedia:</b> |              |                |            |           |              |                 |            |           |  |
| <b>  Carcinoma or Adenoma</b>             |              |                |            |           |              |                 |            |           |  |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 1/50 (2%) |              | 0/49 (0%)       | 0/49 (0%)  | 0/49 (0%) |  |
|   |              | 0/46 (0%)      | 0/48 (0%)  |           |              | 0/46 (0%)       | 1/47 (2%)  | 0/50 (0%) |  |
|   |              | 0/48 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 2/50 (4%)       | 1/50 (2%)  | 2/50 (4%) |  |
|   |              | 0/48 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/48 (0%)       | 1/50 (2%)  | 1/50 (2%) |  |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 2/49 (4%)  | 0/47 (0%) |  |
|   |              | 1/49 (2%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)       | 0/50 (0%)  | 1/46 (2%) |  |
|   |              | 0/49 (0%)      | 1/48 (2%)  | 0/48 (0%) |              | 0/49 (0%)       | 0/50 (0%)  | 0/49 (0%) |  |
|   |              | 0/49 (0%)      | 0/47 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) |  |
|   |              | 0/49 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/48 (0%)       | 0/49 (0%)  | 1/49 (2%) |  |
|   |              | 1/50 (2%)      | 0/45 (0%)  | 0/49 (0%) |              | 0/48 (0%)       | 1/47 (2%)  | 0/48 (0%) |  |
| <b>Overall Incidence</b>                  | <b>Total</b> | 4/1418 (0.28%) | Mean 0.28% | SD 0.71%  | <b>Total</b> | 14/1466 (0.95%) | Mean 0.95% | SD 1.38%  |  |
| .....                                     |              |                |            |           |              |                 |            |           |  |
| <b>*Prostate:</b>                         |              |                |            |           |              |                 |            |           |  |
| <b>  Adenoma</b>                          |              |                |            |           |              |                 |            |           |  |
|   |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              |                 |            |           |  |
|   |              | 0/49 (0%)      | 1/50 (2%)  |           |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/49 (0%)  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |              | 0/50 (0%)       | 0/50 (0%)  |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |              | 0/50 (0%)       | 0/50 (0%)  |           |  |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  |           |  |
| <b>Overall Incidence</b>                  | <b>Total</b> | 1/1444 (0.07%) | Mean 0.07% | SD 0.37%  |              |                 |            |           |  |
| .....                                     |              |                |            |           |              |                 |            |           |  |
| <b>*Prostate:</b>                         |              |                |            |           |              |                 |            |           |  |
| <b>  Carcinoma or Adenoma</b>             |              |                |            |           |              |                 |            |           |  |
|   |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              |                 |            |           |  |
|   |              | 0/49 (0%)      | 1/50 (2%)  |           |              |                 |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |              | 0/50 (0%)       |            |           |  |
|   |              | 0/50 (0%)      | 0/48 (0%)  | 0/50 (0%) |              | 0/50 (0%)       |            |           |  |
| <b>Overall Incidence</b>                  | <b>Total</b> | 1/1444 (0.07%) | Mean 0.07% | SD 0.37%  |              |                 |            |           |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
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|                             |              | Male   |         |      |       | Female |       |              |                |
|-----------------------------|--------------|--------|---------|------|-------|--------|-------|--------------|----------------|
| <b>*Prostate:</b>           |              |        |         |      |       |        |       |              |                |
| <b>Hemangioma</b>           |              |        |         |      |       |        |       |              |                |
|                             |              | 0/50   | (0%)    | 0/49 | (0%)  | 1/50   | (2%)  |              |                |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  |        |       |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)  |              |                |
|                             |              | 0/50   | (0%)    | 0/48 | (0%)  | 0/50   | (0%)  |              |                |
| <b>Overall Incidence</b>    | <b>Total</b> | 1/1444 | (0.07%) | Mean | 0.07% | SD     | 0.37% |              |                |
| .....                       |              |        |         |      |       |        |       |              |                |
| <b>*Salivary Glands:</b>    |              |        |         |      |       |        |       |              |                |
| <b>Carcinoma</b>            |              |        |         |      |       |        |       |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  |        |       | 0/50         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 1/50         | (2%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/49 | (0%)  | 1/50   | (2%)  | 0/50         | (0%)           |
| <b>Overall Incidence</b>    | <b>Total</b> | 1/1446 | (0.07%) | Mean | 0.07% | SD     | 0.37% | <b>Total</b> | 1/1491 (0.07%) |
|                             |              |        |         |      |       |        |       | <b>Mean</b>  | 0.07%          |
|                             |              |        |         |      |       |        |       | <b>SD</b>    | 0.37%          |
| .....                       |              |        |         |      |       |        |       |              |                |
| <b>*Salivary Glands:</b>    |              |        |         |      |       |        |       |              |                |
| <b>Carcinoma or Adenoma</b> |              |        |         |      |       |        |       |              |                |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  |        |       | 0/49         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 1/50         | (2%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)           |
|                             |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)           |
|                             |              | 0/50   | (0%)    | 0/49 | (0%)  | 1/50   | (2%)  | 0/50         | (0%)           |
| <b>Overall Incidence</b>    | <b>Total</b> | 1/1446 | (0.07%) | Mean | 0.07% | SD     | 0.37% | <b>Total</b> | 1/1491 (0.07%) |
|                             |              |        |         |      |       |        |       | <b>Mean</b>  | 0.07%          |
|                             |              |        |         |      |       |        |       | <b>SD</b>    | 0.37%          |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

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 Vehicle: ALL VEHICLES

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|                                  |              | Male   |         |      |       | Female |       |              |        |         |      |       |      |       |
|----------------------------------|--------------|--------|---------|------|-------|--------|-------|--------------|--------|---------|------|-------|------|-------|
| <b>*Salivary Glands:</b>         |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
| <b>Mast Cell Tumor Malignant</b> |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/49   | (0%)    | 0/50 | (0%)  |        |       | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 1/50   | (2%)  | 0/50         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/49         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                  |              | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>         | <b>Total</b> | 1/1446 | (0.07%) | Mean | 0.07% | SD     | 0.37% | <b>Total</b> | 0/1491 | (0%)    | Mean | 0%    | SD   | 0%    |
| .....                            |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
| <b>#Seminal Vesicle:</b>         |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
| <b>Adenoma</b>                   |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 1/50   | (2%)    | 0/50 | (0%)  |        |       |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  |              |        |         |      |       |      |       |
| <b>Overall Incidence</b>         | <b>Total</b> | 2/1449 | (0.14%) | Mean | 0.14% | SD     | 0.52% |              |        |         |      |       |      |       |
| .....                            |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
| <b>#Skeletal Muscle:</b>         |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
| <b>Fibrosarcoma</b>              |              |        |         |      |       |        |       |              |        |         |      |       |      |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 1/50         | (2%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  |        |       | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                                  |              | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50         | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b>         | <b>Total</b> | 0/1449 | (0%)    | Mean | 0%    | SD     | 0%    | <b>Total</b> | 1/1498 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
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 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |       | Male   |         |      |       | Female |       |       |        |         |      |       |      |       |
|--------------------------|-------|--------|---------|------|-------|--------|-------|-------|--------|---------|------|-------|------|-------|
| <b>#Skeletal Muscle:</b> |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Hemangiosarcoma</b>   |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 2/50 | (4%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  |        |       | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 1/50    | (2%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 1/50   | (2%)    | 0/50 | (0%)  | 1/50   | (2%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |      |       |
| <b>Overall Incidence</b> | Total | 5/1449 | (0.35%) | Mean | 0.34% | SD     | 0.94% | Total | 2/1498 | (0.13%) | Mean | 0.13% | SD   | 0.51% |
| .....                    |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>#Skeletal Muscle:</b> |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Myxosarcoma</b>       |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 1/50  | (2%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  |        |       | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | Total | 0/1449 | (0%)    | Mean | 0%    | SD     | 0%    | Total | 1/1498 | (0.07%) | Mean | 0.07% | SD   | 0.37% |
| .....                    |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>#Skeletal Muscle:</b> |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Rhabdomyosarcoma</b>  |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 1/50    | (2%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  |        |       | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 1/50   | (2%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 3/50  | (6%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 1/50  | (2%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 1/50   | (2%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 2/50    | (4%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | Total | 2/1449 | (0.14%) | Mean | 0.14% | SD     | 0.52% | Total | 7/1498 | (0.47%) | Mean | 0.47% | SD   | 1.36% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |              | Male           |            |           |              | Female         |            |           |  |
|--|--------------|----------------|------------|-----------|--------------|----------------|------------|-----------|--|
| <b>#Skeletal Muscle:</b>                               |              |                |            |           |              |                |            |           |  |
| <b>Rhabdomyosarcoma or Rhabdomyoma</b>                 |              |                |            |           |              |                |            |           |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 3/50 (6%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 2/50 (4%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                               | <b>Total</b> | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | <b>Total</b> | 7/1498 (0.47%) | Mean 0.47% | SD 1.36%  |  |
| .....  |              |                |            |           |              |                |            |           |  |
| <b>#Skeletal Muscle:</b>                               |              |                |            |           |              |                |            |           |  |
| <b>Sarcoma</b>   |              |                |            |           |              |                |            |           |  |
|  |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                               | <b>Total</b> | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | <b>Total</b> | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |  |
| .....  |              |                |            |           |              |                |            |           |  |
| <b>#Skin:</b>  |              |                |            |           |              |                |            |           |  |
| <b>Basal Cell Adenoma or Basosquamous Tumor Benign</b> |              |                |            |           |              |                |            |           |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  |           |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)      | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                               | <b>Total</b> | 0/1449 (0%)    | Mean 0%    | SD 0%     | <b>Total</b> | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male   |      |      |      | Female |      |       |        |         |      |       |    |       |
|--|-------|--------|------|------|------|--------|------|-------|--------|---------|------|-------|----|-------|
| <b>#Skin:</b>  |       |        |      |      |      |        |      |       |        |         |      |       |    |       |
| <b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b> |       |        |      |      |      |        |      |       |        |         |      |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 1/50  | (2%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 1/50  | (2%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%) | 0/49 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>   | Total | 0/1449 | (0%) | Mean | 0%   | SD     | 0%   | Total | 2/1498 | (0.13%) | Mean | 0.13% | SD | 0.51% |

|                             |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|-----------------------------|-------|--------|---------|------|-------|------|-------|-------|--------|---------|------|-------|----|-------|
| <b>#Skin:</b>               |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
| <b>Basal Cell Carcinoma</b> |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 1/50    | (2%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 1/50   | (2%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>    | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total | 2/1498 | (0.13%) | Mean | 0.13% | SD | 0.51% |

|  |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|--|-------|--------|---------|------|-------|------|-------|-------|--------|---------|------|-------|----|-------|
| <b>#Skin:</b>  |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
| <b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b> |       |        |         |      |       |      |       |       |        |         |      |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 1/50    | (2%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 1/50   | (2%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>   | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total | 2/1498 | (0.13%) | Mean | 0.13% | SD | 0.51% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male           |            |           |       | Female         |            |           |           |
|--|-------|----------------|------------|-----------|-------|----------------|------------|-----------|-----------|
| <b>#Skin:</b>  |       |                |            |           |       |                |            |           |           |
| <b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b> |       |                |            |           |       |                |            |           |           |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  |           |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) |
|  |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>   | Total | 1/1449 (0.07%) | Mean 0.07% | SD 0.37%  | Total | 4/1498 (0.27%) | Mean 0.27% | SD 0.69%  |           |

|   |       |                |            |           |       |               |           |           |           |
|---|-------|----------------|------------|-----------|-------|---------------|-----------|-----------|-----------|
| <b>#Skin:</b>   |       |                |            |           |       |               |           |           |           |
| <b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b> |       |                |            |           |       |               |           |           |           |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  |           |       | 0/50 (0%)     | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)     | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)     | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |       | 1/50 (2%)     | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)      | 0/49 (0%)  | 0/50 (0%) |       | 0/50 (0%)     | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>  | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total | 6/1498 (0.4%) | Mean 0.4% | SD 0.81%  |           |

|                                  |       |             |           |           |       |                |            |           |           |
|----------------------------------|-------|-------------|-----------|-----------|-------|----------------|------------|-----------|-----------|
| <b>#Skin:</b>                    |       |             |           |           |       |                |            |           |           |
| <b>Basosquamous Tumor Benign</b> |       |             |           |           |       |                |            |           |           |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) |           |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 1/50 (2%)      | 0/50 (0%)  | 0/49 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                  |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>         | Total | 0/1449 (0%) | Mean 0%   | SD 0%     | Total | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |       | Male           |            |           |           | Female         |            |           |           |
|--------------------------|-------|----------------|------------|-----------|-----------|----------------|------------|-----------|-----------|
| <b>#Skin:</b>            |       |                |            |           |           |                |            |           |           |
| <b>Fibroma</b>           |       |                |            |           |           |                |            |           |           |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                          |       | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b> | Total | 4/1449 (0.28%) | Mean 0.28% | SD 0.71%  | Total     | 1/1498 (0.07%) | Mean 0.07% | SD 0.37%  |           |

|   |       |                 |            |           |            |                 |            |          |  |
|---|-------|-----------------|------------|-----------|------------|-----------------|------------|----------|--|
| <b>#Skin:</b>   |       |                 |            |           |            |                 |            |          |  |
| <b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b> |       |                 |            |           |            |                 |            |          |  |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 5/50 (10%) | 3/50 (6%)       | 0/50 (0%)  |          |  |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 8/50 (16%) | 2/50 (4%)       | 5/50 (10%) |          |  |
|   |       | 2/50 (4%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)  | 1/50 (2%)       | 4/50 (8%)  |          |  |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%)  | 1/50 (2%)       | 4/50 (8%)  |          |  |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)  | 0/50 (0%)       | 3/49 (6%)  |          |  |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/50 (0%)  | 4/50 (8%)       | 3/50 (6%)  |          |  |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 3/50 (6%) | 2/50 (4%)  | 6/50 (12%)      | 3/50 (6%)  |          |  |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 2/50 (4%)  | 2/50 (4%)       | 2/49 (4%)  |          |  |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 2/50 (4%) | 2/50 (4%)  | 1/50 (2%)       | 1/50 (2%)  |          |  |
|   |       | 1/50 (2%)       | 1/49 (2%)  | 0/50 (0%) | 2/50 (4%)  | 4/50 (8%)       | 4/50 (8%)  |          |  |
| <b>Overall Incidence</b>  | Total | 18/1449 (1.24%) | Mean 1.24% | SD 1.55%  | Total      | 78/1498 (5.21%) | Mean 5.21% | SD 3.81% |  |

|                          |       |                |            |           |           |                 |            |         |  |
|--------------------------|-------|----------------|------------|-----------|-----------|-----------------|------------|---------|--|
| <b>#Skin:</b>            |       |                |            |           |           |                 |            |         |  |
| <b>Fibrosarcoma</b>      |       |                |            |           |           |                 |            |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 3/50 (6%) | 2/50 (4%)       | 0/50 (0%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 4/50 (8%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%) | 0/50 (0%)       | 3/50 (6%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 3/50 (6%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 3/50 (6%)  |         |  |
|                          |       | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 1/50 (2%) | 0/50 (0%)       | 1/49 (2%)  |         |  |
|                          |       | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 1/50 (2%) | 1/50 (2%)       | 0/50 (0%)  |         |  |
|                          |       | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 4/50 (8%)  |         |  |
| <b>Overall Incidence</b> | Total | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | Total     | 31/1498 (2.07%) | Mean 2.07% | SD 2.6% |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |              | Male            |            |           |              | Female          |            |          |  |
|--|--------------|-----------------|------------|-----------|--------------|-----------------|------------|----------|--|
| <b>#Skin:</b>  |              |                 |            |           |              |                 |            |          |  |
| <b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b> |              |                 |            |           |              |                 |            |          |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 5/50 (10%)   | 3/50 (6%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  |           | 8/50 (16%)   | 2/50 (4%)       | 5/50 (10%) |          |  |
|  |              | 2/50 (4%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)    | 1/50 (2%)       | 4/50 (8%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%)    | 1/50 (2%)       | 4/50 (8%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 3/50 (6%)    | 0/50 (0%)       | 3/49 (6%)  |          |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/50 (0%)    | 4/50 (8%)       | 3/50 (6%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 2/50 (4%) | 2/50 (4%)    | 6/50 (12%)      | 3/50 (6%)  |          |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 2/50 (4%)    | 2/50 (4%)       | 2/49 (4%)  |          |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  | 2/50 (4%) | 2/50 (4%)    | 1/50 (2%)       | 1/50 (2%)  |          |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 2/50 (4%)    | 4/50 (8%)       | 4/50 (8%)  |          |  |
| <b>Overall Incidence</b>   | <b>Total</b> | 14/1449 (0.97%) | Mean 0.97% | SD 1.38%  | <b>Total</b> | 78/1498 (5.21%) | Mean 5.21% | SD 3.81% |  |
| .....  |              |                 |            |           |              |                 |            |          |  |
| <b>#Skin:</b>  |              |                 |            |           |              |                 |            |          |  |
| <b>Fibrous Histiocytoma</b>  |              |                 |            |           |              |                 |            |          |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  |           | 1/50 (2%)    | 1/50 (2%)       | 0/50 (0%)  |          |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 1/50 (2%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/49 (0%)  |          |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%)    | 2/50 (4%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 2/50 (4%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 1/49 (2%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 1/50 (2%)    | 3/50 (6%)       | 0/50 (0%)  |          |  |
| <b>Overall Incidence</b>   | <b>Total</b> | 7/1449 (0.48%)  | Mean 0.48% | SD 1.02%  | <b>Total</b> | 10/1498 (0.67%) | Mean 0.67% | SD 1.42% |  |
| .....  |              |                 |            |           |              |                 |            |          |  |
| <b>#Skin:</b>  |              |                 |            |           |              |                 |            |          |  |
| <b>Granular Cell Tumor Benign</b>                                  |              |                 |            |           |              |                 |            |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  |           | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/49 (0%)  |          |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/49 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)       | 0/50 (0%)  |          |  |
| <b>Overall Incidence</b>   | <b>Total</b> | 1/1449 (0.07%)  | Mean 0.07% | SD 0.37%  | <b>Total</b> | 0/1498 (0%)     | Mean 0%    | SD 0%    |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |              | Male    |         |      |       |      |       | Female       |         |         |      |       |      |       |
|--------------------------|--------------|---------|---------|------|-------|------|-------|--------------|---------|---------|------|-------|------|-------|
| <b>#Skin:</b>            |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
| <b>Hemangioma</b>        |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  |      |       | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 1/50 | (2%)  | 2/50         | (4%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 1/50  | (2%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 1/50  | (2%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 1/50         | (2%)    | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 1/50 | (2%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 2/50         | (4%)    | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | <b>Total</b> | 2/1449  | (0.14%) | Mean | 0.14% | SD   | 0.52% | <b>Total</b> | 7/1498  | (0.47%) | Mean | 0.47% | SD   | 1.14% |
| .....                    |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
| <b>#Skin:</b>            |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
| <b>Hemangiosarcoma</b>   |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
|                          |              | 1/50    | (2%)    | 0/50 | (0%)  | 1/50 | (2%)  | 1/50         | (2%)    | 1/50    | (2%) | 1/50  | (2%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  |      |       | 1/50         | (2%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 2/50 | (4%)  | 1/50 | (2%)  | 1/50         | (2%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 2/50         | (4%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 1/50    | (2%)    | 0/50 | (0%)  | 1/50 | (2%)  | 0/50         | (0%)    | 0/50    | (0%) | 1/49  | (2%) |       |
|                          |              | 1/50    | (2%)    | 0/50 | (0%)  | 1/50 | (2%)  | 0/50         | (0%)    | 0/50    | (0%) | 1/50  | (2%) |       |
|                          |              | 0/50    | (0%)    | 1/50 | (2%)  | 2/50 | (4%)  | 2/50         | (4%)    | 1/50    | (2%) | 0/50  | (0%) |       |
|                          |              | 1/50    | (2%)    | 0/50 | (0%)  | 0/50 | (0%)  | 1/50         | (2%)    | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50    | (0%)    | 1/50 | (2%)  | 2/50 | (4%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 1/50  | (2%) |       |
| <b>Overall Incidence</b> | <b>Total</b> | 16/1449 | (1.1%)  | Mean | 1.1%  | SD   | 1.37% | <b>Total</b> | 14/1498 | (0.93%) | Mean | 0.93% | SD   | 1.26% |
| .....                    |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
| <b>#Skin:</b>            |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
| <b>Liposarcoma</b>       |              |         |         |      |       |      |       |              |         |         |      |       |      |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  |      |       | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 1/50    | (2%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |              | 0/50    | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50         | (0%)    | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | <b>Total</b> | 0/1449  | (0%)    | Mean | 0%    | SD   | 0%    | <b>Total</b> | 1/1498  | (0.07%) | Mean | 0.07% | SD   | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |              | Male   |      |         |       | Female |        |         |            |          |      |      |      |
|--------------------------|--------------|--------|------|---------|-------|--------|--------|---------|------------|----------|------|------|------|
| <b>#Skin:</b>            |              |        |      |         |       |        |        |         |            |          |      |      |      |
| <b>Myxosarcoma</b>       |              |        |      |         |       |        |        |         |            |          |      |      |      |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 1/50    | (2%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  |        |        | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%) | 0/49    | (0%)  | 0/50   | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b> | <b>Total</b> | 0/1449 | (0%) | Mean 0% | SD 0% | Total  | 1/1498 | (0.07%) | Mean 0.07% | SD 0.37% |      |      |      |

|   |              |        |         |            |          |       |         |         |            |          |      |      |      |
|---|--------------|--------|---------|------------|----------|-------|---------|---------|------------|----------|------|------|------|
| <b>#Skin:</b>   |              |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b> |              |        |         |            |          |       |         |         |            |          |      |      |      |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 2/50 | (4%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     |       |         | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 1/50  | (2%)    | 0/50    | (0%)       | 0/50     | (0%) | 2/50 | (4%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 2/49 | (4%) |
|   |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|   |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b>                                  | <b>Total</b> | 1/1449 | (0.07%) | Mean 0.07% | SD 0.37% | Total | 10/1498 | (0.67%) | Mean 0.67% | SD 1.33% |      |      |      |

|  |              |        |         |            |          |       |         |         |            |          |      |      |      |
|--|--------------|--------|---------|------------|----------|-------|---------|---------|------------|----------|------|------|------|
| <b>#Skin:</b>  |              |        |         |            |          |       |         |         |            |          |      |      |      |
| <b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b> |              |        |         |            |          |       |         |         |            |          |      |      |      |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 2/50 | (4%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     |       |         | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 1/50  | (2%)    | 0/50    | (0%)       | 0/50     | (0%) | 2/50 | (4%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 2/49 | (4%) |
|  |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|  |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50  | (0%)    | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b>   | <b>Total</b> | 1/1449 | (0.07%) | Mean 0.07% | SD 0.37% | Total | 10/1498 | (0.67%) | Mean 0.67% | SD 1.33% |      |      |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied











Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                  |       | Male    |         |      |       |      |       | Female |         |         |      |       |       |       |
|----------------------------------|-------|---------|---------|------|-------|------|-------|--------|---------|---------|------|-------|-------|-------|
| <b>*Spleen:</b>                  |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
| <b>Hemangioma</b>                |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/48    | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)    | 0/50    | (0%) | 0/48  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 1/50  | (2%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/48   | (0%)    | 0/49    | (0%) | 0/48  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/47  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/49  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/48   | (0%)    | 0/49    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 1/50    | (2%)    | 0/47 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/48  | (0%)  |       |
| <b>Overall Incidence</b>         | Total | 1/1438  | (0.07%) | Mean | 0.07% | SD   | 0.37% | Total  | 1/1478  | (0.07%) | Mean | 0.07% | SD    | 0.37% |
| .....                            |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
| <b>*Spleen:</b>                  |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
| <b>Hemangiosarcoma</b>           |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
|                                  |       | 1/50    | (2%)    | 1/50 | (2%)  | 3/50 | (6%)  | 0/50   | (0%)    | 1/50    | (2%) | 5/50  | (10%) |       |
|                                  |       | 2/48    | (4%)    | 0/50 | (0%)  |      |       | 1/50   | (2%)    | 2/50    | (4%) | 1/48  | (2%)  |       |
|                                  |       | 0/50    | (0%)    | 1/50 | (2%)  | 3/50 | (6%)  | 0/49   | (0%)    | 0/50    | (0%) | 2/50  | (4%)  |       |
|                                  |       | 0/49    | (0%)    | 2/50 | (4%)  | 1/50 | (2%)  | 1/49   | (2%)    | 1/50    | (2%) | 0/50  | (0%)  |       |
|                                  |       | 1/50    | (2%)    | 1/50 | (2%)  | 0/50 | (0%)  | 1/48   | (2%)    | 4/49    | (8%) | 1/48  | (2%)  |       |
|                                  |       | 2/50    | (4%)    | 1/50 | (2%)  | 2/49 | (4%)  | 0/49   | (0%)    | 1/50    | (2%) | 0/47  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 1/50 | (2%)  | 2/50 | (4%)  | 2/49   | (4%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 1/49    | (2%)    | 1/49 | (2%)  | 2/50 | (4%)  | 0/49   | (0%)    | 1/50    | (2%) | 1/49  | (2%)  |       |
|                                  |       | 2/49    | (4%)    | 2/50 | (4%)  | 1/49 | (2%)  | 1/48   | (2%)    | 0/49    | (0%) | 1/50  | (2%)  |       |
|                                  |       | 1/50    | (2%)    | 2/47 | (4%)  | 1/50 | (2%)  | 1/49   | (2%)    | 0/50    | (0%) | 0/48  | (0%)  |       |
| <b>Overall Incidence</b>         | Total | 37/1438 | (2.57%) | Mean | 2.58% | SD   | 1.7%  | Total  | 28/1478 | (1.89%) | Mean | 1.89% | SD    | 2.36% |
| .....                            |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
| <b>*Spleen:</b>                  |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
| <b>Mast Cell Tumor Malignant</b> |       |         |         |      |       |      |       |        |         |         |      |       |       |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/48    | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)    | 0/50    | (0%) | 0/48  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/48   | (0%)    | 0/49    | (0%) | 0/48  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 1/49   | (2%)    | 0/50    | (0%) | 0/47  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/49  | (0%)  |       |
|                                  |       | 0/49    | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/48   | (0%)    | 0/49    | (0%) | 0/50  | (0%)  |       |
|                                  |       | 0/50    | (0%)    | 0/47 | (0%)  | 0/50 | (0%)  | 0/49   | (0%)    | 0/50    | (0%) | 0/48  | (0%)  |       |
| <b>Overall Incidence</b>         | Total | 0/1438  | (0%)    | Mean | 0%    | SD   | 0%    | Total  | 1/1478  | (0.07%) | Mean | 0.07% | SD    | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied





Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |              | Male            |            |           |              | Female          |            |           |  |
|--|--------------|-----------------|------------|-----------|--------------|-----------------|------------|-----------|--|
| <b>#Stomach, Forestomach:</b>                        |              |                 |            |           |              |                 |            |           |  |
| <b>Squamous Cell Carcinoma or Papilloma Squamous</b> |              |                 |            |           |              |                 |            |           |  |
|  |              | 2/50 (4%)       | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) |  |
|  |              | 0/50 (0%)       | 2/50 (4%)  |           |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 2/50 (4%) |              | 1/50 (2%)       | 1/50 (2%)  | 1/50 (2%) |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) |              | 1/50 (2%)       | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 2/50 (4%)  | 0/50 (0%) |              | 0/50 (0%)       | 2/50 (4%)  | 1/49 (2%) |  |
|  |              | 9/50 (18%)      | 0/50 (0%)  | 0/50 (0%) |              | 3/50 (6%)       | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) |              | 2/50 (4%)       | 1/50 (2%)  | 1/50 (2%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) |              | 1/50 (2%)       | 1/50 (2%)  | 2/49 (4%) |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) |              | 1/50 (2%)       | 2/50 (4%)  | 1/50 (2%) |  |
|  |              | 2/50 (4%)       | 1/49 (2%)  | 0/50 (0%) |              | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) |  |
| <b>Overall Incidence</b>                             | <b>Total</b> | 26/1449 (1.79%) | Mean 1.79% | SD 3.48%  | <b>Total</b> | 28/1498 (1.87%) | Mean 1.87% | SD 1.48%  |  |
| .....  |              |                 |            |           |              |                 |            |           |  |
| <b>#Stomach, Forestomach:</b>                        |              |                 |            |           |              |                 |            |           |  |
| <b>Squamous Cell Papilloma</b>                       |              |                 |            |           |              |                 |            |           |  |
|  |              | 2/50 (4%)       | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) |  |
|  |              | 0/50 (0%)       | 2/50 (4%)  |           |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 1/50 (2%) |              | 1/50 (2%)       | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 2/50 (4%)  | 0/50 (0%) |              | 0/50 (0%)       | 2/50 (4%)  | 1/49 (2%) |  |
|  |              | 8/50 (16%)      | 0/50 (0%)  | 0/50 (0%) |              | 3/50 (6%)       | 1/50 (2%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 2/50 (4%)       | 1/50 (2%)  | 1/50 (2%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)       | 1/50 (2%)  | 2/49 (4%) |  |
|  |              | 0/50 (0%)       | 1/50 (2%)  | 0/50 (0%) |              | 1/50 (2%)       | 2/50 (4%)  | 1/50 (2%) |  |
|  |              | 2/50 (4%)       | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) |  |
| <b>Overall Incidence</b>                             | <b>Total</b> | 20/1449 (1.38%) | Mean 1.38% | SD 3.17%  | <b>Total</b> | 26/1498 (1.74%) | Mean 1.74% | SD 1.56%  |  |
| .....  |              |                 |            |           |              |                 |            |           |  |
| <b>#Stomach, Glandular:</b>                          |              |                 |            |           |              |                 |            |           |  |
| <b>Adenoma</b>                                       |              |                 |            |           |              |                 |            |           |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  |           |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 1/49 (2%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  |
| <b>Overall Incidence</b>                             | <b>Total</b> | 0/1449 (0%)     | Mean 0%    | SD 0%     | <b>Total</b> | 2/1498 (0.13%)  | Mean 0.13% | SD 0.51%  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |       | Male   |         |      |       | Female |       |       |                |
|--------------------------|-------|--------|---------|------|-------|--------|-------|-------|----------------|
| <b>*Testes:</b>          |       |        |         |      |       |        |       |       |                |
| <b>Hemangiosarcoma</b>   |       |        |         |      |       |        |       |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  |        |       |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  |       |                |
|                          |       | 0/50   | (0%)    | 1/49 | (2%)  | 0/50   | (0%)  |       |                |
| <b>Overall Incidence</b> | Total | 1/1449 | (0.07%) | Mean | 0.07% | SD     | 0.38% |       |                |
| .....                    |       |        |         |      |       |        |       |       |                |
| <b>*Thymus:</b>          |       |        |         |      |       |        |       |       |                |
| <b>Thymoma Benign</b>    |       |        |         |      |       |        |       |       |                |
|                          |       | 0/45   | (0%)    | 0/44 | (0%)  | 0/49   | (0%)  | 0/47  | (0%)           |
|                          |       | 0/38   | (0%)    | 0/41 | (0%)  |        |       | 0/46  | (0%)           |
|                          |       | 0/45   | (0%)    | 0/47 | (0%)  | 0/38   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/47   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/44   | (0%)    | 0/43 | (0%)  | 0/48   | (0%)  | 0/47  | (0%)           |
|                          |       | 0/48   | (0%)    | 0/42 | (0%)  | 0/38   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/48   | (0%)    | 0/41 | (0%)  | 0/45   | (0%)  | 0/50  | (0%)           |
|                          |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/49   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/49   | (0%)    | 0/41 | (0%)  | 0/47   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/46   | (0%)    | 0/42 | (0%)  | 0/44   | (0%)  | 1/48  | (2%)           |
|                          |       |        |         |      |       |        |       | 0/44  | (0%)           |
|                          |       |        |         |      |       |        |       | 0/48  | (0%)           |
|                          |       |        |         |      |       |        |       | 0/46  | (0%)           |
| <b>Overall Incidence</b> | Total | 0/1297 | (0%)    | Mean | 0%    | SD     | 0%    | Total | 1/1437 (0.07%) |
|                          |       |        |         |      |       |        |       | Mean  | 0.07%          |
|                          |       |        |         |      |       |        |       | SD    | 0.38%          |
| .....                    |       |        |         |      |       |        |       |       |                |
| <b>*Thymus:</b>          |       |        |         |      |       |        |       |       |                |
| <b>Thymoma Malignant</b> |       |        |         |      |       |        |       |       |                |
|                          |       | 0/45   | (0%)    | 0/44 | (0%)  | 0/49   | (0%)  | 0/47  | (0%)           |
|                          |       | 0/38   | (0%)    | 0/41 | (0%)  |        |       | 0/46  | (0%)           |
|                          |       | 0/45   | (0%)    | 1/47 | (2%)  | 0/38   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/47   | (0%)  | 1/47  | (2%)           |
|                          |       | 0/44   | (0%)    | 0/43 | (0%)  | 0/48   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/48   | (0%)    | 1/42 | (2%)  | 0/38   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/48   | (0%)    | 0/41 | (0%)  | 0/45   | (0%)  | 0/50  | (0%)           |
|                          |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/49   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/49   | (0%)    | 0/41 | (0%)  | 0/47   | (0%)  | 0/49  | (0%)           |
|                          |       | 0/46   | (0%)    | 0/42 | (0%)  | 0/44   | (0%)  | 0/48  | (0%)           |
|                          |       |        |         |      |       |        |       | 0/44  | (0%)           |
|                          |       |        |         |      |       |        |       | 0/48  | (0%)           |
|                          |       |        |         |      |       |        |       | 0/46  | (0%)           |
| <b>Overall Incidence</b> | Total | 2/1297 | (0.15%) | Mean | 0.16% | SD     | 0.58% | Total | 1/1437 (0.07%) |
|                          |       |        |         |      |       |        |       | Mean  | 0.07%          |
|                          |       |        |         |      |       |        |       | SD    | 0.39%          |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |       | Male   |         |      |       | Female |       |       |        |         |      |       |      |       |
|--|-------|--------|---------|------|-------|--------|-------|-------|--------|---------|------|-------|------|-------|
| <b>*Thymus:</b>                        |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Thymoma: Benign, Malignant, NOS</b> |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|  |       | 0/45   | (0%)    | 0/44 | (0%)  | 0/49   | (0%)  | 0/47  | (0%)   | 0/46    | (0%) | 0/50  | (0%) |       |
|  |       | 0/38   | (0%)    | 0/41 | (0%)  |        |       | 0/49  | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|  |       | 0/45   | (0%)    | 1/47 | (2%)  | 0/38   | (0%)  | 0/49  | (0%)   | 1/47    | (2%) | 0/47  | (0%) |       |
|  |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/47   | (0%)  | 0/46  | (0%)   | 0/49    | (0%) | 0/48  | (0%) |       |
|  |       | 0/44   | (0%)    | 0/43 | (0%)  | 0/48   | (0%)  | 0/49  | (0%)   | 0/47    | (0%) | 0/47  | (0%) |       |
|  |       | 0/48   | (0%)    | 1/42 | (2%)  | 0/38   | (0%)  | 0/50  | (0%)   | 0/49    | (0%) | 0/43  | (0%) |       |
|  |       | 0/48   | (0%)    | 0/41 | (0%)  | 0/45   | (0%)  | 0/49  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|  |       | 0/47   | (0%)    | 0/47 | (0%)  | 0/49   | (0%)  | 0/49  | (0%)   | 0/49    | (0%) | 0/48  | (0%) |       |
|  |       | 0/49   | (0%)    | 0/41 | (0%)  | 0/47   | (0%)  | 0/46  | (0%)   | 1/48    | (2%) | 0/48  | (0%) |       |
|  |       | 0/46   | (0%)    | 0/42 | (0%)  | 0/44   | (0%)  | 0/49  | (0%)   | 0/44    | (0%) | 0/46  | (0%) |       |
| <b>Overall Incidence</b>               | Total | 2/1297 | (0.15%) | Mean | 0.16% | SD     | 0.58% | Total | 2/1437 | (0.14%) | Mean | 0.14% | SD   | 0.53% |
| .....                                  |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>*Thyroid Gland:</b>                 |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Adenoma</b>                         |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/49   | (0%)    | 0/50 | (0%)  |        |       | 0/49  | (0%)   | 0/50    | (0%) | 0/48  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/48    | (0%) | 0/48  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/46  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/48   | (0%)  | 1/50  | (2%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/49   | (0%)  | 0/50  | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/48 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
| <b>Overall Incidence</b>               | Total | 0/1441 | (0%)    | Mean | 0%    | SD     | 0%    | Total | 1/1484 | (0.07%) | Mean | 0.07% | SD   | 0.37% |
| .....                                  |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>*Thyroid Gland: C-Cell:</b>         |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
| <b>Carcinoma</b>                       |       |        |         |      |       |        |       |       |        |         |      |       |      |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/49   | (0%)    | 0/50 | (0%)  |        |       | 0/49  | (0%)   | 0/50    | (0%) | 0/48  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/48    | (0%) | 0/48  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 1/50    | (2%) | 0/46  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/48   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50   | (0%)  | 0/50  | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|  |       | 0/50   | (0%)    | 1/50 | (2%)  | 0/49   | (0%)  | 0/50  | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|  |       | 0/50   | (0%)    | 0/48 | (0%)  | 0/50   | (0%)  | 1/50  | (2%)   | 0/50    | (0%) | 0/49  | (0%) |       |
| <b>Overall Incidence</b>               | Total | 1/1441 | (0.07%) | Mean | 0.07% | SD     | 0.37% | Total | 2/1484 | (0.13%) | Mean | 0.13% | SD   | 0.51% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   |       | Male            |            |           |           | Female          |            |           |           |           |           |
|---|-------|-----------------|------------|-----------|-----------|-----------------|------------|-----------|-----------|-----------|-----------|
| <b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b> |       |                 |            |           |           |                 |            |           |           |           |           |
|   |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) | 0/46 (0%) | 0/46 (0%) | 0/46 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)       | 1/50 (2%)  | 0/49 (0%) | 0/49 (0%) | 0/50 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
| <b>Overall Incidence</b>                            | Total | 1/1441 (0.07%)  | Mean 0.07% | SD 0.37%  | Total     | 2/1484 (0.13%)  | Mean 0.13% | SD 0.51%  |           |           |           |
| .....   |       |                 |            |           |           |                 |            |           |           |           |           |
| <b>*Thyroid Gland: Follicular Cell: Adenoma</b>     |       |                 |            |           |           |                 |            |           |           |           |           |
|   |       | 0/50 (0%)       | 1/49 (2%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%) | 3/50 (6%)       | 2/49 (4%)  | 2/49 (4%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
|   |       | 1/50 (2%)       | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 1/48 (2%)  | 1/48 (2%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 3/50 (6%) | 3/50 (6%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 1/46 (2%) | 1/46 (2%) | 1/46 (2%) |
|   |       | 1/50 (2%)       | 3/50 (6%)  | 0/48 (0%) | 0/48 (0%) | 0/50 (0%)       | 3/50 (6%)  | 3/50 (6%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 2/50 (4%)  | 2/50 (4%) | 1/49 (2%) | 1/49 (2%) | 1/49 (2%) |
|   |       | 1/50 (2%)       | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) | 1/50 (2%)       | 0/49 (0%)  | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 3/50 (6%)       | 0/48 (0%)  | 3/50 (6%) | 3/50 (6%) | 3/50 (6%)       | 3/50 (6%)  | 3/50 (6%) | 1/49 (2%) | 1/49 (2%) | 1/49 (2%) |
| <b>Overall Incidence</b>                            | Total | 19/1441 (1.32%) | Mean 1.31% | SD 2.16%  | Total     | 25/1484 (1.68%) | Mean 1.68% | SD 2.11%  |           |           |           |
| .....   |       |                 |            |           |           |                 |            |           |           |           |           |
| <b>*Thyroid Gland: Follicular Cell: Carcinoma</b>   |       |                 |            |           |           |                 |            |           |           |           |           |
|   |       | 0/50 (0%)       | 1/49 (2%)  | 1/50 (2%) | 1/50 (2%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/49 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 1/50 (2%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 0/49 (0%)       | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 1/50 (2%) | 1/50 (2%) | 0/50 (0%)       | 0/48 (0%)  | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) | 0/48 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 1/50 (2%)  | 1/50 (2%) | 0/46 (0%) | 0/46 (0%) | 0/46 (0%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/48 (0%) | 0/48 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
|   |       | 1/50 (2%)       | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 1/49 (2%) | 1/49 (2%) | 1/49 (2%) |
|   |       | 0/50 (0%)       | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) | 0/50 (0%)       | 2/49 (4%)  | 2/49 (4%) | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) |
|   |       | 0/50 (0%)       | 0/48 (0%)  | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
| <b>Overall Incidence</b>                            | Total | 5/1441 (0.35%)  | Mean 0.35% | SD 0.77%  | Total     | 7/1484 (0.47%)  | Mean 0.47% | SD 1.02%  |           |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|  |              | Male            |            |           |  | Female    |                 |            |          |  |  |
|--|--------------|-----------------|------------|-----------|--|-----------|-----------------|------------|----------|--|--|
| <b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b> |              |                 |            |           |  |           |                 |            |          |  |  |
|  |              | 0/50 (0%)       | 2/49 (4%)  | 1/50 (2%) |  | 2/50 (4%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/49 (0%)       | 0/50 (0%)  |           |  | 0/49 (0%) | 1/50 (2%)       | 0/48 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 2/50 (4%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/49 (0%)       | 1/50 (2%)  | 1/50 (2%) |  | 3/50 (6%) | 2/49 (4%)       | 0/49 (0%)  |          |  |  |
|  |              | 1/50 (2%)       | 2/50 (4%)  | 1/50 (2%) |  | 0/50 (0%) | 1/48 (2%)       | 0/48 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 3/50 (6%) |  | 0/50 (0%) | 1/50 (2%)       | 1/46 (2%)  |          |  |  |
|  |              | 1/50 (2%)       | 3/50 (6%)  | 0/48 (0%) |  | 0/50 (0%) | 3/50 (6%)       | 0/50 (0%)  |          |  |  |
|  |              | 1/50 (2%)       | 0/49 (0%)  | 0/50 (0%) |  | 1/50 (2%) | 2/50 (4%)       | 2/49 (4%)  |          |  |  |
|  |              | 1/50 (2%)       | 0/50 (0%)  | 0/49 (0%) |  | 1/50 (2%) | 2/49 (4%)       | 1/50 (2%)  |          |  |  |
|  |              | 3/50 (6%)       | 0/48 (0%)  | 3/50 (6%) |  | 3/50 (6%) | 3/50 (6%)       | 1/49 (2%)  |          |  |  |
| <b>Overall Incidence</b>                                     | <b>Total</b> | 24/1441 (1.67%) | Mean 1.66% | SD 2.15%  |  | Total     | 32/1484 (2.16%) | Mean 2.15% | SD 2.17% |  |  |
| .....  |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>#Tissue NOS: Carcinoma</b>                                |              |                 |            |           |  |           |                 |            |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  |           |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 1/50 (2%)       | 0/49 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
| <b>Overall Incidence</b>                                     | <b>Total</b> | 0/1449 (0%)     | Mean 0%    | SD 0%     |  | Total     | 1/1498 (0.07%)  | Mean 0.07% | SD 0.37% |  |  |
| .....  |              |                 |            |           |  |           |                 |            |          |  |  |
| <b>#Tissue NOS: Hemangiosarcoma</b>                          |              |                 |            |           |  |           |                 |            |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  |           |  | 0/50 (0%) | 1/50 (2%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/49 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/50 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
|  |              | 0/50 (0%)       | 0/49 (0%)  | 0/50 (0%) |  | 0/50 (0%) | 0/50 (0%)       | 0/50 (0%)  |          |  |  |
| <b>Overall Incidence</b>                                     | <b>Total</b> | 0/1449 (0%)     | Mean 0%    | SD 0%     |  | Total     | 1/1498 (0.07%)  | Mean 0.07% | SD 0.37% |  |  |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                    |              | Male   |      |         |       | Female       |        |         |            |          |      |      |      |
|------------------------------------|--------------|--------|------|---------|-------|--------------|--------|---------|------------|----------|------|------|------|
| <b>#Tissue NOS:</b>                |              |        |      |         |       |              |        |         |            |          |      |      |      |
| <b>Plasma Cell Tumor Malignant</b> |              |        |      |         |       |              |        |         |            |          |      |      |      |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 1/50     | (2%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  |              |        | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/49 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/50    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
|                                    |              | 0/50   | (0%) | 0/49    | (0%)  | 0/50         | (0%)   | 0/50    | (0%)       | 0/50     | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b>           | <b>Total</b> | 0/1449 | (0%) | Mean 0% | SD 0% | <b>Total</b> | 1/1498 | (0.07%) | Mean 0.07% | SD 0.37% |      |      |      |

|                             |              |        |         |            |          |              |        |      |         |       |      |      |      |
|-----------------------------|--------------|--------|---------|------------|----------|--------------|--------|------|---------|-------|------|------|------|
| <b>#Tissue NOS:</b>         |              |        |         |            |          |              |        |      |         |       |      |      |      |
| <b>Schwannoma Malignant</b> |              |        |         |            |          |              |        |      |         |       |      |      |      |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     |              |        | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/49 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 1/50   | (2%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/49 | (0%) |
|                             |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                             |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b>    | <b>Total</b> | 1/1449 | (0.07%) | Mean 0.07% | SD 0.37% | <b>Total</b> | 0/1498 | (0%) | Mean 0% | SD 0% |      |      |      |

|                          |              |        |         |            |          |              |        |      |         |       |      |      |      |
|--------------------------|--------------|--------|---------|------------|----------|--------------|--------|------|---------|-------|------|------|------|
| <b>#Tongue:</b>          |              |        |         |            |          |              |        |      |         |       |      |      |      |
| <b>Fibroma</b>           |              |        |         |            |          |              |        |      |         |       |      |      |      |
|                          |              | 0/50   | (0%)    | 1/50       | (2%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     |              |        | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/49 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/49 | (0%) |
|                          |              | 0/50   | (0%)    | 0/50       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
|                          |              | 0/50   | (0%)    | 0/49       | (0%)     | 0/50         | (0%)   | 0/50 | (0%)    | 0/50  | (0%) | 0/50 | (0%) |
| <b>Overall Incidence</b> | <b>Total</b> | 1/1449 | (0.07%) | Mean 0.07% | SD 0.37% | <b>Total</b> | 0/1498 | (0%) | Mean 0% | SD 0% |      |      |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied



Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                |              | Male           |            |           |              | Female         |            |           |           |
|--------------------------------|--------------|----------------|------------|-----------|--------------|----------------|------------|-----------|-----------|
| <b>#Tongue:</b>                |              |                |            |           |              |                |            |           |           |
| <b>Squamous Cell Carcinoma</b> |              |                |            |           |              |                |            |           |           |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/49 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>       | <b>Total</b> | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | <b>Total</b> | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |

|  |              |                |            |           |              |                |            |           |           |
|--|--------------|----------------|------------|-----------|--------------|----------------|------------|-----------|-----------|
| <b>#Tongue:</b>                                      |              |                |            |           |              |                |            |           |           |
| <b>Squamous Cell Carcinoma or Papilloma Squamous</b> |              |                |            |           |              |                |            |           |           |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/49 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/49 (0%) |
|  |              | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|  |              | 0/50 (0%)      | 0/49 (0%)  | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 2/50 (4%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>                             | <b>Total</b> | 2/1449 (0.14%) | Mean 0.14% | SD 0.52%  | <b>Total</b> | 4/1498 (0.27%) | Mean 0.27% | SD 0.87%  |           |

|                                |              |             |           |           |              |                |            |           |           |
|--------------------------------|--------------|-------------|-----------|-----------|--------------|----------------|------------|-----------|-----------|
| <b>#Tongue:</b>                |              |             |           |           |              |                |            |           |           |
| <b>Squamous Cell Papilloma</b> |              |             |           |           |              |                |            |           |           |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/49 (0%) | 0/49 (0%) |
|                                |              | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                |              | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)    | 0/50 (0%)      | 1/50 (2%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>       | <b>Total</b> | 0/1449 (0%) | Mean 0%   | SD 0%     | <b>Total</b> | 2/1498 (0.13%) | Mean 0.13% | SD 0.51%  |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                          |       | Male   |         |      |       |      |       | Female |        |         |      |       |      |       |
|--------------------------|-------|--------|---------|------|-------|------|-------|--------|--------|---------|------|-------|------|-------|
| <b>#Tooth:</b>           |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>Odontoma</b>          |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 1/50 | (2%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 2/50 | (4%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 1/50 | (2%)  | 1/50 | (2%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | Total | 5/1449 | (0.35%) | Mean | 0.34% | SD   | 0.94% | Total  | 0/1498 | (0%)    | Mean | 0%    | SD   | 0%    |
| .....                    |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>*Urinary Bladder:</b> |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>Hemangioma</b>        |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/47   | (0%)    | 0/50 | (0%)  |      |       | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/48   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 1/50   | (2%)    | 1/50 | (2%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/47  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/48 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/45  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | Total | 2/1439 | (0.14%) | Mean | 0.14% | SD   | 0.52% | Total  | 0/1483 | (0%)    | Mean | 0%    | SD   | 0%    |
| .....                    |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>*Urinary Bladder:</b> |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
| <b>Hemangiosarcoma</b>   |       |        |         |      |       |      |       |        |        |         |      |       |      |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/47   | (0%)    | 0/50 | (0%)  |      |       | 1/50   | (2%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/48   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/49   | (0%)   | 0/50    | (0%) | 0/47  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 1/48 | (2%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/45  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/50 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/50  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/49   | (0%)    | 0/50 | (0%)  | 0/49 | (0%)  | 0/50   | (0%)   | 0/49    | (0%) | 0/49  | (0%) |       |
|                          |       | 0/50   | (0%)    | 0/49 | (0%)  | 0/50 | (0%)  | 0/50   | (0%)   | 0/50    | (0%) | 0/50  | (0%) |       |
| <b>Overall Incidence</b> | Total | 1/1439 | (0.07%) | Mean | 0.07% | SD   | 0.39% | Total  | 1/1483 | (0.07%) | Mean | 0.07% | SD   | 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
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**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                    |       | Male        |           |           |                | Female         |            |           |           |
|------------------------------------|-------|-------------|-----------|-----------|----------------|----------------|------------|-----------|-----------|
| <b>*Urinary Bladder:</b>           |       |             |           |           |                |                |            |           |           |
| <b>Plasma Cell Tumor Malignant</b> |       |             |           |           |                |                |            |           |           |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/47 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/48 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/49 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/49 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/47 (0%) | 0/47 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/48 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/45 (0%) | 0/45 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/49 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/49 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 0/1439 (0%) | Mean 0%   | SD 0%     | Total          | 1/1483 (0.07%) | Mean 0.07% | SD 0.37%  |           |
| .....                              |       |             |           |           |                |                |            |           |           |
| <b>*Urinary Bladder:</b>           |       |             |           |           |                |                |            |           |           |
| <b>Sarcoma</b>                     |       |             |           |           |                |                |            |           |           |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 1/50 (2%) | 0/50 (0%) |
|                                    |       | 0/47 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/48 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/49 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/49 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/47 (0%) | 0/47 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/48 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/45 (0%) | 0/45 (0%) |
|                                    |       | 0/50 (0%)   | 0/50 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
|                                    |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/49 (0%)   | 0/50 (0%) | 0/49 (0%) | 0/50 (0%)      | 0/49 (0%)      | 0/50 (0%)  | 0/49 (0%) | 0/49 (0%) |
|                                    |       | 0/50 (0%)   | 0/49 (0%) | 0/50 (0%) | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) | 0/50 (0%) |
| <b>Overall Incidence</b>           | Total | 0/1439 (0%) | Mean 0%   | SD 0%     | Total          | 1/1483 (0.07%) | Mean 0.07% | SD 0.37%  |           |
| .....                              |       |             |           |           |                |                |            |           |           |
| <b>#Uterus:</b>                    |       |             |           |           |                |                |            |           |           |
| <b>Adenoma</b>                     |       |             |           |           |                |                |            |           |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |           |
|                                    |       |             |           |           | 1/50 (2%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/49 (0%)  | 0/49 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 1/50 (2%)  | 1/50 (2%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 1/50 (2%)      | 0/50 (0%)  | 0/50 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/49 (0%)  | 0/49 (0%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 1/50 (2%)  | 1/50 (2%) |           |
|                                    |       |             |           |           | 0/50 (0%)      | 0/50 (0%)      | 0/50 (0%)  | 0/50 (0%) |           |
| <b>Overall Incidence</b>           | Total |             |           |           | 4/1498 (0.27%) | Mean 0.27%     | SD 0.69%   |           |           |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|                          | Male                 |      | Female     |      |          |      |
|--------------------------|----------------------|------|------------|------|----------|------|
| <b>#Uterus:</b>          |                      |      |            |      |          |      |
| <b>Carcinoma</b>         |                      |      |            |      |          |      |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 3/50                 | (6%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 1/50       | (2%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b> | Total 5/1498 (0.33%) |      | Mean 0.33% |      | SD 1.18% |      |
| .....                    |                      |      |            |      |          |      |
| <b>#Uterus:</b>          |                      |      |            |      |          |      |
| <b>Hemangioma</b>        |                      |      |            |      |          |      |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 2/50       | (4%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 1/50       | (2%) | 0/50     | (0%) |
| <b>Overall Incidence</b> | Total 3/1498 (0.2%)  |      | Mean 0.2%  |      | SD 0.81% |      |
| .....                    |                      |      |            |      |          |      |
| <b>#Uterus:</b>          |                      |      |            |      |          |      |
| <b>Hemangiosarcoma</b>   |                      |      |            |      |          |      |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 1/50       | (2%) | 1/50     | (2%) |
|                          | 0/50                 | (0%) | 1/50       | (2%) | 0/50     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b> | Total 4/1498 (0.27%) |      | Mean 0.27% |      | SD 0.69% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
**Route: ALL ROUTES**  
**Vehicle: ALL VEHICLES**

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|                          | Male                  |      | Female     |      |          |      |
|--------------------------|-----------------------|------|------------|------|----------|------|
| <b>#Uterus:</b>          |                       |      |            |      |          |      |
| <b>Leiomyoma</b>         |                       |      |            |      |          |      |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 0/50                  | (0%) | 1/50       | (2%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b> | Total 3/1498 (0.2%)   |      | Mean 0.2%  |      | SD 0.61% |      |
| .....                    |                       |      |            |      |          |      |
| <b>#Uterus:</b>          |                       |      |            |      |          |      |
| <b>Leiomyosarcoma</b>    |                       |      |            |      |          |      |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 2/50       | (4%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 1/50       | (2%) | 0/49     | (0%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 0/50                  | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b> | Total 4/1498 (0.27%)  |      | Mean 0.27% |      | SD 0.87% |      |
| .....                    |                       |      |            |      |          |      |
| <b>#Uterus:</b>          |                       |      |            |      |          |      |
| <b>Polyp Stromal</b>     |                       |      |            |      |          |      |
|                          | 2/50                  | (4%) | 1/50       | (2%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 2/50       | (4%) | 0/50     | (0%) |
|                          | 3/50                  | (6%) | 1/50       | (2%) | 1/50     | (2%) |
|                          | 4/50                  | (8%) | 0/50       | (0%) | 0/50     | (0%) |
|                          | 2/50                  | (4%) | 1/50       | (2%) | 0/49     | (0%) |
|                          | 2/50                  | (4%) | 3/50       | (6%) | 0/50     | (0%) |
|                          | 0/50                  | (0%) | 3/50       | (6%) | 4/50     | (8%) |
|                          | 0/50                  | (0%) | 2/50       | (4%) | 0/49     | (0%) |
|                          | 1/50                  | (2%) | 0/50       | (0%) | 1/50     | (2%) |
|                          | 2/50                  | (4%) | 1/50       | (2%) | 1/50     | (2%) |
| <b>Overall Incidence</b> | Total 37/1498 (2.47%) |      | Mean 2.47% |      | SD 2.5%  |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|   | Male                 |      | Female     |      |          |      |
|---|----------------------|------|------------|------|----------|------|
| <b>#Uterus:</b>                         |                      |      |            |      |          |      |
| <b>Sarcoma Stromal</b>                  |                      |      |            |      |          |      |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 1/49     | (2%) |
|   | 0/50                 | (0%) | 1/50       | (2%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>                | Total 2/1498 (0.13%) |      | Mean 0.13% |      | SD 0.51% |      |
| .....                                   |                      |      |            |      |          |      |
| <b>#Uterus:</b>                         |                      |      |            |      |          |      |
| <b>Sarcoma Stromal or Polyp Stromal</b> |                      |      |            |      |          |      |
|   | 2/50                 | (4%) | 1/50       | (2%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 2/50       | (4%) | 0/50     | (0%) |
|   | 3/50                 | (6%) | 1/50       | (2%) | 1/50     | (2%) |
|   | 4/50                 | (8%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 2/50                 | (4%) | 1/50       | (2%) | 1/49     | (2%) |
|   | 2/50                 | (4%) | 4/50       | (8%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 3/50       | (6%) | 4/50     | (8%) |
|   | 0/50                 | (0%) | 2/50       | (4%) | 0/49     | (0%) |
|   | 1/50                 | (2%) | 0/50       | (0%) | 1/50     | (2%) |
|   | 2/50                 | (4%) | 1/50       | (2%) | 1/50     | (2%) |
| <b>Overall Incidence</b>                | Total 39/1498 (2.6%) |      | Mean 2.6%  |      | SD 2.58% |      |
| .....                                   |                      |      |            |      |          |      |
| <b>#Uterus:</b>                         |                      |      |            |      |          |      |
| <b>Schwannoma Malignant</b>             |                      |      |            |      |          |      |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 1/50       | (2%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 1/50                 | (2%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/49     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
|   | 0/50                 | (0%) | 0/50       | (0%) | 0/50     | (0%) |
| <b>Overall Incidence</b>                | Total 2/1498 (0.13%) |      | Mean 0.13% |      | SD 0.51% |      |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                                |       | Male                 |      |            | Female |          |        |         |            |          |
|--------------------------------|-------|----------------------|------|------------|--------|----------|--------|---------|------------|----------|
| <b>#Vagina:</b>                |       |                      |      |            |        |          |        |         |            |          |
| <b>Squamous Cell Carcinoma</b> |       |                      |      |            |        |          |        |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/49     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 1/50     | (2%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/49     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
| <b>Overall Incidence</b>       |       | Total 1/1498 (0.07%) |      | Mean 0.07% |        | SD 0.37% |        |         |            |          |
| .....                          |       |                      |      |            |        |          |        |         |            |          |
| <b>#Vagina:</b>                |       |                      |      |            |        |          |        |         |            |          |
| <b>Squamous Cell Papilloma</b> |       |                      |      |            |        |          |        |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/49     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/49     | (0%)   |         |            |          |
|                                |       | 1/50                 | (2%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
|                                |       | 0/50                 | (0%) | 0/50       | (0%)   | 0/50     | (0%)   |         |            |          |
| <b>Overall Incidence</b>       |       | Total 1/1498 (0.07%) |      | Mean 0.07% |        | SD 0.37% |        |         |            |          |
| .....                          |       |                      |      |            |        |          |        |         |            |          |
| <b>#Zymbal's Gland:</b>        |       |                      |      |            |        |          |        |         |            |          |
| <b>Carcinoma</b>               |       |                      |      |            |        |          |        |         |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/49   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/49   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/50 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
|                                | 0/50  | (0%)                 | 0/49 | (0%)       | 0/50   | (0%)     | 0/50   | (0%)    |            |          |
| <b>Overall Incidence</b>       | Total | 0/1449               | (0%) | Mean 0%    | SD 0%  | Total    | 1/1498 | (0.07%) | Mean 0.07% | SD 0.37% |

\*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied

Version: May2009  
 Contract/Lab: All Laboratories  
 Species: MICE  
 Strain: B6C3F1  
 Length of Study: CHRONIC

**Toxicology Data Management System**  
 Tumor Incidence for Selected Control Animal Groups  
 Route: ALL ROUTES  
 Vehicle: ALL VEHICLES

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|                             |       | Male   |      |      |      | Female |      |       |        |         |      |       |    |       |
|-----------------------------|-------|--------|------|------|------|--------|------|-------|--------|---------|------|-------|----|-------|
| <b>#Zymbal's Gland:</b>     |       |        |      |      |      |        |      |       |        |         |      |       |    |       |
| <b>Carcinoma or Adenoma</b> |       |        |      |      |      |        |      |       |        |         |      |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 1/50  | (2%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/49    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/50 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
|                             |       | 0/50   | (0%) | 0/49 | (0%) | 0/50   | (0%) | 0/50  | (0%)   | 0/50    | (0%) |       |    |       |
| <b>Overall Incidence</b>    | Total | 0/1449 | (0%) | Mean | 0%   | SD     | 0%   | Total | 1/1498 | (0.07%) | Mean | 0.07% | SD | 0.37% |

.....  
 \*: Denominator is number of animals with tissues examined microscopically  
 #: Denominator is number of animals necropsied