



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

By Route and Vehicle

MICE

June 2013

REPORT DESCRIPTION

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

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" 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:

| Male | | | Female | | |
|-------------|----|----|---------------|----|----|
| 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.

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| Route | Vehicle | Page Number |
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Version: Jun2013

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Page: 4

Report Date: 06/05/2013

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 |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 059903104 | 03/17/05 | 726 | 50(1) | 34(687) | 54.6 | Ginkgo biloba extract |
| Battelle Columbus Laboratory | 052000604 | 04/03/07 | 730 | 50(1) | 26(663) | 55.6 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052000706 | 08/24/04 | 730 | 50(1) | 34(689) | 56.4 | Kava kava extract |
| Battelle Columbus Laboratory | 052010704 | 10/26/04 | 730 | 50(1) | 34(665) | 55.7 | N,N-Dimethyl-p-toluidine |
| Battelle Columbus Laboratory | 052032004 | 08/07/07 | 730 | 50(1) | 33(687) | 55.8 | Tetrabromobisphenol A |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 059903104 | 03/18/05 | 727 | 50(5) | 31(628) | 64.5 | Ginkgo biloba extract |
| Battelle Columbus Laboratory | 052000604 | 04/02/07 | 729 | 50(5) | 33(702) | 66.6 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052000706 | 08/23/04 | 729 | 50(5) | 38(695) | 66.2 | Kava kava extract |
| Battelle Columbus Laboratory | 052010704 | 10/25/04 | 729 | 50(5) | 43(715) | 66.6 | N,N-Dimethyl-p-toluidine |
| Battelle Columbus Laboratory | 052032004 | 08/06/07 | 729 | 50(5) | 40(711) | 66.5 | Tetrabromobisphenol A |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 5
 Report Date: 06/05/2013

| | | Male | | | Female | | | |
|------------------------------------|-------|-----------------|-------------|-------------|-------------|-----------------|-------------|----------|
| #All Organs: | | | | | | | | |
| Benign Tumors | | | | | | | | |
| | | 38/50 (76%) | 33/50 (66%) | 34/50 (68%) | 25/50 (50%) | 17/50 (34%) | 26/50 (52%) | |
| | | 36/50 (72%) | 38/50 (76%) | | 24/50 (48%) | 22/50 (44%) | | |
| Overall Incidence | Total | 179/250 (71.6%) | Mean 71.6% | SD 4.56% | Total | 114/250 (45.6%) | Mean 45.6% | SD 7.13% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Tumors | | | | | | | | |
| | | 35/50 (70%) | 27/50 (54%) | 32/50 (64%) | 28/50 (56%) | 19/50 (38%) | 19/50 (38%) | |
| | | 29/50 (58%) | 21/50 (42%) | | 21/50 (42%) | 18/50 (36%) | | |
| Overall Incidence | Total | 144/250 (57.6%) | Mean 57.6% | SD 10.62% | Total | 105/250 (42%) | Mean 42% | SD 8.12% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | |
| | | 44/50 (88%) | 48/50 (96%) | 47/50 (94%) | 35/50 (70%) | 30/50 (60%) | 39/50 (78%) | |
| | | 45/50 (90%) | 47/50 (94%) | | 35/50 (70%) | 32/50 (64%) | | |
| Overall Incidence | Total | 231/250 (92.4%) | Mean 92.4% | SD 3.29% | Total | 171/250 (68.4%) | Mean 68.4% | SD 6.84% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) | 1/50 (2%) | | |
| Overall Incidence | Total | 4/250 (1.6%) | Mean 1.6% | SD 2.19% | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 9/50 (18%) | 4/50 (8%) | 6/50 (12%) | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | |
| | | 8/50 (16%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 28/250 (11.2%) | Mean 11.2% | SD 6.42% | Total | 4/250 (1.6%) | Mean 1.6% | SD 1.67% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 6
 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------------------------------------------------------------------|-------|----------------|------------|------------|-------------|----------------|---------------------|
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 9/50 (18%) | 4/50 (8%) | 8/50 (16%) | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) |
| | | 8/50 (16%) | 3/50 (6%) | | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | 32/250 (12.8%) | Mean 12.8% | SD 5.4% | Total | 7/250 (2.8%) | Mean 2.8% SD 1.1% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Histiocytic Sarcoma | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 3/50 (6%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 6/250 (2.4%) | Mean 2.4% SD 2.19% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | |
| | | 1/50 (2%) | 3/50 (6%) | 2/50 (4%) | 11/50 (22%) | 6/50 (12%) | 6/50 (12%) |
| | | 4/50 (8%) | 3/50 (6%) | | 15/50 (30%) | 9/50 (18%) | |
| Overall Incidence | Total | 13/250 (5.2%) | Mean 5.2% | SD 2.28% | Total | 47/250 (18.8%) | Mean 18.8% SD 7.56% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Mesothelioma: Benign | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 7
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|--------------|-----------|-----------|-------|--------------|------------|-----------|--|
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 2/49 (4%) | 0/50 (0%) | |
| | | 3/50 (6%) | 1/50 (2%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 5/250 (2%) | Mean 2% | SD 2.45% | Total | 2/249 (0.8%) | Mean 0.82% | SD 1.83% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Strain: B6C3F1
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 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%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/249 (1.2%) | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 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%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/249 (1.2%) | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | |
| #Blood Vessel: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 9
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Bone Marrow: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Bone: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 11
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 12
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

Page: 13
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|----------------|------------|------------|-------|---------------|-----------|------------|--|
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 4/50 (8%) | 6/50 (12%) | 5/50 (10%) | | 5/50 (10%) | 3/50 (6%) | 5/50 (10%) | |
| | | 11/50 (22%) | 7/50 (14%) | | | 1/50 (2%) | 2/50 (4%) | | |
| Overall Incidence | Total | 33/250 (13.2%) | Mean 13.2% | SD 5.4% | Total | 16/250 (6.4%) | Mean 6.4% | SD 3.58% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 14
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------|-------|----------------|------------|------------|-------|---------------|-----------|------------|--|
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 3/50 (6%) | 1/50 (2%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 5/250 (2%) | Mean 2% | SD 2.45% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 7/50 (14%) | 7/50 (14%) | 5/50 (10%) | | 6/50 (12%) | 3/50 (6%) | 5/50 (10%) | |
| | | 11/50 (22%) | 8/50 (16%) | | | 1/50 (2%) | 3/50 (6%) | | |
| Overall Incidence | Total | 38/250 (15.2%) | Mean 15.2% | SD 4.38% | Total | 18/250 (7.2%) | Mean 7.2% | SD 3.9% | |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

Page: 15
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Intestine Large: Cecum: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Leiomyoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 16
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 17
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Intestine Small: Ileum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 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%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 3/50 (6%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 6/250 (2.4%) | Mean 2.4% | SD 2.61% | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 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%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 3/50 (6%) | 3/50 (6%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 9/250 (3.6%) | Mean 3.6% | SD 2.61% | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 2/50 (4%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 4/250 (1.6%) | Mean 1.6% | SD 1.67% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------|-------|---------------|-----------|------------|-------|--------------|-----------|-----------|-----------|
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Liver: Hemangiosarcoma | | | | | | | | | |
| | | 9/50 (18%) | 4/50 (8%) | 5/50 (10%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 6/50 (12%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 24/250 (9.6%) | Mean 9.6% | SD 6.54% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|-----------------|-------------|-------------|-------|----------------|-------------|-------------|--|
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 3/50 (6%) | 3/50 (6%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 2/50 (4%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 9/250 (3.6%) | Mean 3.6% | SD 2.61% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 31/50 (62%) | 26/50 (52%) | 27/50 (54%) | | 17/50 (34%) | 7/50 (14%) | 8/50 (16%) | |
| | | 29/50 (58%) | 32/50 (64%) | | | 17/50 (34%) | 13/50 (26%) | | |
| Overall Incidence | Total | 145/250 (58%) | Mean 58% | SD 5.1% | Total | 62/250 (24.8%) | Mean 24.8% | SD 9.55% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 22/50 (44%) | 12/50 (24%) | 20/50 (40%) | | 9/50 (18%) | 6/50 (12%) | 3/50 (6%) | |
| | | 22/50 (44%) | 11/50 (22%) | | | 6/50 (12%) | 2/50 (4%) | | |
| Overall Incidence | Total | 87/250 (34.8%) | Mean 34.8% | SD 10.92% | Total | 26/250 (10.4%) | Mean 10.4% | SD 5.55% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 24/50 (48%) | 15/50 (30%) | 20/50 (40%) | | 10/50 (20%) | 6/50 (12%) | 3/50 (6%) | |
| | | 22/50 (44%) | 12/50 (24%) | | | 6/50 (12%) | 2/50 (4%) | | |
| Overall Incidence | Total | 93/250 (37.2%) | Mean 37.2% | SD 9.96% | Total | 27/250 (10.8%) | Mean 10.8% | SD 6.26% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 39/50 (78%) | 35/50 (70%) | 38/50 (76%) | | 20/50 (40%) | 12/50 (24%) | 10/50 (20%) | |
| | | 38/50 (76%) | 39/50 (78%) | | | 20/50 (40%) | 15/50 (30%) | | |
| Overall Incidence | Total | 189/250 (75.6%) | Mean 75.6% | SD 3.29% | Total | 77/250 (30.8%) | Mean 30.8% | SD 9.12% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|---------------|-------------|-------------|-------|----------------|-------------|-------------|--|
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 39/50 (78%) | 36/50 (72%) | 38/50 (76%) | | 20/50 (40%) | 12/50 (24%) | 10/50 (20%) | |
| | | 38/50 (76%) | 39/50 (78%) | | | 20/50 (40%) | 15/50 (30%) | | |
| Overall Incidence | Total | 190/250 (76%) | Mean 76% | SD 2.45% | Total | 77/250 (30.8%) | Mean 30.8% | SD 9.12% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 4/50 (8%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 4/250 (1.6%) | Mean 1.6% | SD 3.58% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | Female | | | |
|-----------------------------------------------------------------------|-------|----------------|-------------|-------------|-----------|---------------|-----------|----------|
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 8/50 (16%) | 4/50 (8%) | 9/50 (18%) | 0/50 (0%) | 1/50 (2%) | 2/50 (4%) | |
| | | 11/50 (22%) | 6/50 (12%) | | 2/50 (4%) | 5/50 (10%) | | |
| Overall Incidence | Total | 38/250 (15.2%) | Mean 15.2% | SD 5.4% | Total | 10/250 (4%) | Mean 4% | SD 3.74% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | |
| | | 11/50 (22%) | 4/50 (8%) | 2/50 (4%) | 1/50 (2%) | 2/50 (4%) | 2/50 (4%) | |
| | | 2/50 (4%) | 4/50 (8%) | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 23/250 (9.2%) | Mean 9.2% | SD 7.43% | Total | 6/250 (2.4%) | Mean 2.4% | SD 1.67% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 17/50 (34%) | 8/50 (16%) | 11/50 (22%) | 1/50 (2%) | 3/50 (6%) | 4/50 (8%) | |
| | | 13/50 (26%) | 10/50 (20%) | | 2/50 (4%) | 6/50 (12%) | | |
| Overall Incidence | Total | 59/250 (23.6%) | Mean 23.6% | SD 6.84% | Total | 16/250 (6.4%) | Mean 6.4% | SD 3.85% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Lymph Node, Mandibular: Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 27
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Mammary Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroadenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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
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| | | Male | | | Female | | |
|------------------------------------|-------|------------|-----------|-----------|----------------|--------------|-------------------|
| #Oral Mucosa: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% SD 1.1% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Choriocarcinoma | | | | | | | |
| | | | | | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) |
| | | | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | 1/249 (0.4%) | Mean 0.4% | SD 0.89% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Cystadenocarcinoma | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | 0/249 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Cystadenoma | | | | | | | |
| | | | | | 2/50 (4%) | 1/50 (2%) | 5/49 (10%) |
| | | | | | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | | | | 11/249 (4.42%) | Mean 4.44% | SD 3.37% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | 0/249 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
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| | Male | Female |
|-----------------------------------------------------|--------------------|---------------------|
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangioma | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 1/50 (2%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 1/249 (0.4%) | Mean 0.4% SD 0.89% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 1/49 (2%) |
| Overall Incidence | Total 1/249 (0.4%) | Mean 0.41% SD 0.91% |
| | | |
| *Ovary: | | |
| Plasma Cell Tumor Malignant | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |

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

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 Strain: B6C3F1
 Length of Study: CHRONIC

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| | Male | Female |
|------------------------------|--------------------|-------------------|
| *Ovary: | | |
| Sarcoma | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Benign | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Malignant | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Tubulostromal Adenoma | | |
| | 0/50 (0%) | 1/50 (2%) |
| | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total 2/249 (0.8%) | Mean 0.8% SD 1.1% |
| | | |
| *Ovary: | | |
| Yolk Sac Carcinoma | | |
| | 0/50 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/249 (0%) | Mean 0% SD 0% |

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

Version: Jun2013
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Toxicology Data Management System
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| | | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|------------|-----------|-----------|-------|----------------|------------|-----------|--|
| *Pancreas: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Pancreas: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 4/50 (8%) | 3/49 (6%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/48 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 10/247 (4.05%) | Mean 4.02% | SD 3.18% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/48 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 4/50 (8%) | 3/49 (6%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/48 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 10/247 (4.05%) | Mean 4.02% | SD 3.18% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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| | | Male | | | | Female | | | |
|-------------------------------------------|-------|--------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 1/49 (2%) | | 1/50 (2%) | 1/49 (2%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/48 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | Total | 3/247 (1.21%) | Mean 1.21% | SD 1.1% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 1/49 (2%) | | 1/50 (2%) | 1/49 (2%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/48 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | Total | 3/247 (1.21%) | Mean 1.21% | SD 1.1% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/249 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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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| | | Male | | | | Female | | | |
|----------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| *Salivary Glands: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | | | | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/250 (1.2%) | Mean 1.2% | SD 2.68% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------------------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/250 (1.2%) | Mean 1.2% | SD 2.68% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | Male | | | | | Female | | | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|--------------|------|------|-----------|----------|-------|--------------|------|------|-----------|----------|------|
| #Skin: | | | | | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 1/50 | (2%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | | | Mean 0.4% | SD 0.89% | Total | 3/250 (1.2%) | | | Mean 1.2% | SD 1.1% | |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 3/50 | (6%) | 1/50 | (2%) | 0/50 | (0%) |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 2/50 | (4%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | | | Mean 0.8% | SD 1.1% | Total | 7/250 (2.8%) | | | Mean 2.8% | SD 2.28% | |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 2/50 | (4%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | | | Mean 0.4% | SD 0.89% | Total | 3/250 (1.2%) | | | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 3/50 | (6%) | 1/50 | (2%) | 0/50 | (0%) |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 2/50 | (4%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | | | Mean 0.8% | SD 1.1% | Total | 7/250 (2.8%) | | | Mean 2.8% | SD 2.28% | |
| | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | | | Mean 0% | SD 0% | Total | 0/250 (0%) | | | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|-----------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|----------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|--------------|-----------|-----------|-----------|--------------|-----------|----------|
| #Skin: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 3/50 (6%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 4/250 (1.6%) | Mean 1.6% | SD 2.61% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Benign | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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| | | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Spinal Cord: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| | | 0/48 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 2/50 (4%) | | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) | |
| | | 3/48 (6%) | 1/50 (2%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 7/248 (2.82%) | Mean 2.85% | SD 2.37% | Total | 2/248 (0.81%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | |
| | | 0/48 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| | | 0/48 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/248 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|---------------|------------|------------|-------|--------------|-----------|-----------|--|
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 9/50 (18%) | | 2/50 (4%) | 1/50 (2%) | 3/50 (6%) | |
| | | 1/50 (2%) | 5/50 (10%) | | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 17/250 (6.8%) | Mean 6.8% | SD 7.29% | Total | 7/250 (2.8%) | Mean 2.8% | SD 2.28% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 8/50 (16%) | | 2/50 (4%) | 1/50 (2%) | 3/50 (6%) | |
| | | 1/50 (2%) | 5/50 (10%) | | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 15/250 (6%) | Mean 6% | SD 6.78% | Total | 7/250 (2.8%) | Mean 2.8% | SD 2.28% | |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|-----------------------------|-------|---------------|------------|-----------|-----------|--------------|--------------------|
| #Stomach, Glandular: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% SD 0.89% |
| | | | | | | | |
| *Testes: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | | |
| | | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | | | |
| | | | | | | | |
| *Testes: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | |
| | | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Neoplasm NOS | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/48 (0%) | 0/47 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/242 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/50 (0%) | 1/49 (2%) | 0/48 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/48 (0%) | 0/47 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/242 (0.41%) | Mean 0.41% | SD 0.91% | Total | 0/249 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 46
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|---------------|------------|-----------|-------|--------------|-----------|-----------|--|
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/48 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/48 (0%) | 0/47 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/242 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 1/49 (2%) | 0/48 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/48 (0%) | 0/47 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/242 (0.41%) | Mean 0.41% | SD 0.91% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (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%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (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%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 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%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/249 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/249 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Tissue NOS: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 5/50 (10%) | 2/50 (4%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 7/250 (2.8%) | Mean 2.8% | SD 4.38% | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Urethra: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | Total | 0/250 (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

Page: 50
 Report Date: 06/05/2013

| | Male | | Female | | |
|------------------------------------|-------|--------------|-----------|-----------|--|
| #Uterus: Hemangiosarcoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | |
| #Uterus: Leiomyoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | |
| #Uterus: Leiomyosarcoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | |
| | | | | | |
| #Uterus: Polyp Stromal | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | |
| | | | | | |
| #Uterus: Sarcoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/05/2013

| | | | | | Male | | | | | | Female | | | |
|-----------------------------------------|-------|-------|--------|------|-------|-------|--------|-------|-------|------|--------|----|----|----|
| #Uterus: | | | | | | | | | | | | | | |
| Sarcoma Stromal | | | | | | | | | | | | | | |
| | | | | | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | | | |
| | | | | | | 0/50 | (0%) | 2/50 | (4%) | | | | | |
| Overall Incidence | | | | | Total | 3/250 | (1.2%) | Mean | 1.2% | SD | 1.79% | | | |
| | | | | | | | | | | | | | | |
| #Uterus: | | | | | | | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | | | | | | | |
| | | | | | | 2/50 | (4%) | 0/50 | (0%) | 2/50 | (4%) | | | |
| | | | | | | 0/50 | (0%) | 2/50 | (4%) | | | | | |
| Overall Incidence | | | | | Total | 6/250 | (2.4%) | Mean | 2.4% | SD | 2.19% | | | |
| | | | | | | | | | | | | | | |
| #Vagina: | | | | | | | | | | | | | | |
| Liposarcoma | | | | | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | | |
| | | | | | | 0/50 | (0%) | 0/50 | (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/250 | (0%) | Mean | 0% | SD | 0% | | | |
| | | | | | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 1/250 | (0.4%) | Mean | 0.4% | SD | 0.89% | Total | 0/250 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 1/250 | (0.4%) | Mean | 0.4% | SD | 0.89% | Total | 0/250 | (0%) | Mean | 0% | SD | 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: METHYLCELLULOSE

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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 |
|-----------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|----------------------------|
| Male | | | | | | | |
| Southern Research Institute | 059903706 | 06/30/03 | 729 | 50(1) | 40(701) | 53.9 | alpha/beta Thujone mixture |
| Female | | | | | | | |
| Southern Research Institute | 059903706 | 06/30/03 | 731 | 50(5) | 37(668) | 64.7 | alpha/beta Thujone mixture |

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 32/50 (64%) | | | 22/50 (44%) | | |
| Overall Incidence | Total | 32/50 (64%) | Mean 64% | SD 0% | Total | 22/50 (44%) | Mean 44% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 30/50 (60%) | | | 19/50 (38%) | | |
| Overall Incidence | Total | 30/50 (60%) | Mean 60% | SD 0% | Total | 19/50 (38%) | Mean 38% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 45/50 (90%) | | | 35/50 (70%) | | |
| Overall Incidence | Total | 45/50 (90%) | Mean 90% | SD 0% | Total | 35/50 (70%) | Mean 70% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 4/50 (8%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 4/50 (8%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|-----------|---------|-------|------------|------------|----------|-------|
| #All Organs: | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 4/50 (8%) | | | 6/50 (12%) | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 6/50 (12%) | Mean 12% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------|-------|------|---------|------------|--------|---------|-----------|
| #All Organs: | | | | | | | |
| Osteosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 | (4%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 1/50 (2%) |
| | | | | | | Mean 2% | SD 0% |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | Mean 2% | SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Benign | | | | | | | |
| | | 0/49 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | |
| | | 1/49 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/49 | (2.04%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

Page: 56
 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------|-------|--------------|------------|-------|-----------|-----------|---------|-------|
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 1/49 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Blood Vessel: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|-------|--------|------|---------|-------|
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|--------------------------------------------------|-------|------|------|---------|--------|-------|------|---------|
| *Brain: | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| *Brain: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | Mean 2% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/49 | (0%) | | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/49 | (0%) | | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Coagulating Gland: | | | | | | | | |
| Granular Cell Tumor | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Coagulating Gland: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | Female | | |
|--------------------------------|-------|-------------|----------|-------|------------|------------|----------------|
| #Esophagus: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Eye: | | | | | | | |
| Melanoma Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Adenoma | | | | | | | |
| | | 8/50 (16%) | | | 5/50 (10%) | | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total | 5/50 (10%) | Mean 10% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 2/50 (4%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 10/50 (20%) | | | 6/50 (12%) | | |
| Overall Incidence | Total | 10/50 (20%) | Mean 20% | SD 0% | Total | 6/50 (12%) | Mean 12% SD 0% |
| | | | | | | | |
| *Heart: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Large: Cecum: Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Large: Cecum: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Large: Cecum: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Large: Cecum: Leiomyoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Large: Cecum: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Large: Colon/Rectum: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

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

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| | | Male | | | Female | | |
|--------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------------|
| #Intestine Small: Ileum: | | | | | | | |
| Polyp Adenomatous | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | |
| Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | Female | | |
|---------------------------------------------------------------------|-------|-----------|---------|-------|--------|--------------|------------------|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: Adenoma | | | | | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/48 (2.08%) | Mean 2.08% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | Female | | |
|-----------------------------------------------------|-------|------|------|---------|--------|---------|------------|
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 0/48 | (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 4/50 | (8%) | | 1/48 | (2%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | 1/48 | (2.08%) | Mean 2.08% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 0/50 | (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 0/50 | (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 0/50 | (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 0/50 | (0%) | Mean 0% |
| | | | | SD 0% | | | SD 0% |

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

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| | | Male | | | | Female | | | |
|---------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Liver: Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|-------|-------|----------|--------|-------|----------|-------|
| *Liver: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 2/50 | (4%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | Mean 2% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatoblastoma | | | | | | | | |
| | | 3/50 | (6%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 3/50 | (6%) | Mean 6% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | |
| | | 24/50 | (48%) | | | 13/50 | (26%) | |
| Overall Incidence | Total | 24/50 | (48%) | Mean 48% | SD 0% | Total | 13/50 | (26%) |
| | | | | | | | Mean 26% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | |
| | | 16/50 | (32%) | | | 3/50 | (6%) | |
| Overall Incidence | Total | 16/50 | (32%) | Mean 32% | SD 0% | Total | 3/50 | (6%) |
| | | | | | | | Mean 6% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | |
| | | 18/50 | (36%) | | | 3/50 | (6%) | |
| Overall Incidence | Total | 18/50 | (36%) | Mean 36% | SD 0% | Total | 3/50 | (6%) |
| | | | | | | | Mean 6% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | |
| | | 33/50 | (66%) | | | 15/50 | (30%) | |
| Overall Incidence | Total | 33/50 | (66%) | Mean 66% | SD 0% | Total | 15/50 | (30%) |
| | | | | | | | Mean 30% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 33/50 (66%) | | | 15/50 (30%) | | | |
| Overall Incidence | Total | 33/50 (66%) | Mean 66% | SD 0% | Total | 15/50 (30%) | Mean 30% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangioma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | Female | | |
|-----------------------------------------------------------------------|-------|-------|-------|----------|--------|-------|-----------|
| *Liver: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 7/50 | (14%) | | | 3/50 | (6%) |
| Overall Incidence | Total | 7/50 | (14%) | Mean 14% | SD 0% | Total | 3/50 (6%) |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | |
| | | 6/50 | (12%) | | | 1/50 | (2%) |
| Overall Incidence | Total | 6/50 | (12%) | Mean 12% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 13/50 | (26%) | | | 4/50 | (8%) |
| Overall Incidence | Total | 13/50 | (26%) | Mean 26% | SD 0% | Total | 4/50 (8%) |
| | | | | | | | |
| *Lung: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Lung: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

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| | Male | | | | Female | | | |
|-----------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Mammary Gland: | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Mammary Gland: | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Mesentery: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | Female | | |
|---------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Nose: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Nose: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Oral Mucosa: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | Male | Female |
|-----------------------------------------------------|-------|-------------------------------|
| *Ovary: | | |
| Choriocarcinoma | | |
| Overall Incidence | Total | 1/48 (2%) Mean 2.08% SD 0% |
| | | |
| *Ovary: | | |
| Cystadenocarcinoma | | |
| Overall Incidence | Total | 0/48 (0%) Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Cystadenoma | | |
| Overall Incidence | Total | 2/48 (4%) Mean 4.17% SD 0% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor Benign | | |
| Overall Incidence | Total | 0/48 (0%) Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| Overall Incidence | Total | 0/48 (0%) Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangioma | | |
| Overall Incidence | Total | 0/48 (0%) Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | Male | | Female | |
|------------------------------------|------|-------|--------------|---------------------|
| *Ovary: | | | | |
| Hemangiosarcoma | | | | |
| | | | 0/48 (0%) | |
| Overall Incidence | | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Luteoma | | | | |
| | | | 0/48 (0%) | |
| Overall Incidence | | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Plasma Cell Tumor Malignant | | | | |
| | | | 1/48 (2%) | |
| Overall Incidence | | Total | 1/48 (2.08%) | Mean 2.08% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Sarcoma | | | | |
| | | | 0/48 (0%) | |
| Overall Incidence | | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Teratoma Benign | | | | |
| | | | 0/48 (0%) | |
| Overall Incidence | | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Teratoma Malignant | | | | |
| | | | 0/48 (0%) | |
| Overall Incidence | | Total | 0/48 (0%) | Mean 0% SD 0% |
| | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| Male | | | | | Female | | | | | |
|-------------------------------------------------------------|--|--|--|--|-----------|--------------|------|-------|----|----|
| *Ovary: | | | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | | | |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | |
| *Ovary: | | | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | | | |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean | 0% | SD | 0% |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean | 0% | SD | 0% |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | |
| Adenoma | | | | | | | | | | |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | 2/49 (4%) | | | | | |
| Overall Incidence | | | | | Total | 2/49 (4.08%) | Mean | 4.08% | SD | 0% |
| | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 0/48 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/48 (0%) | Mean | 0% | SD | 0% |
| | | | | | 0/49 (0%) | | | | | |
| Overall Incidence | | | | | Total | 0/49 (0%) | Mean | 0% | SD | 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | Female | | |
|---------------------------------------------------------------------------|-------|-----------|---------|-------|-----------|--------------|---------------------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/48 (0%) | | | 2/49 (4%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *: Denominator is number of animals with tissues examined microscopically | | | | | | | |
| #: Denominator is number of animals necropsied | | | | | | | |

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | Female | | |
|----------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------------|
| *Salivary Glands: | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Myxoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Seminal Vesicle: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Rhabdomyosarcoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|---------|-------|
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 3/50 | (6%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 3/50 | (6%) | Mean 6% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | Male | | | | Female | | | | |
|--------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|---------|-------|
| #Skin: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 3/50 | (6%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 3/50 (6%) | Mean 6% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Melanoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neural Crest Tumor | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Osteosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|---------|-------|
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 1/50 | (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 1/50 | (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Spinal Cord: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Spleen: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 | (2%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | Mean 2% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Spleen: | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Spleen: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | Mean 2% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | Male | | | | Female | | | |
|-----------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/44 | (0%) | | | 0/46 | (0%) | | |
| Overall Incidence | Total | 0/44 | (0%) | Mean 0% | SD 0% | Total | 0/46 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|-----------------------------------------|-------|------|---------|------------|--------|-------|-----------|
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/44 | (0%) | | 0/46 | (0%) | |
| Overall Incidence | Total | 0/44 | (0%) | Mean 0% | SD 0% | Total | 0/46 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Malignant | | | | | | | |
| | | 0/44 | (0%) | | 0/46 | (0%) | |
| Overall Incidence | Total | 0/44 | (0%) | Mean 0% | SD 0% | Total | 0/46 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 0/44 | (0%) | | 0/46 | (0%) | |
| Overall Incidence | Total | 0/44 | (0%) | Mean 0% | SD 0% | Total | 0/46 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/49 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/49 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/49 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/49 | (2.04%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|--------------------------------------------------------------|-------|--------------|------------|-------|--------|-----------|---------------|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | |
| Overall Incidence | Total | 1/49 (2%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 2/49 (4.08%) | Mean 4.08% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Tissue NOS: Sarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | Male | | | | Female | | | |
|------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|---------------|
| #Tongue: | | | | | | | | |
| Fibroma | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Tongue: | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Tongue: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Tooth: | | | | | | | | |
| Odontoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| #Urethra: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | | |
| *Urinary Bladder: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|--------|-------|---------|-------|
| *Urinary Bladder: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | Mean 2% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: METHYLCELLULOSE

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| | | | | Male | | | | | Female | |
|-----------------------------------------|-------|------|------|---------|-------|-------|------|---------|---------|-------|
| #Uterus: | | | | | | | | | | |
| Polyp Stromal | | | | | | | | | | |
| | | | | | | 1/50 | (2%) | | | |
| Overall Incidence | | | | Total | 1/50 | (2%) | | Mean 2% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma Stromal | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | | | |
| | | | | | | 1/50 | (2%) | | | |
| Overall Incidence | | | | Total | 1/50 | (2%) | | Mean 2% | SD 0% | |
| | | | | | | | | | | |
| #Vagina: | | | | | | | | | | |
| Liposarcoma | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |

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

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: METHYLCELLULOSE

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Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-----------------------------|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma or Adenoma | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

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 |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|-------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052000506 | 02/10/04 | 730 | 50(1) | 32(691) | 51.1 | Ginseng |
| Battelle Columbus Laboratory | 052020304 | 07/10/07 | 730 | 50(1) | 33(694) | 52.6 | Green tea extract |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052000506 | 02/09/04 | 729 | 50(5) | 38(711) | 63.9 | Ginseng |
| Battelle Columbus Laboratory | 052020304 | 07/09/07 | 729 | 50(5) | 34(665) | 62.9 | Green tea extract |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|--------------------------------------|-------|--------------|-------------|----------|-------|--------------|-------------|-----------|--|
| #All Organs: | | | | | | | | | |
| Benign Tumors | | | | | | | | | |
| | | 38/50 (76%) | 43/50 (86%) | | | 33/50 (66%) | 20/50 (40%) | | |
| Overall Incidence | Total | 81/100 (81%) | Mean 81% | SD 7.07% | Total | 53/100 (53%) | Mean 53% | SD 18.38% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Tumors | | | | | | | | | |
| | | 26/50 (52%) | 28/50 (56%) | | | 15/50 (30%) | 18/50 (36%) | | |
| Overall Incidence | Total | 54/100 (54%) | Mean 54% | SD 2.83% | Total | 33/100 (33%) | Mean 33% | SD 4.24% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | | |
| | | 46/50 (92%) | 49/50 (98%) | | | 42/50 (84%) | 29/50 (58%) | | |
| Overall Incidence | Total | 95/100 (95%) | Mean 95% | SD 4.24% | Total | 71/100 (71%) | Mean 71% | SD 18.38% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/100 (3%) | Mean 3% | SD 1.41% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 4/50 (8%) | 5/50 (10%) | | | 0/50 (0%) | 2/50 (4%) | | |
| Overall Incidence | Total | 9/100 (9%) | Mean 9% | SD 1.41% | Total | 2/100 (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | | |
| | | 5/50 (10%) | 7/50 (14%) | | | 1/50 (2%) | 2/50 (4%) | | |
| Overall Incidence | Total | 12/100 (12%) | Mean 12% | SD 2.83% | Total | 3/100 (3%) | Mean 3% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|-------|------|---------|----------|--------|--------|-------|----------|
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 4/50 | (8%) | 4/50 | (8%) | 9/50 | (18%) | 7/50 | (14%) |
| Overall Incidence | Total | 8/100 | (8%) | Mean 8% | SD 0% | Total | 16/100 | (16%) | Mean 16% |
| | | | | | | | | | SD 2.83% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

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

Version: Jun2013
 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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| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|---------|------------|----------|--------|-------|---------|------------------|
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/49 | (2%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 2/99 | (2.02%) | Mean 2.02% | SD 0.03% | Total | 0/99 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | 1/50 | (2%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | Total | 1/99 | (1.01%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------------|-------|------------|-----------|----------|-----------|--------------|---------|----------|--|
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | | 1/50 (2%) | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 1/99 (1.01%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| #Blood Vessel: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|-------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | | Male | | | | Female | | | |
|--------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------------|
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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Toxicology Data Management System
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| | | Male | | | | Female | | | |
|--------------------------------|-------|--------------|------------|----------|------------|--------------|----------|----------|--|
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 11/50 (22%) | 7/50 (14%) | | 7/50 (14%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 18/100 (18%) | Mean 18% | SD 5.66% | Total | 9/100 (9%) | Mean 9% | SD 7.07% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 0% | Total | 2/100 (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 12/50 (24%) | 8/50 (16%) | | 7/50 (14%) | 4/50 (8%) | | | |
| Overall Incidence | Total | 20/100 (20%) | Mean 20% | SD 5.66% | Total | 11/100 (11%) | Mean 11% | SD 4.24% | |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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 Route: GAVAGE
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| | | Male | | | | Female | | | | | |
|----------------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------|-------|------|
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|--------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Intestine Small: Ileum: | | | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|---------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Islets, Pancreatic: Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | | | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | 2/50 | (4%) | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 4/100 | (4%) | Mean 4% | SD 0% | Total | 2/100 | (2%) | Mean 2% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | 2/50 | (4%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|---------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 3/50 | (6%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 4/100 | (4%) | Mean 4% | SD 2.83% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Liver: Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|--------------|-------------|----------|-------------|--------------|----------|-----------|--|
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/50 (4%) | 3/50 (6%) | | 0/50 (0%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 5/100 (5%) | Mean 5% | SD 1.41% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 3/100 (3%) | Mean 3% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 34/50 (68%) | 35/50 (70%) | | 21/50 (42%) | 12/50 (24%) | | | |
| Overall Incidence | Total | 69/100 (69%) | Mean 69% | SD 1.41% | Total | 33/100 (33%) | Mean 33% | SD 12.73% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 14/50 (28%) | 15/50 (30%) | | 2/50 (4%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 29/100 (29%) | Mean 29% | SD 1.41% | Total | 7/100 (7%) | Mean 7% | SD 4.24% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 14/50 (28%) | 17/50 (34%) | | 2/50 (4%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 31/100 (31%) | Mean 31% | SD 4.24% | Total | 7/100 (7%) | Mean 7% | SD 4.24% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 39/50 (78%) | 40/50 (80%) | | 23/50 (46%) | 14/50 (28%) | | | |
| Overall Incidence | Total | 79/100 (79%) | Mean 79% | SD 1.41% | Total | 37/100 (37%) | Mean 37% | SD 12.73% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|--------------|-------------|----------|-------------|--------------|----------|-----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 39/50 (78%) | 40/50 (80%) | | 23/50 (46%) | 14/50 (28%) | | |
| Overall Incidence | Total | 79/100 (79%) | Mean 79% | SD 1.41% | Total | 37/100 (37%) | Mean 37% | SD 12.73% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------|-------|--------------|-------------|----------|------------|--------------|-----------|----------|--|
| *Liver: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 9/50 (18%) | 12/50 (24%) | | 6/50 (12%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 21/100 (21%) | Mean 21% | SD 4.24% | Total | 11/100 (11%) | Mean 11% | SD 1.41% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 3/50 (6%) | 2/50 (4%) | | 1/50 (2%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 5/100 (5%) | Mean 5% | SD 1.41% | Total | 2/100 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 12/50 (24%) | 14/50 (28%) | | 7/50 (14%) | 6/50 (12%) | | | |
| Overall Incidence | Total | 26/100 (26%) | Mean 26% | SD 2.83% | Total | 13/100 (13%) | Mean 13% | SD 1.41% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | | | |
|-----------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|----------|
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | | |
|---------------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|
| *Nose: | | | | | | | | | | |
| Adenoma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/48 | (2%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/98 | (1.02%) | Mean 1.04% | SD 1.47% |
| | | | | | | | | | | |
| *Nose: | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/98 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| #Oral Mucosa: | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 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: WATER

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| | Male | Female |
|-----------------------------------------------------|--------------------|-------------------|
| *Ovary: | | |
| Choriocarcinoma | | |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/100 (0%) | Mean 0% SD 0% |
| *Ovary: | | |
| Cystadenocarcinoma | | |
| | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total 1/100 (1%) | Mean 1% SD 1.41% |
| *Ovary: | | |
| Cystadenoma | | |
| | 7/50 (14%) | 3/50 (6%) |
| Overall Incidence | Total 10/100 (10%) | Mean 10% SD 5.66% |
| *Ovary: | | |
| Granulosa Cell Tumor Benign | | |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/100 (0%) | Mean 0% SD 0% |
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/100 (0%) | Mean 0% SD 0% |
| *Ovary: | | |
| Hemangioma | | |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/100 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | Male | | | Female | |
|------------------------------------|------|-------|------------|-----------|----------|
| *Ovary: | | | | | |
| Hemangiosarcoma | | | | | |
| | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | |
| *Ovary: | | | | | |
| Luteoma | | | | | |
| | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | |
| *Ovary: | | | | | |
| Plasma Cell Tumor Malignant | | | | | |
| | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | |
| *Ovary: | | | | | |
| Sarcoma | | | | | |
| | | | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | | Total | 1/100 (1%) | Mean 1% | SD 1.41% |
| | | | | | |
| *Ovary: | | | | | |
| Teratoma Benign | | | | | |
| | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | |
| *Ovary: | | | | | |
| Teratoma Malignant | | | | | |
| | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| Male | | | | | Female | | | | | | | | | |
|-------------------------------------------------------------|-------|-------|---------|------|--------|-------|-------|-------|-------|------|------|----|----|-------|
| *Ovary: | | | | | | | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | | | | | | | |
| | | | | | 0/50 | (0%) | 0/50 | (0%) | | | | | | |
| Overall Incidence | | | | | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | | | |
| | | | | | | | | | | | | | | |
| *Ovary: | | | | | | | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | | | | | | | |
| | | | | | 0/50 | (0%) | 0/50 | (0%) | | | | | | |
| Overall Incidence | | | | | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | | | |
| | | | | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/49 | (2%) | | | 1/50 | (2%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 2/99 | (2.02%) | Mean | 2.02% | SD | 0.03% | Total | 1/100 | (1%) | Mean | 1% | SD | 1.41% |
| | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | | | | | | |
|-------------------------------------------------------------|-------|--------------|------|------|-------|--------|-------|-------|------------|------|------|----|----|-------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/49 | (2%) | | | 1/50 | (2%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 2/99 (2.02%) | | Mean | 2.02% | SD | 0.03% | Total | 1/100 (1%) | | Mean | 1% | SD | 1.41% |
| | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/99 (0%) | | Mean | 0% | SD | 0% | Total | 1/100 (1%) | | Mean | 1% | SD | 1.41% |
| | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/49 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/99 (0%) | | Mean | 0% | SD | 0% | Total | 1/100 (1%) | | Mean | 1% | SD | 1.41% |
| | | | | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | | Mean | 0% | SD | 0% | Total | 0/100 (0%) | | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | | Mean | 0% | SD | 0% | Total | 0/100 (0%) | | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | | Mean | 0% | SD | 0% | Total | 0/100 (0%) | | Mean | 0% | SD | 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | | | |
|----------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| *Salivary Glands: | | | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | | | |
| Myxoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | | | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Skeletal Muscle: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 4/50 | (8%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 4/100 | (4%) | Mean 4% | SD 5.66% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|--------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Skin: | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 3/50 | (6%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 3/100 | (3%) | Mean 3% | SD 4.24% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 4/50 | (8%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 4/100 | (4%) | Mean 4% | SD 5.66% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------------|
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

Page: 123
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|------------------|
| #Skin: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% SD 2.83% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% SD 2.83% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|-----------------------------------------------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Skin: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|------------|-----------|-------|-----------|------------|---------|----------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Spinal Cord: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|----------|
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 2/50 | (4%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| *Spleen: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| *Spleen: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% |
| | | | | | | | | | SD 2.83% |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|-----------------------------|-------|-------|------|---------|----------|--------|-------|------|---------------|
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | | |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/47 | (0%) | 0/44 | (0%) | 0/48 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/91 | (0%) | Mean 0% | SD 0% | Total | 0/95 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/47 | (0%) | 0/44 | (0%) | 0/48 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/91 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/47 | (0%) | 0/44 | (0%) | 0/48 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/91 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/47 | (0%) | 0/44 | (0%) | 0/48 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/91 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|------------|-----------|-------|-----------|------------|---------|-------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------------|
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Urethra: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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| | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-------|-----------|------------|---------|-------|
| *Urinary Bladder: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: WATER

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|------------------|-------|-----------|------------|---------|----------|
| #Uterus: | | | | | | | | |
| Polyp Stromal | | | | | | | | |
| | | | 0/50 (0%) | | 2/50 (4%) | | | |
| Overall Incidence | | | Total 2/100 (2%) | | Mean 2% | | | SD 2.83% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | | |
| Overall Incidence | | | Total 0/100 (0%) | | Mean 0% | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma Stromal | | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | | |
| Overall Incidence | | | Total 0/100 (0%) | | Mean 0% | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | |
| | | | 0/50 (0%) | | 2/50 (4%) | | | |
| Overall Incidence | | | Total 2/100 (2%) | | Mean 2% | | | SD 2.83% |
| | | | | | | | | |
| #Vagina: | | | | | | | | |
| Liposarcoma | | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | | |
| Overall Incidence | | | Total 0/100 (0%) | | Mean 0% | | | SD 0% |
| | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: WATER

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Report Date: 06/05/2013

| Male | | | | | Female | | | | |
|-----------------------------|-------|-------|------|------|--------|------|------|-------|------------|
| #Zymbal's Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 (0%) |
| | | | | | | | | Mean | 0% |
| | | | | | | | | SD | 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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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 |
|--------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|-------------------------------------|
| Male | | | | | | | |
| Battelle Northwest | 052001106 | 07/21/03 | 729 | 50(5) | 37(689) | 53.4 | 1-Bromopropane |
| Battelle Northwest | 056031106 | 05/15/06 | 729 | 50(5) | 39(715) | 54.3 | Cobalt |
| Battelle Northwest | 059901706 | 08/18/03 | 729 | 50(5) | 31(686) | 53.8 | Diethylamine |
| Battelle Northwest | 052051504 | 05/05/08 | 729 | 50(5) | 39(709) | 52.6 | Metal working fluids (CIMSTAR 3800) |
| Battelle Northwest | 059302506 | 06/23/03 | 729 | 50(5) | 36(695) | 52.9 | Tetralin |
| Battelle Northwest | 052030306 | 06/20/05 | 729 | 50(5) | 29(680) | 53.1 | Vinylidene chloride |
| Female | | | | | | | |
| Battelle Northwest | 052001106 | 07/21/03 | 731 | 50(5) | 36(698) | 61.2 | 1-Bromopropane |
| Battelle Northwest | 056031106 | 05/15/06 | 731 | 50(5) | 36(686) | 66.7 | Cobalt |
| Battelle Northwest | 059901706 | 08/18/03 | 731 | 50(5) | 32(684) | 60.7 | Diethylamine |
| Battelle Northwest | 052051504 | 05/05/08 | 731 | 50(5) | 39(696) | 59.2 | Metal working fluids (CIMSTAR 3800) |
| Battelle Northwest | 059302506 | 06/23/03 | 731 | 50(5) | 31(663) | 62.1 | Tetralin |
| Battelle Northwest | 052030306 | 06/20/05 | 731 | 50(5) | 36(687) | 66.0 | Vinylidene chloride |

Version: Jun2013
 Contract/Lab: All Laboratories
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------------------|-------------|-------------|-------|------------------|-------------|-------------|--|
| #All Organs: | | | | | | | | | |
| Benign Tumors | | | | | | | | | |
| | | 36/50 (72%) | 35/50 (70%) | 33/50 (66%) | | 22/50 (44%) | 29/50 (58%) | 25/50 (50%) | |
| | | 39/50 (78%) | 42/50 (84%) | 43/50 (86%) | | 26/50 (52%) | 24/50 (48%) | 32/50 (64%) | |
| Overall Incidence | Total | 228/300 (76%) | Mean 76% | SD 8% | Total | 158/300 (52.67%) | Mean 52.67% | SD 7.23% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Tumors | | | | | | | | | |
| | | 30/50 (60%) | 36/50 (72%) | 36/50 (72%) | | 33/50 (66%) | 31/50 (62%) | 23/50 (46%) | |
| | | 26/50 (52%) | 26/50 (52%) | 37/50 (74%) | | 30/50 (60%) | 27/50 (54%) | 33/50 (66%) | |
| Overall Incidence | Total | 191/300 (63.67%) | Mean 63.67% | SD 10.31% | Total | 177/300 (59%) | Mean 59% | SD 7.77% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | | |
| | | 47/50 (94%) | 45/50 (90%) | 48/50 (96%) | | 42/50 (84%) | 40/50 (80%) | 41/50 (82%) | |
| | | 46/50 (92%) | 47/50 (94%) | 49/50 (98%) | | 41/50 (82%) | 40/50 (80%) | 45/50 (90%) | |
| Overall Incidence | Total | 282/300 (94%) | Mean 94% | SD 2.83% | Total | 249/300 (83%) | Mean 83% | SD 3.74% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.1% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/50 (4%) | 7/50 (14%) | 7/50 (14%) | | 4/50 (8%) | 3/50 (6%) | 5/50 (10%) | |
| | | 1/50 (2%) | 4/50 (8%) | 2/50 (4%) | | 3/50 (6%) | 2/50 (4%) | 4/50 (8%) | |
| Overall Incidence | Total | 23/300 (7.67%) | Mean 7.67% | SD 5.28% | Total | 21/300 (7%) | Mean 7% | SD 2.1% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|----------------|------------|------------|-------|-----------------|-------------|-------------|--|
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | | |
| | | 2/50 (4%) | 7/50 (14%) | 7/50 (14%) | | 4/50 (8%) | 3/50 (6%) | 5/50 (10%) | |
| | | 2/50 (4%) | 5/50 (10%) | 3/50 (6%) | | 3/50 (6%) | 2/50 (4%) | 4/50 (8%) | |
| Overall Incidence | Total | 26/300 (8.67%) | Mean 8.67% | SD 4.68% | Total | 21/300 (7%) | Mean 7% | SD 2.1% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 2/50 (4%) | 2/50 (4%) | 2/50 (4%) | |
| Overall Incidence | Total | 5/300 (1.67%) | Mean 1.67% | SD 1.51% | Total | 9/300 (3%) | Mean 3% | SD 1.1% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 2/50 (4%) | 4/50 (8%) | 2/50 (4%) | | 17/50 (34%) | 14/50 (28%) | 8/50 (16%) | |
| | | 3/50 (6%) | 2/50 (4%) | 2/50 (4%) | | 18/50 (36%) | 12/50 (24%) | 14/50 (28%) | |
| Overall Incidence | Total | 15/300 (5%) | Mean 5% | SD 1.67% | Total | 83/300 (27.67%) | Mean 27.67% | SD 7.2% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
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| | | Male | | | | Female | | | |
|--------------------------------|-------|----------------|------------|------------|-------|---------------|------------|-----------|--|
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 4/49 (8%) | 1/50 (2%) | 6/50 (12%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 9/49 (18%) | 2/49 (4%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 23/297 (7.74%) | Mean 7.77% | SD 6.49% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 3/50 (6%) | 1/50 (2%) | 0/50 (0%) | |
| | | 1/48 (2%) | 1/47 (2%) | 1/50 (2%) | | 1/49 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 4/295 (1.36%) | Mean 1.37% | SD 1.06% | Total | 6/299 (2.01%) | Mean 2.01% | SD 2.19% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/48 (0%) | 0/47 (0%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/295 (0.34%) | Mean 0.33% | SD 0.82% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 4/50 (8%) | 1/50 (2%) | 0/50 (0%) | |
| | | 1/48 (2%) | 1/47 (2%) | 2/50 (4%) | | 1/49 (2%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 5/295 (1.69%) | Mean 1.7% | SD 1.52% | Total | 8/299 (2.68%) | Mean 2.67% | SD 3.01% | |
| | | | | | | | | | |
| #Blood Vessel: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Bone Marrow: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/48 (0%) | 1/50 (2%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 4/298 (1.34%) | Mean 1.33% | SD 1.63% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/48 (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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 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%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

#: Denominator is number of animals with tissues examined microscopically

*: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|--------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|-----------|
| #Bone: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 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%) |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 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%) |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|-------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|--------------------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|-----------|
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/46 (0%) | 0/43 (0%) | 0/46 (0%) | 0/46 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/44 (0%) | 0/46 (0%) | 0/45 (0%) | 0/45 (0%) |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/270 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/46 (0%) | 0/43 (0%) | 0/46 (0%) | 0/46 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/44 (0%) | 0/46 (0%) | 0/45 (0%) | 0/45 (0%) |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/270 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|--------------------------------|-------|--------------|------------|------------|-------|----------------|------------|-----------|-----------|
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 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%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 7/50 (14%) | 6/50 (12%) | 4/50 (8%) | | 3/50 (6%) | 3/50 (6%) | 3/50 (6%) | 3/50 (6%) |
| | | 7/50 (14%) | 2/50 (4%) | 7/50 (14%) | | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) |
| Overall Incidence | Total | 33/300 (11%) | Mean 11% | SD 4.15% | Total | 13/300 (4.33%) | Mean 4.33% | SD 1.97% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------|-------|-----------------|-------------|------------|-------|---------------|------------|------------|--|
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 3/50 (6%) | 2/50 (4%) | 4/50 (8%) | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | |
| | | 5/50 (10%) | 3/50 (6%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 3/50 (6%) | |
| Overall Incidence | Total | 17/300 (5.67%) | Mean 5.67% | SD 3.44% | Total | 8/300 (2.67%) | Mean 2.67% | SD 2.42% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 10/50 (20%) | 8/50 (16%) | 8/50 (16%) | | 5/50 (10%) | 3/50 (6%) | 5/50 (10%) | |
| | | 12/50 (24%) | 5/50 (10%) | 7/50 (14%) | | 2/50 (4%) | 2/50 (4%) | 4/50 (8%) | |
| Overall Incidence | Total | 50/300 (16.67%) | Mean 16.67% | SD 4.84% | Total | 21/300 (7%) | Mean 7% | SD 2.76% | |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Large: Cecum: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Leiomyoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

Page: 147
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Ileum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 4/50 (8%) | 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%) | |
| Overall Incidence | Total | 6/300 (2%) | Mean 2% | SD 3.35% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

Page: 148
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------|-------|----------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 4/50 (8%) | 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%) | 1/50 (2%) | |
| Overall Incidence | Total | 6/300 (2%) | Mean 2% | SD 3.35% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 4/50 (8%) | 2/50 (4%) | 2/50 (4%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 10/300 (3.33%) | Mean 3.33% | SD 2.73% | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

Page: 149
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/48 (0%) | 0/49 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 2/50 (4%) | 2/49 (4%) | 2/50 (4%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 8/296 (2.7%) | Mean 2.68% | SD 2.08% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/48 (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%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/48 (0%) | 0/49 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 2/50 (4%) | 2/49 (4%) | 2/50 (4%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 8/296 (2.7%) | Mean 2.68% | SD 2.08% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 150
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 151
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|----------------|------------|-----------|-------|------------|-----------|-----------|--|
| *Kidney: Renal Tubule: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/298 (0.34%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 4/50 (8%) | 2/50 (4%) | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/49 (2%) | 2/50 (4%) | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | |
| Overall Incidence | Total | 10/299 (3.34%) | Mean 3.34% | SD 2.73% | Total | 6/300 (2%) | Mean 2% | SD 1.79% | |

#: Denominator is number of animals with tissues examined microscopically

*: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 152
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|------------------|-------------|-------------|-------------|------------------|-------------|-----------|--|
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 5/299 (1.67%) | Mean 1.67% | SD 1.51% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 30/50 (60%) | 28/50 (56%) | 28/50 (56%) | 19/50 (38%) | 19/50 (38%) | 14/50 (28%) | | |
| | | 24/50 (48%) | 33/49 (67%) | 37/50 (74%) | 14/50 (28%) | 14/50 (28%) | 25/50 (50%) | | |
| Overall Incidence | Total | 180/299 (60.2%) | Mean 60.22% | SD 9.23% | Total | 105/300 (35%) | Mean 35% | SD 8.83% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 15/50 (30%) | 25/50 (50%) | 20/50 (40%) | 5/50 (10%) | 10/50 (20%) | 4/50 (8%) | | |
| | | 11/50 (22%) | 11/49 (22%) | 26/50 (52%) | 10/50 (20%) | 7/50 (14%) | 8/50 (16%) | | |
| Overall Incidence | Total | 108/299 (36.12%) | Mean 36.07% | SD 13.29% | Total | 44/300 (14.67%) | Mean 14.67% | SD 5.01% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 16/50 (32%) | 27/50 (54%) | 20/50 (40%) | 5/50 (10%) | 10/50 (20%) | 4/50 (8%) | | |
| | | 11/50 (22%) | 11/49 (22%) | 27/50 (54%) | 10/50 (20%) | 7/50 (14%) | 8/50 (16%) | | |
| Overall Incidence | Total | 112/299 (37.46%) | Mean 37.41% | SD 14.48% | Total | 44/300 (14.67%) | Mean 14.67% | SD 5.01% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 38/50 (76%) | 38/50 (76%) | 40/50 (80%) | 24/50 (48%) | 25/50 (50%) | 16/50 (32%) | | |
| | | 32/50 (64%) | 37/49 (76%) | 44/50 (88%) | 20/50 (40%) | 20/50 (40%) | 28/50 (56%) | | |
| Overall Incidence | Total | 229/299 (76.59%) | Mean 76.59% | SD 7.77% | Total | 133/300 (44.33%) | Mean 44.33% | SD 8.62% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|------------------|-------------|-------------|-------|------------------|-------------|-------------|--|
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 38/50 (76%) | 39/50 (78%) | 40/50 (80%) | | 24/50 (48%) | 25/50 (50%) | 16/50 (32%) | |
| | | 32/50 (64%) | 37/49 (76%) | 45/50 (90%) | | 20/50 (40%) | 20/50 (40%) | 28/50 (56%) | |
| Overall Incidence | Total | 231/299 (77.26%) | Mean 77.25% | SD 8.38% | Total | 133/300 (44.33%) | Mean 44.33% | SD 8.62% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------|-------|-----------------|-------------|-------------|-------|----------------|------------|------------|-----------|
| *Liver: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (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%) |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (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%) |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 6/50 (12%) | 7/50 (14%) | 4/50 (8%) | | 1/50 (2%) | 3/49 (6%) | 2/50 (4%) | |
| | | 5/50 (10%) | 10/50 (20%) | 7/50 (14%) | | 1/50 (2%) | 6/50 (12%) | 3/50 (6%) | |
| Overall Incidence | Total | 39/300 (13%) | Mean 13% | SD 4.15% | Total | 16/299 (5.35%) | Mean 5.35% | SD 3.73% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 8/50 (16%) | 11/50 (22%) | 12/50 (24%) | | 0/50 (0%) | 5/49 (10%) | 3/50 (6%) | |
| | | 8/50 (16%) | 11/50 (22%) | 9/50 (18%) | | 4/50 (8%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 59/300 (19.67%) | Mean 19.67% | SD 3.44% | Total | 13/299 (4.35%) | Mean 4.37% | SD 4.33% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 13/50 (26%) | 16/50 (32%) | 15/50 (30%) | | 1/50 (2%) | 8/49 (16%) | 5/50 (10%) | |
| | | 13/50 (26%) | 20/50 (40%) | 13/50 (26%) | | 4/50 (8%) | 6/50 (12%) | 4/50 (8%) | |
| Overall Incidence | Total | 90/300 (30%) | Mean 30% | SD 5.51% | Total | 28/299 (9.36%) | Mean 9.39% | SD 4.77% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|-----------|-----------|-------|----------------|------------|-----------|-----------|
| #Mammary Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 4/50 (8%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 11/300 (3.67%) | Mean 3.67% | SD 2.34% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 4/50 (8%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 11/300 (3.67%) | Mean 3.67% | SD 2.34% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroadenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 158
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|------------|--|
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 5/50 (10%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 12/300 (4%) | Mean 4% | SD 3.1% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

Page: 159
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|----------------|------------|-----------|-----------|
| #Oral Mucosa: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Choriocarcinoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 0/297 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Cystadenocarcinoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 0/297 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Cystadenoma | | | | | | | | | |
| | | | | | | 3/50 (6%) | 1/48 (2%) | 3/49 (6%) | |
| | | | | | | 2/50 (4%) | 2/50 (4%) | 1/50 (2%) | |
| Overall Incidence | Total | | | | Total | 12/297 (4.04%) | Mean 4.03% | SD 1.8% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) | |
| | | | | | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 1/297 (0.34%) | Mean 0.33% | SD 0.82% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | Male | Female |
|-----------------------------------------------------|----------------------------|--------------------------------------|
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.33% SD 0.82% |
| | | |
| *Ovary: | | |
| Hemangioma | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/297 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 1/49 (2%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.34% SD 0.83% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 1/50 (2%) | 0/48 (0%) |
| | 1/50 (2%) | 1/50 (2%) |
| Overall Incidence | Total 4/297 (1.35%) | Mean 1.33% SD 1.03% |
| | | |
| *Ovary: | | |
| Plasma Cell Tumor Malignant | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/297 (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | Male | Female |
|------------------------------|----------------------------|-----------------------------------|
| *Ovary: | | |
| Sarcoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/297 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Benign | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.33% SD 0.82% |
| | | |
| *Ovary: | | |
| Teratoma Malignant | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.33% SD 0.82% |
| | | |
| *Ovary: | | |
| Tubulostromal Adenoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/297 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Yolk Sac Carcinoma | | |
| | 0/50 (0%) | 1/48 (2%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.35% SD 0.85% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|---------------|------------|-----------|-------|-----------------|-------------|-------------|-----------|
| *Pancreas: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/297 (0.34%) | Mean 0.35% | SD 0.85% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Pancreas: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/297 (0.34%) | Mean 0.35% | SD 0.85% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/46 (2%) | 0/47 (0%) | 0/50 (0%) | | 5/46 (11%) | 3/47 (6%) | 10/50 (20%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 5/50 (10%) | 6/49 (12%) | 8/50 (16%) | |
| Overall Incidence | Total | 1/292 (0.34%) | Mean 0.36% | SD 0.89% | Total | 37/292 (12.67%) | Mean 12.58% | SD 4.79% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/46 (0%) | 0/47 (0%) | 0/50 (0%) | | 1/46 (2%) | 0/47 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/292 (0%) | Mean 0% | SD 0% | Total | 1/292 (0.34%) | Mean 0.36% | SD 0.89% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/46 (2%) | 0/47 (0%) | 0/50 (0%) | | 6/46 (13%) | 3/47 (6%) | 10/50 (20%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 5/50 (10%) | 6/49 (12%) | 8/50 (16%) | |
| Overall Incidence | Total | 1/292 (0.34%) | Mean 0.36% | SD 0.89% | Total | 38/292 (13.01%) | Mean 12.95% | SD 4.72% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|-------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/46 (0%) | 0/47 (0%) | 0/50 (0%) | | 0/46 (0%) | 0/47 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/292 (0.34%) | Mean 0.34% | SD 0.83% | Total | 3/292 (1.03%) | Mean 1.01% | SD 1.68% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/46 (0%) | 0/47 (0%) | 0/50 (0%) | | 0/46 (0%) | 0/47 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/292 (0.34%) | Mean 0.34% | SD 0.83% | Total | 3/292 (1.03%) | Mean 1.01% | SD 1.68% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Salivary Glands: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|---------------|------------|-----------|-------|----------------|------------|-----------|-----------|
| #Skin: | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | |
| | | 0/50 (0%) | 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%) |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| ----- | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 8/50 (16%) | 2/50 (4%) | 4/50 (8%) | |
| | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | Total | 17/300 (5.67%) | Mean 5.67% | SD 5.72% | |
| ----- | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| ----- | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 8/50 (16%) | 2/50 (4%) | 4/50 (8%) | |
| | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | Total | 17/300 (5.67%) | Mean 5.67% | SD 5.72% | |
| ----- | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|-----------------------------------|-------|---------------|------------|-----------|-------|------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.67% | Total | 3/300 (1%) | Mean 1% | SD 1.67% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------|-------|---------------|------------|-----------|-------|------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 7/50 (14%) | 2/50 (4%) | 4/50 (8%) | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | Total | 15/300 (5%) | Mean 5% | SD 5.18% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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| | | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|-----------|-----------|-------|----------------|------------|-----------|-----------|
| #Spinal Cord: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/48 (4%) | 3/50 (6%) | 3/50 (6%) | | 1/50 (2%) | 2/49 (4%) | 2/50 (4%) | 2/50 (4%) |
| | | 0/50 (0%) | 1/49 (2%) | 2/50 (4%) | | 1/50 (2%) | 1/50 (2%) | 3/50 (6%) | 3/50 (6%) |
| Overall Incidence | Total | 11/297 (3.7%) | Mean 3.7% | SD 2.34% | Total | 10/299 (3.34%) | Mean 3.35% | SD 1.64% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/48 (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%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.34% | SD 0.83% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 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%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 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%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.63% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.67% | Total | 3/300 (1%) | Mean 1% | SD 1.1% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 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%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | | | | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | | | | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/38 (0%) | 0/42 (0%) | 0/38 (0%) | | 0/49 (0%) | 1/46 (2%) | 0/47 (0%) | |
| | | 0/41 (0%) | 0/47 (0%) | 0/39 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/47 (0%) | |
| Overall Incidence | Total | 0/245 (0%) | Mean 0% | SD 0% | Total | 1/281 (0.36%) | Mean 0.36% | SD 0.89% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/38 (0%) | 0/42 (0%) | 0/38 (0%) | | 0/49 (0%) | 0/46 (0%) | 0/47 (0%) | |
| | | 0/41 (0%) | 0/47 (0%) | 0/39 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/47 (0%) | |
| Overall Incidence | Total | 0/245 (0%) | Mean 0% | SD 0% | Total | 0/281 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/38 (0%) | 0/42 (0%) | 0/38 (0%) | | 0/49 (0%) | 0/46 (0%) | 0/47 (0%) | |
| | | 0/41 (0%) | 0/47 (0%) | 0/39 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/47 (0%) | |
| Overall Incidence | Total | 0/245 (0%) | Mean 0% | SD 0% | Total | 0/281 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/38 (0%) | 0/42 (0%) | 0/38 (0%) | | 0/49 (0%) | 0/46 (0%) | 0/47 (0%) | |
| | | 0/41 (0%) | 0/47 (0%) | 0/39 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/47 (0%) | |
| Overall Incidence | Total | 0/245 (0%) | Mean 0% | SD 0% | Total | 0/281 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (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%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/297 (0%) | Mean 0% | SD 0% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Tissue NOS: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 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%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.67% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

Page: 179
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|-----------|
| #Urethra: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/47 (0%) | 0/48 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | Total | 1/294 (0.34%) | Mean 0.33% | SD 0.82% | Total | 1/297 (0.34%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/47 (0%) | 0/48 (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%) | |
| Overall Incidence | Total | 0/294 (0%) | Mean 0% | SD 0% | Total | 0/297 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | Male | | Female | |
|--------------------------|---------------------|------|------------|----------|
| #Uterus: | | | | |
| Hemangiosarcoma | | | | |
| | 0/50 | (0%) | 0/50 | (0%) |
| | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total 3/300 (1%) | | Mean 1% | SD 1.1% |
| | | | | |
| #Uterus: | | | | |
| Leiomyoma | | | | |
| | 0/50 | (0%) | 0/50 | (0%) |
| | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total 1/300 (0.33%) | | Mean 0.33% | SD 0.82% |
| | | | | |
| #Uterus: | | | | |
| Leiomyosarcoma | | | | |
| | 0/50 | (0%) | 0/50 | (0%) |
| | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total 1/300 (0.33%) | | Mean 0.33% | SD 0.82% |
| | | | | |
| #Uterus: | | | | |
| Polyp Stromal | | | | |
| | 0/50 | (0%) | 2/50 | (4%) |
| | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total 6/300 (2%) | | Mean 2% | SD 1.79% |
| | | | | |
| #Uterus: | | | | |
| Sarcoma | | | | |
| | 0/50 | (0%) | 0/50 | (0%) |
| | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total 0/300 (0%) | | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: INHALATION
 Vehicle: AIR

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|------------|-----------|-----------|------------|-----------|-----------|-----------|
| #Uterus: | | | | | | | | | |
| Sarcoma Stromal | | | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) |
| | | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) |
| Overall Incidence | | Total | 0/300 (0%) | | Mean 0% | | SD 0% | | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | | |
| | | | 0/50 (0%) | | 2/50 (4%) | | 1/50 (2%) | | |
| | | | 0/50 (0%) | | 1/50 (2%) | | 2/50 (4%) | | |
| Overall Incidence | | Total | 6/300 (2%) | | Mean 2% | | SD 1.79% | | |
| | | | | | | | | | |
| #Vagina: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | 0/50 (0%) | | |
| Overall Incidence | | Total | 0/300 (0%) | | Mean 0% | | SD 0% | | |
| | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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Report Date: 06/05/2013

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 |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|----------------------------------------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052000904 | 11/09/04 | 730 | 50(1) | 24(645) | 57.1 | beta-Picoline |
| Battelle Columbus Laboratory | 059601406 | 09/26/06 | 730 | 50(1) | 25(660) | 55.9 | Water disinfection byproducts (Bromodichloroacetic acid) |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052000904 | 11/08/04 | 729 | 50(5) | 38(702) | 67.4 | beta-Picoline |
| Battelle Columbus Laboratory | 059601406 | 09/25/06 | 729 | 50(5) | 30(680) | 63.5 | Water disinfection byproducts (Bromodichloroacetic acid) |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 183
 Report Date: 06/05/2013

| | | Male | | | Female | | |
|--------------------------------------|-------|--------------|-------------|----------|-------------|--------------|-------------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 36/50 (72%) | 43/50 (86%) | | 40/50 (80%) | 36/50 (72%) | |
| Overall Incidence | Total | 79/100 (79%) | Mean 79% | SD 9.9% | Total | 76/100 (76%) | Mean 76% SD 5.66% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 36/50 (72%) | 30/50 (60%) | | 29/50 (58%) | 31/50 (62%) | |
| Overall Incidence | Total | 66/100 (66%) | Mean 66% | SD 8.49% | Total | 60/100 (60%) | Mean 60% SD 2.83% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 48/50 (96%) | 48/50 (96%) | | 43/50 (86%) | 45/50 (90%) | |
| Overall Incidence | Total | 96/100 (96%) | Mean 96% | SD 0% | Total | 88/100 (88%) | Mean 88% SD 2.83% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 6/50 (12%) | 5/50 (10%) | | 3/50 (6%) | 6/50 (12%) | |
| Overall Incidence | Total | 11/100 (11%) | Mean 11% | SD 1.41% | Total | 9/100 (9%) | Mean 9% SD 4.24% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 7/50 (14%) | 5/50 (10%) | | 3/50 (6%) | 6/50 (12%) | |
| Overall Incidence | Total | 12/100 (12%) | Mean 12% | SD 2.83% | Total | 9/100 (9%) | Mean 9% SD 4.24% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|------------|-----------|----------|-------------|--------------|----------|-----------|--|
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 3/100 (3%) | Mean 3% | SD 1.41% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 14/50 (28%) | 6/50 (12%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 20/100 (20%) | Mean 20% | SD 11.31% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|---------|------------|----------|--------|---------|------------|----------|
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 2/100 | (2%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 3/100 | (3%) | Mean 3% | SD 1.41% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 2/49 | (4%) | 2/50 | (4%) | 0/49 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 4/99 | (4.04%) | Mean 4.04% | SD 0.06% | 0/98 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/98 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 1/49 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 1/99 | (1.01%) | Mean 1.02% | SD 1.44% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------|-------|------------|-----------|----------|-----------|--------------|------------|----------|
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 1/99 (1.01%) | Mean 1.02% | SD 1.44% |
| | | | | | | | | |
| #Blood Vessel: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 2.83% | Total | 1/99 (1.01%) | Mean 1.02% | SD 1.44% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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| | | Male | | | | Female | | | | | |
|--------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------|----------|------|
| *Bone Marrow: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | |
| Fibroma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | |
| Osteoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | |
| Osteosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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| | | Male | | | | Female | | | |
|-------------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------|
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/97 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/47 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/97 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|--------------|------------|----------|-----------|------------|---------|----------|--|
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 5/50 (10%) | 6/50 (12%) | | 2/50 (4%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 11/100 (11%) | Mean 11% | SD 1.41% | Total | 7/100 (7%) | Mean 7% | SD 4.24% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 2.83% | Total | 2/100 (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 7/50 (14%) | 6/50 (12%) | | 4/50 (8%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 13/100 (13%) | Mean 13% | SD 1.41% | Total | 9/100 (9%) | Mean 9% | SD 1.41% | |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|----------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|
| #Intestine Small: Duodenum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|--------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|
| #Intestine Small: Ileum: | | | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 2/50 | (4%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|-------|---------|------------|----------|--------|-------|------|---------------|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | | | |
| | | 2/50 | (4%) | 2/50 | (4%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 4/100 | (4%) | Mean 4% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | 3/50 | (6%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 5/100 | (5%) | Mean 5% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: Adenoma | | | | | | | | | |
| | | 1/49 | (2%) | 0/50 | (0%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/99 | (1.01%) | Mean 1.02% | SD 1.44% | Total | 0/97 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|-------|---------|------------|----------|--------|------|------|---------|
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | Total | 0/97 | (0%) | Mean 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/49 | (2%) | 0/50 | (0%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/99 | (1.01%) | Mean 1.02% | SD 1.44% | Total | 0/97 | (0%) | Mean 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/99 | (0%) | Mean 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 196
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|---------------------------------------------------------------|-------|-------|------|---------|----------|--------|------|------|---------|-------|------|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 2/50 | (4%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Liver: Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/98 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 197
 Report Date: 06/05/2013

| | | Male | | | Female | | | |
|-----------------------------------------------------------|-------|--------------|-------------|-----------|-------------|----------------|-------------|----------|
| *Liver: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 5/50 (10%) | 1/50 (2%) | | 2/49 (4%) | 2/49 (4%) | | |
| Overall Incidence | Total | 6/100 (6%) | Mean 6% | SD 5.66% | Total | 4/98 (4.08%) | Mean 4.08% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatoblastoma | | | | | | | | |
| | | 6/50 (12%) | 4/50 (8%) | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 10/100 (10%) | Mean 10% | SD 2.83% | Total | 1/98 (1.02%) | Mean 1.02% | SD 1.44% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | |
| | | 33/50 (66%) | 39/50 (78%) | | 38/49 (78%) | 33/49 (67%) | | |
| Overall Incidence | Total | 72/100 (72%) | Mean 72% | SD 8.49% | Total | 71/98 (72.45%) | Mean 72.45% | SD 7.22% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | |
| | | 26/50 (52%) | 12/50 (24%) | | 11/49 (22%) | 9/49 (18%) | | |
| Overall Incidence | Total | 38/100 (38%) | Mean 38% | SD 19.8% | Total | 20/98 (20.41%) | Mean 20.41% | SD 2.89% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | |
| | | 26/50 (52%) | 15/50 (30%) | | 12/49 (24%) | 9/49 (18%) | | |
| Overall Incidence | Total | 41/100 (41%) | Mean 41% | SD 15.56% | Total | 21/98 (21.43%) | Mean 21.43% | SD 4.33% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | |
| | | 45/50 (90%) | 42/50 (84%) | | 40/49 (82%) | 36/49 (73%) | | |
| Overall Incidence | Total | 87/100 (87%) | Mean 87% | SD 4.24% | Total | 76/98 (77.55%) | Mean 77.55% | SD 5.77% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|--------------|-------------|----------|-------------|----------------|-------------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 45/50 (90%) | 42/50 (84%) | | 40/49 (82%) | 36/49 (73%) | | |
| Overall Incidence | Total | 87/100 (87%) | Mean 87% | SD 4.24% | Total | 76/98 (77.55%) | Mean 77.55% | SD 5.77% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 2.83% | Total | 0/98 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/98 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/98 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/98 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/98 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 199
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------|-------|--------------|-------------|----------|-------------|--------------|----------|----------|--|
| *Liver: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/98 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 6/50 (12%) | 13/50 (26%) | | 5/50 (10%) | 3/50 (6%) | | | |
| Overall Incidence | Total | 19/100 (19%) | Mean 19% | SD 9.9% | Total | 8/100 (8%) | Mean 8% | SD 2.83% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 9/50 (18%) | 7/50 (14%) | | 7/50 (14%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 16/100 (16%) | Mean 16% | SD 2.83% | Total | 9/100 (9%) | Mean 9% | SD 7.07% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 14/50 (28%) | 19/50 (38%) | | 11/50 (22%) | 5/50 (10%) | | | |
| Overall Incidence | Total | 33/100 (33%) | Mean 33% | SD 7.07% | Total | 16/100 (16%) | Mean 16% | SD 8.49% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 2.83% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 200
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 201
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|------------------|
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 202
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|-----------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Mammary Gland: | | | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Lipoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 203
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Mucosa: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 204
 Report Date: 06/05/2013

| | Male | Female |
|-----------------------------------------------------|--------------------|---------------------|
| *Ovary: | | |
| Choriocarcinoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Cystadenocarcinoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Cystadenoma | | |
| | 3/49 (6%) | 1/50 (2%) |
| Overall Incidence | Total 4/99 (4.04%) | Mean 4.06% SD 2.92% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor Benign | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangioma | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 205
 Report Date: 06/05/2013

| | Male | | | Female | | |
|------------------------------------|-------|------|------|---------|------|-------|
| *Ovary: | | | | | | |
| Hemangiosarcoma | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Luteoma | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Sarcoma | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Teratoma Benign | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Teratoma Malignant | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 206
 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|-----------|-----------|-------|-----------|--------------|------------|----------|
| *Ovary: | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | |
| | | | 0/49 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | | | | Total | 0/99 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | |
| | | | 0/49 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | | | | Total | 0/99 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| *Pancreas: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 0/97 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pancreas: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 0/97 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/47 (0%) | 0/50 (0%) | | 4/50 (8%) | 2/49 (4%) | | |
| Overall Incidence | Total | 0/97 (0%) | Mean 0% | SD 0% | Total | 6/99 (6.06%) | Mean 6.04% | SD 2.77% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/47 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/97 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 207
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|-------|------|---------|-------|------------|---------|------------|----------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/47 | (0%) | 0/50 | (0%) | 4/50 | (8%) | 2/49 | (4%) |
| Overall Incidence | Total | 0/97 | (0%) | Mean 0% | SD 0% | Total 6/99 | (6.06%) | Mean 6.04% | SD 2.77% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/47 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/97 | (0%) | Mean 0% | SD 0% | Total 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/47 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/97 | (0%) | Mean 0% | SD 0% | Total 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total 0/98 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total 0/98 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total 0/98 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 208
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------|-------|-------|------|---------|----------|--------|-------|------|----------|
| *Salivary Glands: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/98 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/48 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/98 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 209
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|----------|
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 2/50 | (4%) | 4/50 | (8%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | 6/100 | (6%) | Mean 6% | SD 2.83% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 210
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|----------|
| #Skin: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 2/50 | (4%) | 4/50 | (8%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 6/100 | (6%) | Mean 6% |
| | | | | | | | | | SD 2.83% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 0/50 | (0%) | 3/50 | (6%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 3/100 | (3%) | Mean 3% |
| | | | | | | | | | SD 4.24% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 3/100 | (3%) | Mean 3% |
| | | | | | | | | | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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| | | Male | | | | Female | | | |
|----------------------------------|-------|-------|------|---------|----------|--------|-------|------|------------------|
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 212
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|------------------|
| #Skin: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 3/50 | (6%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 3/100 | (3%) | Mean 3% SD 4.24% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 3/50 | (6%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 3/100 | (3%) | Mean 3% SD 4.24% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|----------|
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 3/100 | (3%) | Mean 3% | SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 3/50 | (6%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 3/100 | (3%) | Mean 3% | SD 4.24% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 214
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Spinal Cord: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/46 | (0%) | 0/50 | (0%) | 0/46 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/96 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | | | | |
|------------------------------------------------------|-------|-------|---------|------|-------|--------|-------|-------|-------|---------|------|-------|----|-------|
| *Spleen: | | | | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | | | | |
| | | 1/46 | (2%) | 2/50 | (4%) | | | 1/46 | (2%) | 0/49 | (0%) | | | |
| Overall Incidence | Total | 3/96 | (3.12%) | Mean | 3.09% | SD | 1.29% | Total | 1/95 | (1.05%) | Mean | 1.09% | SD | 1.54% |
| | | | | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | | | | | | |
| | | 0/46 | (0%) | 0/50 | (0%) | | | 0/46 | (0%) | 0/49 | (0%) | | | |
| Overall Incidence | Total | 0/96 | (0%) | Mean | 0% | SD | 0% | Total | 0/95 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | | | | | | |
| | | 0/46 | (0%) | 0/50 | (0%) | | | 0/46 | (0%) | 0/49 | (0%) | | | |
| Overall Incidence | Total | 0/96 | (0%) | Mean | 0% | SD | 0% | Total | 0/95 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 1/100 | (1%) | Mean | 1% | SD | 1.41% |
| | | | | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 1/50 | (2%) | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 1/100 | (1%) | Mean | 1% | SD | 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 216
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------|-------|-------|------|---------|----------|--------|-------|------|---------------|
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | | |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/41 | (0%) | 0/45 | (0%) | 0/45 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/86 | (0%) | Mean 0% | SD 0% | Total | 0/95 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 217
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|------|---------|------------|----------|--------|------|---------|-------|
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/41 | (0%) | 0/45 | (0%) | 0/45 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/86 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/41 | (0%) | 0/45 | (0%) | 0/45 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/86 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/41 | (0%) | 0/45 | (0%) | 0/45 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/86 | (0%) | Mean 0% | SD 0% | 0/95 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/97 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/97 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/49 | (2%) | 1/50 | (2%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 2/99 | (2.02%) | Mean 2.02% | SD 0.03% | 0/97 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

Page: 218
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|--------------|------------|----------|-----------|------------|---------|-------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 0/97 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/49 (2%) | 1/50 (2%) | | 0/48 (0%) | 0/49 (0%) | | | |
| Overall Incidence | Total | 2/99 (2.02%) | Mean 2.02% | SD 0.03% | Total | 0/97 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Page: 219
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Urethra: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/45 | (0%) | 0/50 | (0%) | 0/44 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/95 | (0%) | Mean 0% | SD 0% | 0/94 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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| | Male | | | | Female | | | |
|------------------------------------|-------|-----------|-----------|-------|------------|-----------|---------|----------|
| *Urinary Bladder: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/45 (0%) | 0/50 (0%) | | 0/44 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/95 (0%) | Mean 0% | SD 0% | Total | 0/94 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 1/100 (1%) | Mean 1% | | SD 1.41% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | | | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | | | | 1/100 (1%) | Mean 1% | | SD 1.41% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|-----------------------------------------|-------|------------|------------|-------|-----------|------------|---------------|
| #Uterus: | | | | | | | |
| Polyp Stromal | | | | | | | |
| | | | 2/50 (4%) | | 4/50 (8%) | | |
| Overall Incidence | | Total | 6/100 (6%) | | Mean 6% | | SD 2.83% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Sarcoma | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | |
| Overall Incidence | | Total | 0/100 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Sarcoma Stromal | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | |
| Overall Incidence | | Total | 0/100 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | |
| | | | 2/50 (4%) | | 4/50 (8%) | | |
| Overall Incidence | | Total | 6/100 (6%) | | Mean 6% | | SD 2.83% |
| | | | | | | | |
| #Vagina: | | | | | | | |
| Liposarcoma | | | | | | | |
| | | | 0/50 (0%) | | 0/50 (0%) | | |
| Overall Incidence | | Total | 0/100 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | |
| #Zymbal's Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

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Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-----------------------------|-------|------------|-----------|-------|--------|------------|-----------|-------|
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma or Adenoma | | 0/50 (0%) | 0/50 (0%) | | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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Report Date: 06/05/2013

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 |
|-----------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--------------------------------|
| Male | | | | | | | |
| Southern Research Institute | 058813308 | 12/13/04 | 729 | 50(1) | 30(665) | 54.9 | Trimethylolpropane triacrylate |
| Female | | | | | | | |
| Southern Research Institute | 058813308 | 12/13/04 | 732 | 50(1) | 39(712) | 66.6 | Trimethylolpropane triacrylate |

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 37/50 (74%) | | | 41/50 (82%) | | |
| Overall Incidence | Total | 37/50 (74%) | Mean 74% | SD 0% | Total | 41/50 (82%) | Mean 82% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 38/50 (76%) | | | 38/50 (76%) | | |
| Overall Incidence | Total | 38/50 (76%) | Mean 76% | SD 0% | Total | 38/50 (76%) | Mean 76% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 46/50 (92%) | | | 47/50 (94%) | | |
| Overall Incidence | Total | 46/50 (92%) | Mean 92% | SD 0% | Total | 47/50 (94%) | Mean 94% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 6/50 (12%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 6/50 (12%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------------------------------------------------------------------|-------|-----------|---------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Histiocytic Sarcoma | | | | | | | |
| | | 0/50 (0%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | |
| | | 2/50 (4%) | | | 20/50 (40%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 20/50 (40%) | Mean 40% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Mesothelioma: Benign | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Mesothelioma: Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------|-------|------|-------|----------|--------|-------|-----------|
| #All Organs: | | | | | | | |
| Osteosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 6/50 | (12%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 6/50 | (12%) | Mean 12% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Adrenal Cortex: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Benign | | | | | | | |
| | | 0/49 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | |
| | | 0/49 | (0%) | | 2/50 | (4%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 0/49 (0%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Blood Vessel: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

Page: 228
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

Page: 229
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ACETONE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | | |
|--------------------------------------------------|-------|------|------|---------|--------|-------|-----------|---------|-------|
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|--------------------------------|-------|-------------|----------|-------|------------|------------|----------------|
| #Esophagus: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Eye: | | | | | | | |
| Melanoma Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Adenoma | | | | | | | |
| | | 8/50 (16%) | | | 5/50 (10%) | | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total | 5/50 (10%) | Mean 10% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 3/50 (6%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| #Harderian Gland: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 11/50 (22%) | | | 7/50 (14%) | | |
| Overall Incidence | Total | 11/50 (22%) | Mean 22% | SD 0% | Total | 7/50 (14%) | Mean 14% SD 0% |
| | | | | | | | |
| *Heart: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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 Strain: B6C3F1
 Length of Study: CHRONIC

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| | | Male | | | Female | | |
|-----------------------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------------|
| #Intestine Large: Cecum: Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Cecum: Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Cecum: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Cecum: Leiomyoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Cecum: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Colon/Rectum: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|--------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------------|
| #Intestine Small: Ileum: | | | | | | | |
| Polyp Adenomatous | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Carcinoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | |
| Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|---------------------------------------------------------------------|-------|-----------|---------|-------|--------|--------------|------------------|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|-----------------------------------------------------|-------|--------------|------------|-------|-----------|--------------|------------------|
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 2/49 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% SD 0% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/48 (4%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 2/48 (4.17%) | Mean 4.17% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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| | | Male | | | Female | | |
|---------------------------------------------------------------|-------|--------------|------------|-------|-----------|-----------|---------------|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | |
| | | 2/48 (4%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 2/48 (4.17%) | Mean 4.17% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | |
| | | 0/48 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/48 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: Hemangioma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
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| | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| *Liver: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatoblastoma | | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | |
| | | 34/50 (68%) | | | 34/50 (68%) | | | |
| Overall Incidence | Total | 34/50 (68%) | Mean 68% | SD 0% | Total | 34/50 (68%) | Mean 68% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | |
| | | 22/50 (44%) | | | 12/50 (24%) | | | |
| Overall Incidence | Total | 22/50 (44%) | Mean 44% | SD 0% | Total | 12/50 (24%) | Mean 24% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | |
| | | 26/50 (52%) | | | 12/50 (24%) | | | |
| Overall Incidence | Total | 26/50 (52%) | Mean 52% | SD 0% | Total | 12/50 (24%) | Mean 24% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | |
| | | 37/50 (74%) | | | 37/50 (74%) | | | |
| Overall Incidence | Total | 37/50 (74%) | Mean 74% | SD 0% | Total | 37/50 (74%) | Mean 74% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 38/50 (76%) | | | 37/50 (74%) | | | |
| Overall Incidence | Total | 38/50 (76%) | Mean 76% | SD 0% | Total | 37/50 (74%) | Mean 74% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangioma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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Route: SKIN
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| | | Male | | | Female | | |
|-----------------------------------------------------------------------|-------|-------------|----------|-------|------------|------------|----------------|
| *Liver: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 3/50 (6%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 3/50 (6%) | Mean 6% SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | |
| | | 12/50 (24%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | |
| | | 13/50 (26%) | | | 5/50 (10%) | | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 5/50 (10%) | Mean 10% SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Lung: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
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| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|-----------------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------------|
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| Male | | | | | Female | | | | |
|----------------------------------------------|-------|------|------|---------|--------|-------|------|------|---------------|
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|---------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Nose: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Nose: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Oral Mucosa: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | Male | | Female | |
|-----------------------------------------------------|------|-------|--------------|-----------------------|
| *Ovary: | | | | |
| Choriocarcinoma | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Cystadenocarcinoma | | | | |
| | | 1/47 | (2%) | |
| Overall Incidence | | Total | 1/47 (2.13%) | Mean 2.13% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Cystadenoma | | | | |
| | | 1/47 | (2%) | |
| Overall Incidence | | Total | 1/47 (2.13%) | Mean 2.13% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Granulosa Cell Tumor Benign | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Hemangioma | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ACETONE

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 Report Date: 06/05/2013

| | Male | | Female | |
|------------------------------------|-------|------|--------|--------------------|
| *Ovary: | | | | |
| Hemangiosarcoma | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Luteoma | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Plasma Cell Tumor Malignant | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Sarcoma | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Teratoma Benign | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Teratoma Malignant | | | | |
| | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% SD 0% |
| | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| Male | | | | | Female | | | | | |
|-------------------------------------------------------------|--|--|--|--|------------|--|---------------|--|------------------------|--|
| *Ovary: | | | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | | | |
| | | | | | 0/47 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/47 (0%) | | Mean 0% SD 0% | |
| | | | | | | | | | | |
| *Ovary: | | | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | | | |
| | | | | | 0/47 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/47 (0%) | | Mean 0% SD 0% | |
| | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 1/50 (2%) | | | | | |
| Overall Incidence | | | | | Total | | 1/50 (2%) | | Mean 2% SD 0% | |
| | | | | | 0/49 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/49 (0%) | | Mean 0% SD 0% | |
| | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | |
| | | | | | 1/50 (2%) | | | | | |
| Overall Incidence | | | | | Total | | 1/50 (2%) | | Mean 2% SD 0% | |
| | | | | | 0/49 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/49 (0%) | | Mean 0% SD 0% | |
| | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | |
| Adenoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/50 (0%) | | Mean 0% SD 0% | |
| | | | | | 7/49 (14%) | | | | | |
| Overall Incidence | | | | | Total | | 7/49 (14.29%) | | Mean 14.29% SD 0% | |
| | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | 0/50 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/50 (0%) | | Mean 0% SD 0% | |
| | | | | | 0/49 (0%) | | | | | |
| Overall Incidence | | | | | Total | | 0/49 (0%) | | Mean 0% SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|------|------|---------|-------|--------|---------------|-------------|-------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 7/49 | (14%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 7/49 (14.29%) | Mean 14.29% | SD 0% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|----------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Salivary Glands: | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Myxoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Seminal Vesicle: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Rhabdomyosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Skeletal Muscle: | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | Male | | | | Female | | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|---------|-------|
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 4/50 | (8%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 4/50 (8%) | Mean 8% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | Male | | | | Female | | | |
|--------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|---------|
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 3/50 | (6%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 3/50 (6%) | Mean 6% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 4/50 | (8%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 4/50 (8%) | Mean 8% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 2/50 | (4%) | | | 2/50 | (4%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 2/50 (4%) | Mean 4% |
| | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | | Female | | | |
|----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ACETONE

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| | | Male | | | Female | | |
|----------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Skin: | | | | | | | |
| Melanoma Malignant | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Neural Crest Tumor | | | | | | | |
| | | 0/50 | (0%) | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Osteosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Spinal Cord: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/49 (0%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|------------------------------------------------------|-------|------|---------|------------|--------|-------|-----------|
| *Spleen: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 4/49 | (8%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 4/49 | (8.16%) | Mean 8.16% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Spleen: | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | |
| | | 0/49 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Spleen: | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | |
| | | 0/49 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 3/50 | (6%) | | 2/50 | (4%) | |
| Overall Incidence | Total | 3/50 | (6%) | Mean 6% | SD 0% | Total | 2/50 (4%) |
| | | | | | | | Mean 4% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 3/50 | (6%) | | 2/50 | (4%) | |
| Overall Incidence | Total | 3/50 | (6%) | Mean 6% | SD 0% | Total | 2/50 (4%) |
| | | | | | | | Mean 4% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

Page: 257
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/48 | (0%) | | | 0/47 | (0%) | | |
| Overall Incidence | Total | 0/48 | (0%) | Mean 0% | SD 0% | Total | 0/47 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|-----------------------------------------|-------|------|------|---------|--------|------------|--------------|
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/48 | (0%) | | 0/47 | (0%) | |
| Overall Incidence | Total | 0/48 | (0%) | Mean 0% | SD 0% | Total | 0/47 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Malignant | | | | | | | |
| | | 0/48 | (0%) | | 1/47 | (2%) | |
| Overall Incidence | Total | 0/48 | (0%) | Mean 0% | SD 0% | Total | 1/47 (2.13%) |
| | | | | | | Mean 2.13% | SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 0/48 | (0%) | | 1/47 | (2%) | |
| Overall Incidence | Total | 0/48 | (0%) | Mean 0% | SD 0% | Total | 1/47 (2.13%) |
| | | | | | | Mean 2.13% | SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | Mean 0% | SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|------|------|---------|-------|--------|------|---------|-------|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/49 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/49 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 1/50 | (2%) | Mean 2% | SD 0% |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tissue NOS: Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | Male | | | Female | | |
|------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Tongue: | | | | | | | |
| Fibroma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tongue: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Tooth: | | | | | | | |
| Odontoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Urethra: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Urinary Bladder: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/47 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) |
| | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|--------|-------|------|---------|
| *Urinary Bladder: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/47 | (0%) | | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/47 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | Mean 0% |
| | | | | | | | | SD 0% |
| | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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| | | | | Male | | | | | Female | |
|-----------------------------------------|-------|------|------|---------|-------|-------|------|---------|---------|-------|
| #Uterus: | | | | | | | | | | |
| Polyp Stromal | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma | | | | | | | | | | |
| | | | | | | 1/50 | (2%) | | | |
| Overall Incidence | | | | Total | 1/50 | (2%) | | Mean 2% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma Stromal | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Uterus: | | | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Vagina: | | | | | | | | | | |
| Liposarcoma | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | | | | Total | 0/50 | (0%) | | Mean 0% | SD 0% | |
| | | | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | | | |
| Carcinoma | | | | | | | | | | |
| | | | | | | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |

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

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

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Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-----------------------------|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma or Adenoma | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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Report Date: 06/05/2013

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 |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|----------------------------|
| Male | | | | | | | |
| Southern Research Institute | 059500306 | 04/26/04 | 729 | 50(1) | 34(694) | 54.6 | Methyl trans-styryl ketone |
| Battelle Columbus Laboratory | 059903204 | 09/21/04 | 729 | 50(1) | 37(698) | 56.4 | Pyrogallol |
| Female | | | | | | | |
| Southern Research Institute | 059500306 | 04/26/04 | 731 | 50(1) | 37(709) | 64.6 | Methyl trans-styryl ketone |
| Battelle Columbus Laboratory | 059903204 | 09/20/04 | 729 | 50(1) | 33(675) | 69.3 | Pyrogallol |

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | Female | | |
|--------------------------------------|-------|--------------|-------------|----------|-------------|--------------|--------------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 37/50 (74%) | 42/50 (84%) | | 33/50 (66%) | 34/50 (68%) | |
| Overall Incidence | Total | 79/100 (79%) | Mean 79% | SD 7.07% | Total | 67/100 (67%) | Mean 67% SD 1.41% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 37/50 (74%) | 33/50 (66%) | | 42/50 (84%) | 34/50 (68%) | |
| Overall Incidence | Total | 70/100 (70%) | Mean 70% | SD 5.66% | Total | 76/100 (76%) | Mean 76% SD 11.31% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 49/50 (98%) | 47/50 (94%) | | 48/50 (96%) | 42/50 (84%) | |
| Overall Incidence | Total | 96/100 (96%) | Mean 96% | SD 2.83% | Total | 90/100 (90%) | Mean 90% SD 8.49% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 0% | Total | 1/100 (1%) | Mean 1% SD 1.41% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 6/50 (12%) | 5/50 (10%) | | 5/50 (10%) | 6/50 (12%) | |
| Overall Incidence | Total | 11/100 (11%) | Mean 11% | SD 1.41% | Total | 11/100 (11%) | Mean 11% SD 1.41% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 7/50 (14%) | 6/50 (12%) | | 5/50 (10%) | 7/50 (14%) | |
| Overall Incidence | Total | 13/100 (13%) | Mean 13% | SD 1.41% | Total | 12/100 (12%) | Mean 12% SD 2.83% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|------------|-----------|----------|-------------|--------------|----------|----------|--|
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 4/50 (8%) | 2/50 (4%) | | 20/50 (40%) | 13/50 (26%) | | | |
| Overall Incidence | Total | 6/100 (6%) | Mean 6% | SD 2.83% | Total | 33/100 (33%) | Mean 33% | SD 9.9% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------|-------|----------|----------|--------|------|---------|----------|
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 6/50 | (12%) | 9/50 | (18%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 15/100 | (15%) | Mean 15% | SD 4.24% | 1/100 | (1%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 2/100 | (2%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 1/100 | (1%) | Mean 1% | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|------------------------------------------------------------|-------|------------|-----------|-------|-----------|------------|---------|----------|
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 1/50 (2%) | 2/50 (4%) | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 3/100 (3%) | Mean 3% | SD 1.41% |
| | | | | | | | | |
| #Blood Vessel: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 3/50 (6%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 4/100 (4%) | Mean 4% | SD 2.83% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Bone Marrow: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | |
|--------------------------------|-------|------------|-----------|---------|-------|------------|-----------|-----------|---------|----------|
| *Bone Marrow: | | | | | | | | | | |
| Sarcoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% |
| | | 0/100 (0%) | | | | 0/100 (0%) | | | | |
| #Bone: | | | | | | | | | | |
| Fibroma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% |
| | | 0/100 (0%) | | | | 0/100 (0%) | | | | |
| #Bone: | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 3/50 (6%) | Mean 3% | SD 4.24% |
| | | 0/100 (0%) | | | | 3/100 (3%) | | | | |
| #Bone: | | | | | | | | | | |
| Osteoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% |
| | | 0/100 (0%) | | | | 0/100 (0%) | | | | |
| #Bone: | | | | | | | | | | |
| Osteosarcoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% |
| | | 0/100 (0%) | | | | 0/100 (0%) | | | | |
| #Bone: | | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | 0/50 (0%) | Mean 0% | SD 0% |
| | | 0/100 (0%) | | | | 0/100 (0%) | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Bone: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Oligodendroglioma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------------|
| *Brain: | | | | | | | | | |
| Oligodendroglioma, Glioma, or Astrocytoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/97 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/48 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/97 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Granular Cell Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Coagulating Gland: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 272
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------|-------|--------|-------|----------|----------|--------|-------|------|----------|
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | 6/50 | (12%) | 4/50 | (8%) | 1/50 | (2%) |
| Overall Incidence | Total | 8/100 | (8%) | Mean 8% | SD 5.66% | Total | 5/100 | (5%) | Mean 5% |
| | | | | | | | | | SD 4.24% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | 2/50 | (4%) | 0/50 | (0%) | 2/50 | (4%) |
| Overall Incidence | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% |
| | | | | | | | | | SD 2.83% |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 3/50 | (6%) | 8/50 | (16%) | 4/50 | (8%) | 3/50 | (6%) |
| Overall Incidence | Total | 11/100 | (11%) | Mean 11% | SD 7.07% | Total | 7/100 | (7%) | Mean 7% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 273
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|----------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|-------|------|
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 274
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|------|---------|-------|--------|------|---------|----------|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 1/100 | (1%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 275
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|--------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Intestine Small: Ileum: | | | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 276
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|------------|-----------|----------|-----------|------------|---------|----------|--|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 2/100 (2%) | Mean 2% | SD 0% | Total | 2/100 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 3/100 (3%) | Mean 3% | SD 1.41% | Total | 2/100 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Islets, Pancreatic: Adenoma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 3/100 (3%) | Mean 3% | SD 1.41% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 277
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|-----------------------------------------------------|-------|-------|---------|------------|----------|--------|-------|------|---------|----------|------|
| *Islets, Pancreatic: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 2/50 | (4%) | 2/50 | (4%) | | | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 4/100 | (4%) | Mean 4% | SD 0% | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 1/48 | (2%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/98 | (1.02%) | Mean 1.04% | SD 1.47% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 278
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | |
|---------------------------------------------------------------|-------|-------|---------|------------|----------|--------|-------|---------|------------|----------|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | | |
| | | 1/48 | (2%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 1/98 | (1.02%) | Mean 1.04% | SD 1.47% | Total | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 1/99 | (1.01%) | Mean 1% | SD 1.41% |
| | | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | 1/49 | (2%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 1/99 | (1.01%) | Mean 1.02% | SD 1.44% |
| | | | | | | | | | | |
| *Liver: Hemangioma | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 279
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|--------------|-------------|-----------|-------------|--------------|----------|----------|--|
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 4/50 (8%) | 3/50 (6%) | | 1/50 (2%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 7/100 (7%) | Mean 7% | SD 1.41% | Total | 2/100 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 1/50 (2%) | 4/50 (8%) | | 0/50 (0%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 5/100 (5%) | Mean 5% | SD 4.24% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 31/50 (62%) | 39/50 (78%) | | 30/50 (60%) | 30/50 (60%) | | | |
| Overall Incidence | Total | 70/100 (70%) | Mean 70% | SD 11.31% | Total | 60/100 (60%) | Mean 60% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 28/50 (56%) | 20/50 (40%) | | 23/50 (46%) | 17/50 (34%) | | | |
| Overall Incidence | Total | 48/100 (48%) | Mean 48% | SD 11.31% | Total | 40/100 (40%) | Mean 40% | SD 8.49% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 29/50 (58%) | 21/50 (42%) | | 23/50 (46%) | 18/50 (36%) | | | |
| Overall Incidence | Total | 50/100 (50%) | Mean 50% | SD 11.31% | Total | 41/100 (41%) | Mean 41% | SD 7.07% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 45/50 (90%) | 43/50 (86%) | | 38/50 (76%) | 35/50 (70%) | | | |
| Overall Incidence | Total | 88/100 (88%) | Mean 88% | SD 2.83% | Total | 73/100 (73%) | Mean 73% | SD 4.24% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 280
 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|--------------|-------------|----------|-------------|--------------|----------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 45/50 (90%) | 43/50 (86%) | | 38/50 (76%) | 35/50 (70%) | | |
| Overall Incidence | Total | 88/100 (88%) | Mean 88% | SD 2.83% | Total | 73/100 (73%) | Mean 73% | SD 4.24% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------|-------|--------------|-------------|----------|-----------|------------|---------|----------|--|
| *Liver: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 8/50 (16%) | 12/50 (24%) | | 1/50 (2%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 20/100 (20%) | Mean 20% | SD 5.66% | Total | 3/100 (3%) | Mean 3% | SD 1.41% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 7/50 (14%) | 4/50 (8%) | | 3/50 (6%) | 2/50 (4%) | | | |
| Overall Incidence | Total | 11/100 (11%) | Mean 11% | SD 4.24% | Total | 5/100 (5%) | Mean 5% | SD 1.41% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 14/50 (28%) | 15/50 (30%) | | 4/50 (8%) | 4/50 (8%) | | | |
| Overall Incidence | Total | 29/100 (29%) | Mean 29% | SD 1.41% | Total | 8/100 (8%) | Mean 8% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 282
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mediastinal: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|----------|
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 2/100 | (2%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 2/100 | (2%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| #Mammary Gland: Fibroadenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 284
 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|-----------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Mammary Gland: | | | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 2/50 | (4%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Lipoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 285
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Oral Mucosa: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 286
 Report Date: 06/05/2013

| | Male | | | Female | | |
|-----------------------------------------------------|-------|------|---------|------------|------|----------|
| *Ovary: | | | | | | |
| Choriocarcinoma | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Cystadenocarcinoma | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | | SD 0% |
| | | | | | | |
| *Ovary: | | | | | | |
| Cystadenoma | | | | | | |
| | | 1/49 | (2%) | 2/50 | (4%) | |
| Overall Incidence | Total | 3/99 | (3.03%) | Mean 3.02% | | SD 1.39% |
| | | | | | | |
| *Ovary: | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | |
| | | 0/49 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 1/99 | (1.01%) | Mean 1% | | SD 1.41% |
| | | | | | | |
| *Ovary: | | | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | | | |
| | | 0/49 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 1/99 | (1.01%) | Mean 1% | | SD 1.41% |
| | | | | | | |
| *Ovary: | | | | | | |
| Hemangioma | | | | | | |
| | | 0/49 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 1/99 | (1.01%) | Mean 1% | | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 287
 Report Date: 06/05/2013

| | Male | Female |
|------------------------------------|--------------------|------------------|
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 0/49 (0%) | 1/50 (2%) |
| Overall Incidence | Total 1/99 (1.01%) | Mean 1% SD 1.41% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Plasma Cell Tumor Malignant | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Sarcoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Benign | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Malignant | | |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/99 (0%) | Mean 0% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 288
 Report Date: 06/05/2013

| Male | | | | | Female | | | | | | | | | | |
|-------------------------------------------------------------|--|-------|------|------|--------|------|------|------|-------|-------|---------|------|-------|----|-------|
| *Ovary: | | | | | | | | | | | | | | | |
| Tubulostromal Adenoma | | | | | | | | | | | | | | | |
| | | | | | 0/49 | (0%) | 0/50 | (0%) | | | | | | | |
| Overall Incidence | | | | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | | | | |
| | | | | | | | | | | | | | | | |
| *Ovary: | | | | | | | | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | | | | | | | | |
| | | | | | 0/49 | (0%) | 0/50 | (0%) | | | | | | | |
| Overall Incidence | | | | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | | | | |
| | | | | | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | | | | |
| Overall Incidence | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | | |
| *Pancreas: | | | | | | | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | | | | | | |
| Overall Incidence | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | | | 5/47 | (11%) | 4/50 | (8%) | | | | |
| Overall Incidence | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | Total | 9/97 | (9.28%) | Mean | 9.32% | SD | 1.87% |
| | | | | | | | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | | | | | | | |
| Carcinoma | | | | | | | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | | | 0/47 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | | Total | 0/99 | (0%) | Mean | 0% | SD | 0% | Total | 0/97 | (0%) | Mean | 0% | SD | 0% |
| | | | | | | | | | | | | | | | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 289
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-------------------------------------------------------------|-------|-------|------|---------|-------|--------|---------|------------|----------|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 5/47 | (11%) | 4/50 | (8%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 9/97 | (9.28%) | Mean 9.32% | SD 1.87% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/47 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/97 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/47 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/97 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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| | | Male | | | | Female | | | |
|----------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------------|
| *Salivary Glands: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | 2/100 | (2%) | Mean 2% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 292
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| | | Male | | | | Female | | | | | |
|--------------------------------------------------------------------|-------|-------|------|---------|----------|--------|-------|------|---------|----------|------|
| #Skin: | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 2/100 | (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | | | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 2/100 | (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 1/50 | (2%) | | | 2/50 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/100 | (2%) | Mean 2% | SD 0% | Total | 3/100 | (3%) | Mean 3% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|----------------------------------|-------|-------|------|---------|----------|--------|-------|------|------------------|
| #Skin: | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Melanoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|------------------|
| #Skin: | | | | | | | | | |
| Melanoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibroma or Schwannoma benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 2/100 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|------|----------|
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Benign | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 1/100 | (1%) | Mean 1% |
| | | | | | | | | | SD 1.41% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | Total | 0/100 | (0%) | Mean 0% |
| | | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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| | Male | | | | Female | | | |
|---------------------------------------------------------------------------------------|-------|------------|-----------|-------|-----------|------------|---------|----------|
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Spinal Cord: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/98 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | | | |
|------------------------------------------------------|-------|-------|---------|------------|----------|--------|-------|---------|------------|----------|------|
| *Spleen: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 3/48 | (6%) | 1/50 | (2%) | | | 2/49 | (4%) | 1/50 | (2%) |
| Overall Incidence | Total | 4/98 | (4.08%) | Mean 4.12% | SD 3.01% | Total | 3/99 | (3.03%) | Mean 3.04% | SD 1.47% | |
| | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Spleen: | | | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/48 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/98 | (0%) | Mean 0% | SD 0% | Total | 0/99 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | | | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | Total | 0/100 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | | | |
| | | 4/50 | (8%) | 1/50 | (2%) | | | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 5/100 | (5%) | Mean 5% | SD 4.24% | Total | 2/100 | (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | | | |
| | | 3/50 | (6%) | 1/50 | (2%) | | | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 4/100 | (4%) | Mean 4% | SD 2.83% | Total | 2/100 | (2%) | Mean 2% | SD 0% | |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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| | | Male | | | | Female | | | |
|-----------------------------|-------|-------|------|---------|-------|--------|------|---------|-------|
| #Stomach, Glandular: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/44 | (0%) | 0/48 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/92 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |

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

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

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 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|-----------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/44 | (0%) | 0/48 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/92 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/44 | (0%) | 0/48 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/92 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/44 | (0%) | 0/48 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/92 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/99 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 300
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|--------------------------------------------------------------|-------|------------|-----------|----------|-----------|--------------|------------|----------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/99 (1.01%) | Mean 1.02% | SD 1.44% | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/100 (1%) | Mean 1% | SD 1.41% | Total | 1/99 (1.01%) | Mean 1.02% | SD 1.44% | |
| #Tissue NOS: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 2/100 (2%) | Mean 2% | SD 0% | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 0/100 (0%) | Mean 0% | SD 0% | |
| #Tissue NOS: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 1% | SD 1.41% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 301
 Report Date: 06/05/2013

| | | Male | | | | Female | | | |
|------------------------------------------------------|-------|-------|------|---------|----------|--------|------|---------|-------|
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 1/100 | (1%) | Mean 1% | SD 1.41% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Urethra: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean 0% | SD 0% | 0/100 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/49 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/99 | (0%) | Mean 0% | SD 0% | 0/99 | (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 302
 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|------------------------------------|-------|-----------|-----------|-------|------------|-----------|---------|----------|
| *Urinary Bladder: | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/99 (0%) | Mean 0% | SD 0% | Total | 0/99 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 1/50 (2%) | 1/50 (2%) | | |
| Overall Incidence | Total | | | | 2/100 (2%) | Mean 2% | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | | | | 1/50 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 1/100 (1%) | Mean 1% | | SD 1.41% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Leiomyosarcoma | | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | | | | 0/100 (0%) | Mean 0% | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 303
 Report Date: 06/05/2013

| | Male | | | | Female | | | |
|-----------------------------------------|-------|------------|-------|------------|--------|-------|------|----------|
| #Uterus: | | | | | | | | |
| Polyp Stromal | | | | | | | | |
| | | | 1/50 | (2%) | | 3/50 | (6%) | |
| Overall Incidence | | | Total | 4/100 (4%) | | Mean | 4% | SD 2.83% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | | | Total | 0/100 (0%) | | Mean | 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma Stromal | | | | | | | | |
| | | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | | | Total | 0/100 (0%) | | Mean | 0% | SD 0% |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma Stromal or Polyp Stromal | | | | | | | | |
| | | | 1/50 | (2%) | | 3/50 | (6%) | |
| Overall Incidence | | | Total | 4/100 (4%) | | Mean | 4% | SD 2.83% |
| | | | | | | | | |
| #Vagina: | | | | | | | | |
| Liposarcoma | | | | | | | | |
| | | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | | | Total | 1/100 (1%) | | Mean | 1% | SD 1.41% |
| | | | | | | | | |
| #Zymbal's Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | |
| Overall Incidence | Total | 0/100 (0%) | | Mean | 0% | SD | 0% | |
| | | | | | | Total | 0/50 | (0%) |
| | | | | | | | 0/50 | (0%) |
| | | | | | | | Mean | 0% |
| | | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 304
Report Date: 06/05/2013

| Male | | | | | Female | | | | |
|-----------------------------|-------|-------|------|------|--------|------|------|-------|------------|
| #Zymbal's Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/100 | (0%) | Mean | 0% | SD | 0% | Total | 0/100 (0%) |
| | | | | | | | | Mean | 0% |
| | | | | | | | | SD | 0% |

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