

NTP Historical Controls Report

By Route and Vehicle

MICE

August 2016

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 |
|------------|----------|-------------|
| GAVAGE | CORN OIL | 4 |
| GAVAGE | WATER | 35 |
| INHALATION | AIR | 66 |
| ORAL | WATER | 103 |

Version: Aug2016
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: 08/03/2016

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 | 052000604 | 04/03/07 | 730 | 50(1) | 26(663) | 55.6 | Indole-3-carbinol |
| Southern Research Institute | 052020904 | 02/25/08 | 729 | 50(1) | 29(657) | 55.3 | Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] |
| Battelle Columbus Laboratory | 052032004 | 08/07/07 | 730 | 50(1) | 33(687) | 55.8 | Tetrabromobisphenol A |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052000604 | 04/02/07 | 729 | 50(5) | 33(702) | 66.6 | Indole-3-carbinol |
| Southern Research Institute | 052020904 | 02/25/08 | 731 | 50(5) | 33(679) | 57.7 | Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)] |
| Battelle Columbus Laboratory | 052032004 | 08/06/07 | 729 | 50(5) | 40(711) | 66.5 | Tetrabromobisphenol A |

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|--------------------------------------|-------|------------------|-------------|-------------|-------------|-----------------|-------------|----------|
| #All Organs: | | | | | | | | |
| Benign Tumors | | | | | | | | |
| | | 33/50 (66%) | 30/50 (60%) | 38/50 (76%) | 17/50 (34%) | 24/50 (48%) | 22/50 (44%) | |
| Overall Incidence | Total | 101/150 (67.33%) | Mean 67.33% | SD 8.08% | Total | 63/150 (42%) | Mean 42% | SD 7.21% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant Tumors | | | | | | | | |
| | | 27/50 (54%) | 27/50 (54%) | 21/50 (42%) | 19/50 (38%) | 16/50 (32%) | 18/50 (36%) | |
| Overall Incidence | Total | 75/150 (50%) | Mean 50% | SD 6.93% | Total | 53/150 (35.33%) | Mean 35.33% | SD 3.06% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | |
| | | 48/50 (96%) | 40/50 (80%) | 47/50 (94%) | 30/50 (60%) | 34/50 (68%) | 32/50 (64%) | |
| Overall Incidence | Total | 135/150 (90%) | Mean 90% | SD 8.72% | Total | 96/150 (64%) | Mean 64% | SD 4% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total | 3/150 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 4/50 (8%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 6/150 (4%) | Mean 4% | SD 3.46% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | |
| | | 4/50 (8%) | 1/50 (2%) | 3/50 (6%) | 1/50 (2%) | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | 8/150 (5.33%) | Mean 5.33% | SD 3.06% | Total | 4/150 (2.67%) | Mean 2.67% | SD 1.15% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|----------------|------------|-----------|-------|-----------------|-------------|------------|--|
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 2% | Total | 3/150 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 3/50 (6%) | 5/50 (10%) | 3/50 (6%) | | 6/50 (12%) | 7/50 (14%) | 9/50 (18%) | |
| Overall Incidence | Total | 11/150 (7.33%) | Mean 7.33% | SD 2.31% | Total | 22/150 (14.67%) | Mean 14.67% | SD 3.06% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|----------------------------------------------------------|-------|---------------|------------|-----------|--------|---------------|------------|
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 2/49 (4%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/149 (1.34%) | Mean 1.36% |
| | | | | | | | SD 2.36% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Benign | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/148 (0.68%) | Mean 0.67% |
| | | | | | | | SD 1.15% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/148 (0.68%) | Mean 0.67% |
| | | | | | | | SD 1.15% |
| | | | | | | | |
| #Blood Vessel: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% |
| | | | | | | | SD 1.15% |
| | | | | | | | |
| #Blood Vessel: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Bone Marrow: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/149 (0%) | Mean 0% |
| | | | | | | | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | | | | | |
|----------------------------------|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|------|------|
| *Bone Marrow: | | | | | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/149 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/149 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | | | |
| Fibroma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | | | |
| | | | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | | | |
| Osteoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | | | |
| | | | | | | | | | | | | | |
| #Bone: | | | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|-------------------------------------------|-------|---------------|------------|-----------|-----------|------------|-----------|-------|
| *Brain: | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Coagulating Gland: | | | | | | | | |
| Granular Cell Tumor | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 Contract/Lab: All Laboratories
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 Strain: B6C3F1
 Length of Study: CHRONIC

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

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 Report Date: 08/03/2016

| | | Male | | | Female | | |
|------------------------------------------------------|-------|--------------|------------|------------|-----------|-----------------|-------------------------|
| #Harderian Gland: Adenoma | | | | | | | |
| | | 6/50 (12%) | 5/50 (10%) | 7/50 (14%) | 3/50 (6%) | 9/50 (18%) | 2/50 (4%) |
| Overall Incidence | Total | 18/150 (12%) | Mean 12% | SD 2% | Total | 14/150 (9.33%) | Mean 9.33% SD 7.57% |
| | | | | | | | |
| #Harderian Gland: Carcinoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% SD 1.15% |
| | | | | | | | |
| #Harderian Gland: Carcinoma or Adenoma | | | | | | | |
| | | 7/50 (14%) | 6/50 (12%) | 8/50 (16%) | 3/50 (6%) | 10/50 (20%) | 3/50 (6%) |
| Overall Incidence | Total | 21/150 (14%) | Mean 14% | SD 2% | Total | 16/150 (10.67%) | Mean 10.67% SD 8.08% |
| | | | | | | | |
| *Heart: Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Intestine Large: Cecum: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|------------------------------------|-------|---------------|------------|-----------|---------------------|------------|-----------|
| #Intestine Large: Cecum: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (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%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (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%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (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%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (0%) | Mean 0% | SD 0% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|---------------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| #Intestine Small: Jejunum: Adenoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Jejunum: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Intestine Small: Site Unspecified: Adenoma | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 3.06% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 5/150 (3.33%) | Mean 3.33% | SD 3.06% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------|-------|---------------|------------|-----------|---------------------|------------|-----------|
| #Intestine Small: Site Unspecified: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | |
| Polyp Adenomatous | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Adenoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | Total 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total 0/150 (0%) | Mean 0% | SD 0% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|---------------|------------|-----------|-------|------------|-----------|-----------|-----------|
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/150 (0%) | Mean 0% | SD 0% | | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/150 (0%) | Mean 0% | SD 0% | | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/150 (0%) | Mean 0% | SD 0% | | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/150 (0%) | Mean 0% | SD 0% | | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Cholangiocarcinoma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/150 (0%) | Mean 0% | SD 0% | | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | Total | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | | 0/150 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------------|-------|-----------------|-------------|-------------|-------------|-----------------|-------------------------|
| *Liver: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 4/50 (8%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 4/150 (2.67%) | Mean 2.67% | SD 4.62% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatoblastoma | | | | | | | |
| | | 3/50 (6%) | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 6/150 (4%) | Mean 4% | SD 2% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Adenoma | | | | | | | |
| | | 26/50 (52%) | 23/50 (46%) | 32/50 (64%) | 7/50 (14%) | 5/50 (10%) | 13/50 (26%) |
| Overall Incidence | Total | 81/150 (54%) | Mean 54% | SD 9.17% | Total | 25/150 (16.67%) | Mean 16.67% SD 8.33% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | |
| | | 12/50 (24%) | 18/50 (36%) | 11/50 (22%) | 6/50 (12%) | 4/50 (8%) | 2/50 (4%) |
| Overall Incidence | Total | 41/150 (27.33%) | Mean 27.33% | SD 7.57% | Total | 12/150 (8%) | Mean 8% SD 4% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | |
| | | 15/50 (30%) | 18/50 (36%) | 12/50 (24%) | 6/50 (12%) | 4/50 (8%) | 2/50 (4%) |
| Overall Incidence | Total | 45/150 (30%) | Mean 30% | SD 6% | Total | 12/150 (8%) | Mean 8% SD 4% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | |
| | | 35/50 (70%) | 31/50 (62%) | 39/50 (78%) | 12/50 (24%) | 8/50 (16%) | 15/50 (30%) |
| Overall Incidence | Total | 105/150 (70%) | Mean 70% | SD 8% | Total | 35/150 (23.33%) | Mean 23.33% SD 7.02% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|----------------------------------------------------------------------------|-------|------------------|-------------|-------------|-------------|-----------------|-------------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 36/50 (72%) | 31/50 (62%) | 39/50 (78%) | 12/50 (24%) | 8/50 (16%) | 15/50 (30%) | |
| Overall Incidence | Total | 106/150 (70.67%) | Mean 70.67% | SD 8.08% | Total | 35/150 (23.33%) | Mean 23.33% | SD 7.02% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 4/50 (8%) | 5/50 (10%) | 6/50 (12%) | 1/50 (2%) | 1/50 (2%) | 5/50 (10%) | |
| Overall Incidence | Total | 15/150 (10%) | Mean 10% | SD 2% | Total | 7/150 (4.67%) | Mean 4.67% | SD 4.62% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | |
| | | 4/50 (8%) | 5/50 (10%) | 4/50 (8%) | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 13/150 (8.67%) | Mean 8.67% | SD 1.15% | Total | 3/150 (2%) | Mean 2% | SD 2% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 8/50 (16%) | 10/50 (20%) | 10/50 (20%) | 3/50 (6%) | 1/50 (2%) | 6/50 (12%) | |
| Overall Incidence | Total | 28/150 (18.67%) | Mean 18.67% | SD 2.31% | Total | 10/150 (6.67%) | Mean 6.67% | SD 5.03% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | | | |
|----------------------------------|-------|-------|------|---------|-------|--------|-------|------|---------|-------|------|
| *Lung: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Lymph Node: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (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%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-------------------------------------------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | |
| | | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | |
| | | | | | | | | | |
| #Mammary Gland: Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 1.15% | |
| | | | | | | | | | |
| #Mesentery: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | | | |
|---------------------------------------------------------------------|-------|-------|------|---------|-------|--------|-------|---------|------------|----------|------|
| #Mesentery: | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Mesentery: | | | | | | | | | | | |
| Lipoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Nose: | | | | | | | | | | | |
| Adenoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| *Nose: | | | | | | | | | | | |
| Polyp | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (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%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-------|------------|-----------|-----------|--------|---------------|------------|-----------|
| #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%) | 2/50 (4%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% |
| | | | | | | | | |
| #Oral Mucosa: Squamous Cell Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| *Ovary: Cystadenocarcinoma | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/148 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Ovary: Cystadenoma | | | | | | | | |
| | | | | | | 1/50 (2%) | 2/48 (4%) | 2/50 (4%) |
| Overall Incidence | | | | | Total | 5/148 (3.38%) | Mean 3.39% | SD 1.21% |
| | | | | | | | | |
| *Ovary: Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 0/50 (0%) | 1/48 (2%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 1/148 (0.68%) | Mean 0.69% | SD 1.2% |
| | | | | | | | | |
| *Ovary: Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| Overall Incidence | | | | | Total | 0/148 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 |
|-----------------------------------------------------|---------------------|------------------------|
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/50 (0%) | 1/48 (2%) |
| Overall Incidence | Total 1/148 (0.68%) | Mean 0.69% SD 1.2% |
| | | |
| *Ovary: | | |
| Granulosa-Theca Tumor Malignant | | |
| | 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total 0/148 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total 0/148 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total 0/148 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Sarcoma | | |
| | 0/50 (0%) | 0/48 (0%) |
| Overall Incidence | Total 0/148 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Tubulostromal Adenoma | | |
| | 1/50 (2%) | 0/48 (0%) |
| Overall Incidence | Total 1/148 (0.68%) | Mean 0.67% SD 1.15% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-------------------------------------------------------------|-------|------------|------------|-----------|-----------|---------------|------------|
| *Ovary: | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | |
| | | | 0/50 (0%) | | 0/48 (0%) | | 0/50 (0%) |
| Overall Incidence | | Total | 0/148 (0%) | | Mean 0% | | SD 0% |
| | | | | | | | |
| *Parathyroid Gland: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/48 (0%) | 0/48 (0%) | 0/45 (0%) | 0/43 (0%) | 0/44 (0%) | 0/34 (0%) |
| Overall Incidence | Total | 0/141 (0%) | Mean 0% | SD 0% | Total | 0/121 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | 3/49 (6%) | 5/50 (10%) | 1/50 (2%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 9/149 (6.04%) | Mean 6.04% |
| | | | | | | | SD 4% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 0/149 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | 3/49 (6%) | 5/50 (10%) | 1/50 (2%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 9/149 (6.04%) | Mean 6.04% |
| | | | | | | | SD 4% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 1/149 (0.67%) | Mean 0.68% |
| | | | | | | | SD 1.18% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 0/149 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 1/149 (0.67%) | Mean 0.68% | SD 1.18% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/147 (0%) | Mean 0% | SD 0% | Total | 0/149 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|----------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| *Salivary Glands: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Salivary Glands: | | | | | | | | |
| Myxosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | | | | |
| | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: | | | | | | | | | | | |
| Sarcoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 0/150 | (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | | | |
| #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%) | 1/50 | (2%) |
| Overall Incidence | Total | 0/150 | (0%) | Mean 0% | SD 0% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | | | |
| #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%) | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) |
| Overall Incidence | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 | (0.67%) | Mean 0.67% | SD 1.15% | |
| | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) |
| Overall Incidence | Total | 2/150 | (1.33%) | Mean 1.33% | SD 1.15% | Total | 3/150 | (2%) | Mean 2% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | | | | | | |
|--------------------------------------------------------------------|-------|---------------|------|------------|------|----------|------|-------|---------------|------|------------|------|----------|--|
| #Skin: | | | | | | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) | |
| Overall Incidence | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | |
| | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | | | | | | |
| | | 1/50 | (2%) | 0/50 | (0%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | 1/50 | (2%) | |
| Overall Incidence | Total | 2/150 (1.33%) | | Mean 1.33% | | SD 1.15% | | Total | 3/150 (2%) | | Mean 2% | | SD 0% | |
| | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 0/150 (0%) | | Mean 0% | | SD 0% | | Total | 0/150 (0%) | | Mean 0% | | SD 0% | |
| | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | |
| Hemangioma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 0/150 (0%) | | Mean 0% | | SD 0% | | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | |
| | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | |
| Overall Incidence | Total | 0/150 (0%) | | Mean 0% | | SD 0% | | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | |
| | | | | | | | | | | | | | | |
| #Skin: | | | | | | | | | | | | | | |
| Keratoacanthoma | | | | | | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 1/50 | (2%) | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | | Mean 0.67% | | SD 1.15% | | Total | 0/150 (0%) | | Mean 0% | | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|----------------------------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total | 0/150 (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%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neural Crest Tumor | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (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%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------------------|
| #Skin: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |
| | | | | | | | |
| #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%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |

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

Version: Aug2016
 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: 29
 Report Date: 08/03/2016

| | | Male | | | Female | | | |
|------------------------------------------------------|-------|---------------|------------|------------|-----------|---------------|------------|----------|
| *Spleen: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 3/150 (2%) | Mean 2% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| *Spleen: | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 5/50 (10%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 9/150 (6%) | Mean 6% | SD 3.46% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 1/50 (2%) | 2/50 (4%) | 5/50 (10%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 8/150 (5.33%) | Mean 5.33% | SD 4.16% | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% |
| | | | | | | | | |
| #Stomach, Glandular: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | | |
|----------------------------------------|-------|----------------------------|-------------------------|-----------------------|--------|-------------------------|----------------------|--------------------|
| #Stomach, Glandular: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% | Total | 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| *Testes: | | | | | | | | |
| Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) 2/150 (1.33%) | 2/50 (4%) Mean 1.33% | 0/50 (0%) SD 2.31% | | | | |
| | | | | | | | | |
| *Thymus: | | | | | | | | |
| Neoplasm NOS | | | | | | | | |
| Overall Incidence | Total | 0/49 (0%) 0/136 (0%) | 0/40 (0%) Mean 0% | 0/47 (0%) SD 0% | Total | 0/49 (0%) 0/147 (0%) | 0/48 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| *Thymus: | | | | | | | | |
| Thymoma Benign | | | | | | | | |
| Overall Incidence | Total | 1/49 (2%) 1/136 (0.74%) | 0/40 (0%) Mean 0.68% | 0/47 (0%) SD 1.18% | Total | 0/49 (0%) 0/147 (0%) | 0/48 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| *Thymus: | | | | | | | | |
| Thymoma NOS | | | | | | | | |
| Overall Incidence | Total | 0/49 (0%) 0/136 (0%) | 0/40 (0%) Mean 0% | 0/47 (0%) SD 0% | Total | 0/49 (0%) 0/147 (0%) | 0/48 (0%) Mean 0% | 0/50 (0%) SD 0% |
| | | | | | | | | |
| *Thymus: | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | |
| Overall Incidence | Total | 1/49 (2%) 1/136 (0.74%) | 0/40 (0%) Mean 0.68% | 0/47 (0%) SD 1.18% | Total | 0/49 (0%) 0/147 (0%) | 0/48 (0%) Mean 0% | 0/50 (0%) SD 0% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|---------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------------------|
| *Thyroid Gland: C-Cell: Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 2/150 (1.33%) | Mean 1.33% SD 1.15% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% SD 1.15% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 2/150 (1.33%) | Mean 1.33% SD 1.15% |
| | | | | | | | |
| #Tongue: Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------|-------|---------------|------------|-----------|---------------|------------------------|------------------------|
| #Tongue: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 1/150 (0.67%) | Mean 0.67% SD 1.15% |
| | | | | | | | |
| #Tooth: | | | | | | | |
| Odontoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/150 (1.33%) | Mean 1.33% | SD 2.31% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Urethra: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Urinary Bladder: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/150 (0%) | Mean 0% | SD 0% | Total | 0/149 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Adenoma | | | | | | | |
| | | | | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | | | | 1/150 (0.67%) | Mean 0.67% SD 1.15% | |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | | | | 0/150 (0%) | Mean 0% SD 0% | |
| | | | | | | | |

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

Version: Aug2016
 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: 08/03/2016

| | Male | Female |
|-----------------------------------------------------|----------------------------------|-------------------------------------|
| #Uterus: Hemangioma | | |
| Overall Incidence | Total 0/50 (0%) 1/150 (0.67%) | 1/50 (2%) Mean 0.67% SD 1.15% |
| #Uterus: Hemangiosarcoma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Leiomyoma | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Polyp Stromal | | |
| Overall Incidence | Total 0/50 (0%) 0/150 (0%) | 0/50 (0%) Mean 0% SD 0% |
| #Uterus: Sarcoma Stromal | | |
| Overall Incidence | Total 0/50 (0%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% SD 2.31% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | |
| Overall Incidence | Total 0/50 (0%) 2/150 (1.33%) | 0/50 (0%) Mean 1.33% SD 2.31% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 34
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------|-------|---------------|------------|-----------|-----------|------------|------------------|
| #Zymbal's Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #Zymbal's Gland: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/150 (0.67%) | Mean 0.67% | SD 1.15% | Total | 0/150 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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: 35
Report Date: 08/03/2016

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 | 052020304 | 07/10/07 | 730 | 50(1) | 33(694) | 52.6 | Green Tea Extract |
| Female | | | | | | | |
| 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: Aug2016
 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: 36
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 43/50 (86%) | | | 20/50 (40%) | | |
| Overall Incidence | Total | 43/50 (86%) | Mean 86% | SD 0% | Total | 20/50 (40%) | Mean 40% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 28/50 (56%) | | | 18/50 (36%) | | |
| Overall Incidence | Total | 28/50 (56%) | Mean 56% | SD 0% | Total | 18/50 (36%) | Mean 36% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 49/50 (98%) | | | 29/50 (58%) | | |
| Overall Incidence | Total | 49/50 (98%) | Mean 98% | SD 0% | Total | 29/50 (58%) | Mean 58% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 5/50 (10%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 2/50 (4%) | Mean 4% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 7/50 (14%) | | | 2/50 (4%) | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | 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: Aug2016
 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: 37
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|------------------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|------------|
| #All Organs: | | | | | | | |
| Histiocytic 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% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | |
| | | 4/50 | (8%) | | 7/50 | (14%) | |
| Overall Incidence | Total | 4/50 | (8%) | Mean 8% | SD 0% | Total | 7/50 (14%) |
| | | | | | | | Mean 14% |
| | | | | | | | 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% |
| | | | | | | | |
| #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%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

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

Version: Aug2016
 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: 38
 Report Date: 08/03/2016

| | Male | | | | Female | | | |
|----------------------------------------------------------|-------|--------------|------------|-------|-----------|-----------|---------|-------|
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 1/49 (2%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | |
| | | 0/49 (0%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | |
| | | 0/49 (0%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 0/49 (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% |
| | | | | | | | | |
| #Blood Vessel: | | | | | | | | |
| 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 Marrow: | | | | | | | | |
| 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *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: | | | | | | | | | |
| 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: | | | | | | | | | |
| 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 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% |
| | | | | | | | | | |
| #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% |
| | | | | | | | | | |

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

Version: Aug2016
 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 | | |
|-------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *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 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% |
| | | | | | | | |
| #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 | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|---------------------------------|-------|------------|----------|-------|-----------|-----------|---------|-------|
| #Harderian Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 7/50 (14%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 8/50 (16%) | | | 4/50 (8%) | | | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total | 4/50 (8%) | Mean 8% | 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% |
| | | | | | | | | |
| #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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #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 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: | | | | | | | | | |
| 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: Aug2016
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 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 | | | |
|---------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Small: Jejunum: 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: Jejunum: Carcinoma | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | | | |
| | | 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: Site Unspecified: 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: Site Unspecified: Carcinoma | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | 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: Aug2016
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 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: Site Unspecified: | | | | | | | | | |
| 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% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) | Mean 2% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or 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% |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| 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: Aug2016
 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 | | |
|------------------------------------------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------------|
| *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Adenoma | | | | | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: Cholangiocarcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: Hemangioma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | 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: Aug2016
 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 | | |
|-----------------------------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| *Liver: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 3/50 (6%) | | | 1/50 (2%) | | |
| Overall Incidence | Total | 3/50 (6%) | Mean 6% | SD 0% | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatoblastoma | | | | | | | |
| | | 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: | | | | | | | |
| Hepatocellular Adenoma | | | | | | | |
| | | 35/50 (70%) | | | 12/50 (24%) | | |
| Overall Incidence | Total | 35/50 (70%) | Mean 70% | SD 0% | Total | 12/50 (24%) | Mean 24% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | |
| | | 15/50 (30%) | | | 5/50 (10%) | | |
| Overall Incidence | Total | 15/50 (30%) | Mean 30% | SD 0% | Total | 5/50 (10%) | Mean 10% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | |
| | | 17/50 (34%) | | | 5/50 (10%) | | |
| Overall Incidence | Total | 17/50 (34%) | Mean 34% | SD 0% | Total | 5/50 (10%) | Mean 10% SD 0% |
| | | | | | | | |
| *Liver: | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | |
| | | 40/50 (80%) | | | 14/50 (28%) | | |
| Overall Incidence | Total | 40/50 (80%) | Mean 80% | SD 0% | Total | 14/50 (28%) | Mean 28% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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 Species: MICE
 Strain: B6C3F1
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Toxicology Data Management System
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| | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------|-------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 40/50 (80%) | | | 14/50 (28%) | | | |
| Overall Incidence | Total | 40/50 (80%) | Mean 80% | SD 0% | Total | 14/50 (28%) | Mean 28% | 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: | | | | | | | | |
| 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% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 12/50 (24%) | | | 5/50 (10%) | | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 5/50 (10%) | Mean 10% | SD 0% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar 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% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 14/50 (28%) | | | 6/50 (12%) | | | |
| Overall Incidence | Total | 14/50 (28%) | Mean 28% | SD 0% | Total | 6/50 (12%) | Mean 12% | SD 0% |

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

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| | | Male | | | Female | | |
|----------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Lung: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Lymph Node: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (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%) |
| | | | | | | | |
| #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%) |
| | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | |
| Hemangioma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
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| | | Male | | | | Female | | | |
|-------------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #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: 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% |

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

Version: Aug2016
 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 | | | |
|---------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|---------|------------------|
| #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% |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 1/48 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/48 | (2.08%) | Mean 2.08% SD 0% |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Polyp | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/48 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (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% |

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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| | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------|-------|
| #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% |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Cystadenocarcinoma | | | | | | | | |
| | | | | | 1/50 (2%) | | | |
| Overall Incidence | Total | | | | 1/50 (2%) | Mean 2% | SD 0% | |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Cystadenoma | | | | | | | | |
| | | | | | 3/50 (6%) | | | |
| Overall Incidence | Total | | | | 3/50 (6%) | Mean 6% | SD 0% | |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | 0/50 (0%) | | | |
| Overall Incidence | Total | | | | 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | 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: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
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| | Male | | Female | |
|-----------------------------------------------------|------|-------|-----------|--------------------|
| *Ovary: | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Granulosa-Theca Tumor Malignant | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Hemangiosarcoma | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Luteoma | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Sarcoma | | | | |
| | | 1/50 | (2%) | |
| Overall Incidence | | Total | 1/50 (2%) | Mean 2% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Tubulostromal Adenoma | | | | |
| | | 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: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
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| Male | | | | | Female | | | |
|-------------------------------------------------------------|-------|--------------|------------|-------|--------|-----------|---------|-------|
| *Ovary: | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | |
| | | | | | 0/50 | (0%) | | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Parathyroid Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/41 | (0%) | | |
| Overall Incidence | Total | 0/41 (0%) | Mean 0% | SD 0% | Total | 0/35 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 1/49 | (2%) | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | | | | 1/49 | (2%) | | |
| Overall Incidence | Total | 1/49 (2.04%) | Mean 2.04% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/49 (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 | | |
|-------------------------------------------|-------|------|------|---------|--------|---------|-----------|
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| 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% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| 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% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 0/49 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/49 | (0%) | Mean 0% | SD 0% | Total | 0/50 (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 | | | | | | | |
| | | 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% |
| | | | | | | | |

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

Version: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
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 Length of Study: CHRONIC

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 Tumor Incidence for Selected Control Animal Groups
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| | | Male | | | | Female | | | |
|----------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *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% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxosarcoma | | | | | | | | | |
| | | 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%) | | | 2/50 | (4%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 | (4%) | Mean 4% SD 0% |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | 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: Aug2016
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Toxicology Data Management System
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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% | Total | 0/50 (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%) |
| | | | | | | | |
| #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%) |
| | | | | | | | |
| #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%) |
| | | | | | | | |
| #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% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | |
| | | 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: Aug2016
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
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| | Male | | | | Female | | | |
|--------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 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: Aug2016
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| | Male | | | | Female | | | |
|---------------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Lipoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Melanoma Benign | | | | | | | | |
| | | 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: | | | | | | | | |
| 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: | | | | | | | | |
| 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: Aug2016
 Contract/Lab: All Laboratories
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| | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (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%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #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%) |
| | | | | | | | | |
| #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%) |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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| | | Male | | | | Female | | | | |
|------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------|-------|
| *Spleen: | | | | | | | | | | |
| 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% |
| | | | | | | | | | | |
| *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% |
| | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | |
| Squamous Cell 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% |
| | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | | |
| | | 0/50 | (0%) | | | 2/50 | (4%) | | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 2/50 | (4%) | Mean 4% | SD 0% |
| | | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | | |
| | | 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, 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% |
| | | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: | | | | | | | |
| 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% | | | |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Neoplasm NOS | | | | | | | |
| | | 0/44 (0%) | | | 0/47 (0%) | | |
| Overall Incidence | Total | 0/44 (0%) | Mean 0% | SD 0% | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/44 (0%) | | | 0/47 (0%) | | |
| Overall Incidence | Total | 0/44 (0%) | Mean 0% | SD 0% | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma NOS | | | | | | | |
| | | 0/44 (0%) | | | 0/47 (0%) | | |
| Overall Incidence | Total | 0/44 (0%) | Mean 0% | SD 0% | Total | 0/47 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 0/44 (0%) | | | 0/47 (0%) | | |
| Overall Incidence | Total | 0/44 (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: Aug2016
 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: C-Cell: 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% |
| | | | | | | | | | |
| *Thyroid Gland: C-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% |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: 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% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 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% |

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

Version: Aug2016
 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 | | |
|-----------------------------------|-------|------|------|---------|--------|-----------|-----------|
| #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% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Adenoma | | | | | | | |
| | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | | | | 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: Aug2016
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | Female | |
|-----------------------------------------------------|-------|-----------|---------|-------|
| #Uterus: Hemangioma | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Uterus: Hemangiosarcoma | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Uterus: Leiomyoma | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Uterus: Polyp Stromal | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% |
| #Uterus: Sarcoma Stromal | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
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| Male | | | | | Female | | | | |
|-----------------------------|-------|------|------|---------|--------|-------|------|------|---------------|
| #Zymbal's 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% |
| | | | | | | | | | |
| #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: Aug2016
 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: 08/03/2016

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 | 052060104 | 10/06/08 | 729 | 50(5) | 38(708) | 52.1 | Antimony trioxide |
| Battelle Northwest | 052072504 | 08/31/09 | 729 | 50(5) | 35(697) | 51.1 | 2,3-Butanedione |
| Battelle Northwest | 056031106 | 05/15/06 | 729 | 50(5) | 39(715) | 54.3 | Cobalt |
| Battelle Northwest | 052051504 | 05/05/08 | 729 | 50(5) | 39(709) | 52.6 | Metal Working Fluids: CIMSTAR 3800 |
| Battelle Northwest | 052052304 | 08/03/09 | 729 | 50(5) | 38(692) | 52.4 | Metal Working Fluids: TRIM® VX |
| Battelle Northwest | 051047204 | 01/31/11 | 729 | 50(5) | 40(705) | 52.7 | p-Chloro-a,a,a-trifluorotoluene |
| Female | | | | | | | |
| Battelle Northwest | 052060104 | 10/06/08 | 731 | 50(5) | 36(692) | 54.1 | Antimony trioxide |
| Battelle Northwest | 052072504 | 08/31/09 | 731 | 50(5) | 36(697) | 51.0 | 2,3-Butanedione |
| Battelle Northwest | 056031106 | 05/15/06 | 731 | 50(5) | 36(686) | 66.7 | Cobalt |
| Battelle Northwest | 052051504 | 05/05/08 | 731 | 50(5) | 39(696) | 59.2 | Metal Working Fluids: CIMSTAR 3800 |
| Battelle Northwest | 052052304 | 08/03/09 | 731 | 50(5) | 35(692) | 57.9 | Metal Working Fluids: TRIM® VX |
| Battelle Northwest | 051047204 | 01/31/11 | 731 | 50(5) | 38(700) | 55.9 | p-Chloro-a,a,a-trifluorotoluene |

Version: Aug2016
 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: | | | | | | | | | |
| Benign Tumors | | | | | | | | | |
| | | 37/50 (74%) | 22/50 (44%) | 35/50 (70%) | | 25/50 (50%) | 15/50 (30%) | 29/50 (58%) | |
| | | 39/50 (78%) | 32/50 (64%) | 32/50 (64%) | | 26/50 (52%) | 23/50 (46%) | 24/50 (48%) | |
| Overall Incidence | Total | 197/300 (65.67%) | Mean 65.67% | SD 11.96% | Total | 142/300 (47.33%) | Mean 47.33% | SD 9.44% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Tumors | | | | | | | | | |
| | | 25/50 (50%) | 27/50 (54%) | 36/50 (72%) | | 25/50 (50%) | 24/50 (48%) | 31/50 (62%) | |
| | | 26/50 (52%) | 32/50 (64%) | 25/50 (50%) | | 30/50 (60%) | 27/50 (54%) | 24/50 (48%) | |
| Overall Incidence | Total | 171/300 (57%) | Mean 57% | SD 9.01% | Total | 161/300 (53.67%) | Mean 53.67% | SD 6.12% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | | |
| | | 45/50 (90%) | 37/50 (74%) | 45/50 (90%) | | 35/50 (70%) | 34/50 (68%) | 40/50 (80%) | |
| | | 46/50 (92%) | 42/50 (84%) | 44/50 (88%) | | 41/50 (82%) | 38/50 (76%) | 38/50 (76%) | |
| Overall Incidence | Total | 259/300 (86.33%) | Mean 86.33% | SD 6.62% | Total | 226/300 (75.33%) | Mean 75.33% | SD 5.47% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| 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%) | 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% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | 7/50 (14%) | | 4/50 (8%) | 0/50 (0%) | 3/50 (6%) | |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 3/50 (6%) | 2/50 (4%) | 3/50 (6%) | |
| Overall Incidence | Total | 13/300 (4.33%) | Mean 4.33% | SD 4.97% | Total | 15/300 (5%) | Mean 5% | SD 2.76% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|------------------------------------------------------------------------------------------------|-------|----------------|------------|------------|-------|-----------------|-------------|-------------|--|
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | 7/50 (14%) | | 4/50 (8%) | 0/50 (0%) | 3/50 (6%) | |
| | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | | 3/50 (6%) | 3/50 (6%) | 3/50 (6%) | |
| Overall Incidence | Total | 14/300 (4.67%) | Mean 4.67% | SD 4.84% | Total | 16/300 (5.33%) | Mean 5.33% | SD 2.73% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 3/50 (6%) | 1/50 (2%) | 1/50 (2%) | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 4/50 (8%) | 2/50 (4%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.1% | Total | 13/300 (4.33%) | Mean 4.33% | SD 2.34% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 4/50 (8%) | 6/50 (12%) | 4/50 (8%) | | 7/50 (14%) | 9/50 (18%) | 14/50 (28%) | |
| | | 3/50 (6%) | 6/50 (12%) | 6/50 (12%) | | 18/50 (36%) | 10/50 (20%) | 9/50 (18%) | |
| Overall Incidence | Total | 29/300 (9.67%) | Mean 9.67% | SD 2.66% | Total | 67/300 (22.33%) | Mean 22.33% | SD 8.14% | |
| | | | | | | | | | |
| #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%) | 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: 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------------------------------|-------|----------------|------------|-----------|-------|---------------|------------|-----------|--|
| #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 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%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 4/49 (8%) | 2/50 (4%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| | | 9/49 (18%) | 3/50 (6%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 19/298 (6.38%) | Mean 6.42% | SD 6.52% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| | | 1/48 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/49 (2%) | 2/50 (4%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/297 (0.34%) | Mean 0.35% | SD 0.85% | Total | 6/299 (2.01%) | Mean 2.01% | SD 1.27% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| | | 1/48 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/49 (2%) | 2/50 (4%) | 1/50 (2%) | |
| Overall Incidence | Total | 1/297 (0.34%) | Mean 0.35% | SD 0.85% | Total | 6/299 (2.01%) | Mean 2.01% | SD 1.27% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|-----------|
| #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%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Blood Vessel: | | | | | | | | | |
| 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%) | 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% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/297 (0.34%) | Mean 0.33% | SD 0.82% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/49 (0%) | 1/48 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 2/297 (0.67%) | Mean 0.68% | SD 1.05% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (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: Aug2016
 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (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%) | 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 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%) | 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: | | | | | | | | | |
| 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-------------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *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%) | 0/50 (0%) | | 0/50 (0%) | 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: | | | | | | | | | |
| 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%) | |
| 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (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%) | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|---------------------------------|-------|-----------------|-------------|------------|-------|----------------|------------|-----------|--|
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 6/50 (12%) | 3/50 (6%) | 6/50 (12%) | | 3/50 (6%) | 3/50 (6%) | 3/50 (6%) | |
| | | 7/50 (14%) | 4/50 (8%) | 5/50 (10%) | | 2/50 (4%) | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | 31/300 (10.33%) | Mean 10.33% | SD 2.94% | Total | 14/300 (4.67%) | Mean 4.67% | SD 1.63% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 4/50 (8%) | 1/50 (2%) | 0/50 (0%) | |
| | | 5/50 (10%) | 2/50 (4%) | 1/50 (2%) | | 0/50 (0%) | 3/50 (6%) | 0/50 (0%) | |
| Overall Incidence | Total | 11/300 (3.67%) | Mean 3.67% | SD 3.44% | Total | 8/300 (2.67%) | Mean 2.67% | SD 3.5% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 7/50 (14%) | 3/50 (6%) | 8/50 (16%) | | 7/50 (14%) | 4/50 (8%) | 3/50 (6%) | |
| | | 12/50 (24%) | 6/50 (12%) | 6/50 (12%) | | 2/50 (4%) | 4/50 (8%) | 2/50 (4%) | |
| Overall Incidence | Total | 42/300 (14%) | Mean 14% | SD 5.93% | Total | 22/300 (7.33%) | Mean 7.33% | SD 3.72% | |
| | | | | | | | | | |
| *Heart: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | 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%) | 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: Aug2016
 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: 08/03/2016

| | | 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%) | 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: | | | | | | | | | |
| 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 Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 6/300 (2%) | Mean 2% | SD 1.79% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #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: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 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 | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Ileum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| 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 Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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 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 | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|--------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 2/50 (4%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 7/300 (2.33%) | Mean 2.33% | SD 1.97% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 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%) | 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 Small: Site Unspecified: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 1/50 (2%) | 2/50 (4%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 9/300 (3%) | Mean 3% | SD 2.1% | Total | 3/300 (1%) | Mean 1% | SD 1.1% | |
| | | | | | | | | | |
| #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%) | 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: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 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 | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|---------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 0/49 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/296 (1.01%) | Mean 1% | SD 1.67% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 0/49 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 0/49 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 2/50 (4%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 3/296 (1.01%) | Mean 1% | SD 1.67% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (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: Aug2016
 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 | | | |
|----------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Kidney: Renal Tubule: Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/299 (0%) | Mean 0% | SD 0% | Total | 2/299 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| *Liver: Cholangiocarcinoma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Liver: 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|---------------------------------------------------|-------|-----------------|-------------|-------------|-------|-----------------|-------------|-------------|--|
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 4/50 (8%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 4/300 (1.33%) | Mean 1.33% | SD 3.27% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.63% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | 2/50 (4%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 6/300 (2%) | Mean 2% | SD 1.79% | Total | 3/300 (1%) | Mean 1% | SD 1.1% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 30/50 (60%) | 17/50 (34%) | 28/50 (56%) | | 11/50 (22%) | 6/50 (12%) | 19/50 (38%) | |
| | | 24/50 (48%) | 23/50 (46%) | 25/50 (50%) | | 14/50 (28%) | 9/50 (18%) | 12/50 (24%) | |
| Overall Incidence | Total | 147/300 (49%) | Mean 49% | SD 9.01% | Total | 71/300 (23.67%) | Mean 23.67% | SD 8.89% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 15/50 (30%) | 17/50 (34%) | 25/50 (50%) | | 6/50 (12%) | 5/50 (10%) | 10/50 (20%) | |
| | | 11/50 (22%) | 21/50 (42%) | 8/50 (16%) | | 10/50 (20%) | 7/50 (14%) | 7/50 (14%) | |
| Overall Incidence | Total | 97/300 (32.33%) | Mean 32.33% | SD 12.55% | Total | 45/300 (15%) | Mean 15% | SD 4.15% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 16/50 (32%) | 18/50 (36%) | 27/50 (54%) | | 6/50 (12%) | 6/50 (12%) | 10/50 (20%) | |
| | | 11/50 (22%) | 21/50 (42%) | 9/50 (18%) | | 10/50 (20%) | 7/50 (14%) | 7/50 (14%) | |
| Overall Incidence | Total | 102/300 (34%) | Mean 34% | SD 13.21% | Total | 46/300 (15.33%) | Mean 15.33% | SD 3.72% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------------------------------------------------|-------|-----------------|-------------|-------------|-------|------------------|-------------|-------------|--|
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 39/50 (78%) | 31/50 (62%) | 38/50 (76%) | | 14/50 (28%) | 11/50 (22%) | 25/50 (50%) | |
| | | 32/50 (64%) | 34/50 (68%) | 30/50 (60%) | | 20/50 (40%) | 15/50 (30%) | 18/50 (36%) | |
| Overall Incidence | Total | 204/300 (68%) | Mean 68% | SD 7.48% | Total | 103/300 (34.33%) | Mean 34.33% | SD 9.91% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 39/50 (78%) | 32/50 (64%) | 39/50 (78%) | | 14/50 (28%) | 12/50 (24%) | 25/50 (50%) | |
| | | 32/50 (64%) | 34/50 (68%) | 31/50 (62%) | | 20/50 (40%) | 15/50 (30%) | 18/50 (36%) | |
| Overall Incidence | Total | 207/300 (69%) | Mean 69% | SD 7.24% | Total | 104/300 (34.67%) | Mean 34.67% | SD 9.44% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 3/50 (6%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 5/300 (1.67%) | Mean 1.67% | SD 2.34% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 10/50 (20%) | 5/50 (10%) | 7/50 (14%) | | 1/50 (2%) | 3/50 (6%) | 3/49 (6%) | |
| | | 5/50 (10%) | 6/50 (12%) | 11/50 (22%) | | 1/50 (2%) | 4/50 (8%) | 5/50 (10%) | |
| Overall Incidence | Total | 44/300 (14.67%) | Mean 14.67% | SD 5.16% | Total | 17/299 (5.69%) | Mean 5.69% | SD 3.21% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------|-------|-----------------|-------------|-------------|-------|-----------------|-------------|------------|--|
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 4/50 (8%) | 5/50 (10%) | 11/50 (22%) | | 2/50 (4%) | 3/50 (6%) | 5/49 (10%) | |
| | | 8/50 (16%) | 10/50 (20%) | 6/50 (12%) | | 4/50 (8%) | 5/50 (10%) | 0/50 (0%) | |
| Overall Incidence | Total | 44/300 (14.67%) | Mean 14.67% | SD 5.61% | Total | 19/299 (6.35%) | Mean 6.37% | SD 3.92% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 13/50 (26%) | 9/50 (18%) | 16/50 (32%) | | 3/50 (6%) | 6/50 (12%) | 8/49 (16%) | |
| | | 13/50 (26%) | 14/50 (28%) | 17/50 (34%) | | 4/50 (8%) | 9/50 (18%) | 5/50 (10%) | |
| Overall Incidence | Total | 82/300 (27.33%) | Mean 27.33% | SD 5.61% | Total | 35/299 (11.71%) | Mean 11.72% | SD 4.7% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|-----------|-----------|
| #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%) | 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 | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: 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%) | 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% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: 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%) | 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: 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%) | 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: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 2/50 (4%) | 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 | 4/300 (1.33%) | Mean 1.33% | SD 1.63% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Mammary Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 5/300 (1.67%) | Mean 1.67% | SD 1.51% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma 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%) | 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, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 5/300 (1.67%) | Mean 1.67% | SD 1.51% | |
| | | | | | | | | | |
| #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%) | 0/50 (0%) | | 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|---------------------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Polyp | | | | | | | | | |
| | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/298 (0.34%) | Mean 0.34% | SD 0.83% | 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%) | 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% | |
| | | | | | | | | | |
| #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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|---------------------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #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%) | 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% | |
| | | | | | | | | | |
| #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%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Cystadenocarcinoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/49 (0%) | 0/48 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 0/297 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Cystadenoma | | | | | | | | | |
| | | | | | | 1/50 (2%) | 0/49 (0%) | 1/48 (2%) | |
| | | | | | | 2/50 (4%) | 1/50 (2%) | 2/50 (4%) | |
| Overall Incidence | Total | | | | Total | 7/297 (2.36%) | Mean 2.35% | SD 1.5% | |
| | | | | | | | | | |
| *Ovary: | | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/49 (0%) | 0/48 (0%) | |
| | | | | | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 2/297 (0.67%) | Mean 0.67% | SD 1.03% | |

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

Version: Aug2016
 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: 08/03/2016

| | Male | Female |
|-----------------------------------------------------|----------------------------|--------------------------------------|
| *Ovary: | | |
| Granulosa Cell Tumor Malignant | | |
| | 1/50 (2%) | 0/49 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.33% SD 0.82% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 1/50 (2%) | 0/49 (0%) |
| | 1/50 (2%) | 1/50 (2%) |
| Overall Incidence | Total 3/297 (1.01%) | Mean 1% SD 1.1% |
| | | |
| *Ovary: | | |
| Granulosa-Theca Tumor Malignant | | |
| | 0/50 (0%) | 1/49 (2%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 2/297 (0.67%) | Mean 0.67% SD 1.04% |
| | | |
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 1/50 (2%) | 0/49 (0%) |
| | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total 1/297 (0.34%) | Mean 0.33% SD 0.82% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 0/50 (0%) | 0/49 (0%) |
| | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total 3/297 (1.01%) | Mean 1% SD 1.67% |

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

Version: Aug2016
 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: | | | | | | | |
| Sarcoma | | | | | | | |
| | | | 0/50 (0%) | | 0/49 (0%) | 0/48 (0%) | |
| | | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | | Total 0/297 (0%) | | Mean 0% | SD 0% | |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Tubulostromal Adenoma | | | | | | | |
| | | | 0/50 (0%) | | 0/49 (0%) | 0/48 (0%) | |
| | | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | | Total 0/297 (0%) | | Mean 0% | SD 0% | |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | |
| | | | 0/50 (0%) | | 0/49 (0%) | 1/48 (2%) | |
| | | | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | | | Total 1/297 (0.34%) | | Mean 0.35% | SD 0.85% | |
| | | | | | | | |
| *Parathyroid Gland: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/27 (0%) | 0/40 (0%) | 0/29 (0%) | 0/27 (0%) | 0/38 (0%) | 0/28 (0%) |
| | | 0/34 (0%) | 0/28 (0%) | 0/36 (0%) | 0/26 (0%) | 1/35 (3%) | 0/36 (0%) |
| Overall Incidence | Total | 0/194 (0%) | Mean 0% | SD 0% | Total | 1/190 (0.53%) | Mean 0.48% |
| | | | | | | | SD 1.17% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | 9/49 (18%) | 2/49 (4%) | 3/47 (6%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | 5/50 (10%) | 8/48 (17%) | 4/50 (8%) |
| Overall Incidence | Total | 1/296 (0.34%) | Mean 0.33% | SD 0.82% | Total | 31/293 (10.58%) | Mean 10.58% |
| | | | | | | | SD 5.74% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/47 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 3/48 (6%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 3/293 (1.02%) | Mean 1.04% | SD 2.55% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 9/49 (18%) | 2/49 (4%) | 3/47 (6%) | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 5/50 (10%) | 11/48 (23%) | 4/50 (8%) | |
| Overall Incidence | Total | 1/296 (0.34%) | Mean 0.33% | SD 0.82% | Total | 34/293 (11.6%) | Mean 11.62% | SD 7.39% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/47 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 0/293 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 0/49 (0%) | 1/49 (2%) | 0/47 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 1/293 (0.34%) | Mean 0.34% | SD 0.83% | |
| | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 0/49 (0%) | 1/49 (2%) | 0/47 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/296 (0%) | Mean 0% | SD 0% | Total | 1/293 (0.34%) | Mean 0.34% | SD 0.83% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/47 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/47 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 1/296 (0.34%) | Mean 0.33% | SD 0.82% | Total | 0/293 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 1/299 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Salivary Glands: | | | | | | | | | |
| Myxosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/300 (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%) | 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: | | | | | | | | | |
| 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%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.63% | |
| | | | | | | | | | |
| #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%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.63% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell 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%) | 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: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 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% | |
| | | | | | | | | | |
| #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%) | 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% | |
| | | | | | | | | | |
| #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%) | 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 | 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: Aug2016
 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: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 1/50 (2%) | 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 | 5/300 (1.67%) | Mean 1.67% | SD 1.97% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| 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: | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 1/50 (2%) | 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 | 5/300 (1.67%) | Mean 1.67% | SD 1.97% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| 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: | | | | | | | | | |
| 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: Aug2016
 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 | | | |
|---------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 2/50 (4%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 2/300 (0.67%) | Mean 0.67% | SD 1.63% | 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%) | 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: | | | | | | | | | |
| 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% | |
| | | | | | | | | | |
| #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: | | | | | | | | | |
| Neural Crest Tumor | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| 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: Aug2016
 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: | | | | | | | | | |
| 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%) | 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%) | 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: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) |
| Overall Incidence | Total | 0/300 (0%) | Mean 0% | SD 0% | Total | 3/300 (1%) | Mean 1% | SD 1.67% | |
| | | | | | | | | | |
| #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%) | 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%) | 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 | 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: Aug2016
 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 | | | | | | | | | |
| | | 0/50 (0%) | 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 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%) | 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, 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%) | 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% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 2/49 (4%) | 0/48 (0%) | 3/50 (6%) | | 0/50 (0%) | 0/50 (0%) | 2/49 (4%) | |
| | | 0/50 (0%) | 0/49 (0%) | 1/50 (2%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| Overall Incidence | Total | 6/296 (2.03%) | Mean 2.01% | SD 2.54% | Total | 4/299 (1.34%) | Mean 1.35% | SD 1.66% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|------------------------------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Spleen: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | |
| | | 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 | 1/299 (0.33%) | Mean 0.34% | SD 0.83% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| 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% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.1% | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.03% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | 3/300 (1%) | Mean 1% | SD 1.1% | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.03% | |
| | | | | | | | | | |
| #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%) | 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: Aug2016
 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, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) |
| Overall Incidence | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (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% | | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/41 (0%) | 0/43 (0%) | 0/42 (0%) | | 0/47 (0%) | 0/47 (0%) | 1/46 (2%) | |
| | | 0/41 (0%) | 0/44 (0%) | 0/48 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/259 (0%) | Mean 0% | SD 0% | Total | 1/282 (0.35%) | Mean 0.36% | SD 0.89% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/41 (0%) | 0/43 (0%) | 0/42 (0%) | | 0/47 (0%) | 0/47 (0%) | 0/46 (0%) | |
| | | 0/41 (0%) | 0/44 (0%) | 0/48 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/259 (0%) | Mean 0% | SD 0% | Total | 0/282 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma NOS | | | | | | | | | |
| | | 0/41 (0%) | 0/43 (0%) | 0/42 (0%) | | 1/47 (2%) | 0/47 (0%) | 0/46 (0%) | |
| | | 0/41 (0%) | 0/44 (0%) | 0/48 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/259 (0%) | Mean 0% | SD 0% | Total | 1/282 (0.35%) | Mean 0.35% | SD 0.87% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|-----------------------------------------|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/41 (0%) | 0/43 (0%) | 0/42 (0%) | | 1/47 (2%) | 0/47 (0%) | 0/46 (0%) | |
| | | 0/41 (0%) | 0/44 (0%) | 0/48 (0%) | | 0/44 (0%) | 0/48 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/259 (0%) | Mean 0% | SD 0% | Total | 1/282 (0.35%) | Mean 0.35% | SD 0.87% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 0/298 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/298 (0.34%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/298 (0%) | Mean 0% | SD 0% | Total | 1/298 (0.34%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (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 | 0/298 (0%) | Mean 0% | SD 0% | Total | 2/298 (0.67%) | Mean 0.67% | SD 1.03% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|---------------------------------------------------------------|-------|---------------|------------|-----------|-----------|---------------|------------|-----------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | 0/48 (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 | 0/298 (0%) | Mean 0% | SD 0% | Total | 2/298 (0.67%) | Mean 0.67% | SD 1.03% | |
| | | | | | | | | | |
| #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%) | 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% | |
| | | | | | | | | | |
| #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%) | 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% | |
| | | | | | | | | | |
| #Tooth: Odontoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 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% | |
| | | | | | | | | | |
| #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% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 100
 Report Date: 08/03/2016

| | | Male | | | | Female | | | |
|-----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/48 (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 | 1/297 (0.34%) | Mean 0.33% | SD 0.82% | Total | 0/299 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | | | | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 1/300 (0.33%) | Mean 0.33% | SD 0.82% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | | | | Total | 0/300 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Uterus: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | | | | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | | | | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | |
| Overall Incidence | Total | | | | Total | 4/300 (1.33%) | Mean 1.33% | SD 1.03% | |

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

Version: Aug2016
 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: 101
 Report Date: 08/03/2016

| | | Male | | | Female | | | |
|-----------------------------------------|-------|------------|---------------------|-----------|------------|------------|-----------|-------|
| #Uterus: | | | | | | | | |
| Leiomyoma | | | | | | | | |
| | | | 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% | |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Polyp Stromal | | | | | | | | |
| | | | 4/50 (8%) | | 0/50 (0%) | | 2/50 (4%) | |
| | | | 0/50 (0%) | | 1/50 (2%) | | 0/50 (0%) | |
| Overall Incidence | | | Total 7/300 (2.33%) | | Mean 2.33% | | SD 3.2% | |
| | | | | | | | | |
| #Uterus: | | | | | | | | |
| Sarcoma Stromal | | | | | | | | |
| | | | 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 | | | | | | | | |
| | | | 4/50 (8%) | | 0/50 (0%) | | 2/50 (4%) | |
| | | | 0/50 (0%) | | 1/50 (2%) | | 0/50 (0%) | |
| Overall Incidence | | | Total 7/300 (2.33%) | | Mean 2.33% | | SD 3.2% | |
| | | | | | | | | |
| #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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 102
 Report Date: 08/03/2016

| | | Male | | | | Female | | | | | | | | |
|-----------------------------|-------|------------|------|------|------|--------|------|-------|------------|------|------|----|----|----|
| #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%) | | | |
| 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: Aug2016
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: 103
Report Date: 08/03/2016

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 | 059601406 | 09/26/06 | 730 | 50(1) | 25(660) | 55.9 | Water disinfection byproducts (Bromodichloroacetic Acid) |
| Female | | | | | | | |
| 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: Aug2016
 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: 104
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-------------|-------------|----------------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 43/50 (86%) | | | 36/50 (72%) | | |
| Overall Incidence | Total | 43/50 (86%) | Mean 86% | SD 0% | Total | 36/50 (72%) | Mean 72% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 30/50 (60%) | | | 31/50 (62%) | | |
| Overall Incidence | Total | 30/50 (60%) | Mean 60% | SD 0% | Total | 31/50 (62%) | Mean 62% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 48/50 (96%) | | | 45/50 (90%) | | |
| Overall Incidence | Total | 48/50 (96%) | Mean 96% | SD 0% | Total | 45/50 (90%) | Mean 90% 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 | | | | | | | |
| | | 5/50 (10%) | | | 6/50 (12%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 6/50 (12%) | Mean 12% SD 0% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 5/50 (10%) | | | 6/50 (12%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 6/50 (12%) | Mean 12% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 105
 Report Date: 08/03/2016

| | 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 | | | | | | | | |
| | | 0/50 | (0%) | | | 6/50 | (12%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 6/50 | (12%) |
| | | | | | | | Mean 12% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: 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% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteoma | | | | | | | | |
| | | 0/50 | (0%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | Mean 2% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | |
| | | 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: Aug2016
 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: 106
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|----------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------------|
| *Adrenal Cortex: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 (4%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma 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% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma: Benign, Complex, 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% |
| | | | | | | | |
| #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% |
| | | | | | | | |
| #Blood Vessel: | | | | | | | |
| 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 Marrow: | | | | | | | |
| 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: Aug2016
 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: 107
 Report Date: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *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: | | | | | | | | | |
| 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: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 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: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 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: | | | | | | | | | |
| 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: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------------|
| *Brain: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Brain: | | | | | | | |
| Meningioma Malignant | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Brain: | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | 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% |
| | | | | | | | |
| #Eye: | | | | | | | |
| Melanoma 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: Aug2016
 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: 08/03/2016

| | Male | | | | Female | | | |
|---------------------------------|-------|------------|----------|-------|------------|------------|----------|-------|
| #Harderian Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 6/50 (12%) | | | 5/50 (10%) | | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 5/50 (10%) | Mean 10% | SD 0% |
| | | | | | | | | |
| #Harderian 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% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 6/50 (12%) | | | 5/50 (10%) | | | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total | 5/50 (10%) | Mean 10% | 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% |
| | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 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: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #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 Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | 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: Aug2016
 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 | | |
|---------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Intestine Small: Jejunum: 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: Jejunum: Carcinoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Intestine Small: Jejunum: 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: Site Unspecified: Adenoma | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | |
| | | 2/50 | (4%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | |
| | | 3/50 | (6%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 3/50 | (6%) | Mean 6% | 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: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Intestine Small: Site Unspecified: | | | | | | | |
| Leiomyosarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | |
| Polyp Adenomatous | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) |
| | | | | | | | |
| *Kidney: Pelvis and Transitional Epithelium: | | | | | | | |
| 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: Aug2016
 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: 113
 Report Date: 08/03/2016

| | | Male | | | Female | | |
|------------------------------------------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------------|
| *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Adenoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/50 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: Cholangiocarcinoma | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Liver: Hemangioma | | | | | | | |
| 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: Aug2016
 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: 08/03/2016

| | Male | | | | Female | | | |
|-----------------------------------------------------------|-------|-------------|----------|-------|-------------|----------------|-------------|-------|
| *Liver: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 2/49 (4%) | | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/49 (4.08%) | Mean 4.08% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatoblastoma | | | | | | | | |
| | | 4/50 (8%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | |
| | | 39/50 (78%) | | | 33/49 (67%) | | | |
| Overall Incidence | Total | 39/50 (78%) | Mean 78% | SD 0% | Total | 33/49 (67.35%) | Mean 67.35% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | |
| | | 12/50 (24%) | | | 9/49 (18%) | | | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total | 9/49 (18.37%) | Mean 18.37% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | |
| | | 15/50 (30%) | | | 9/49 (18%) | | | |
| Overall Incidence | Total | 15/50 (30%) | Mean 30% | SD 0% | Total | 9/49 (18.37%) | Mean 18.37% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | |
| | | 42/50 (84%) | | | 36/49 (73%) | | | |
| Overall Incidence | Total | 42/50 (84%) | Mean 84% | SD 0% | Total | 36/49 (73.47%) | Mean 73.47% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|----------------------------------------------------------------------------|-------|-------------|----------|-------|-------------|----------------|-------------|-------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 42/50 (84%) | | | 36/49 (73%) | | | |
| Overall Incidence | Total | 42/50 (84%) | Mean 84% | SD 0% | Total | 36/49 (73.47%) | Mean 73.47% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Liver: | | | | | | | | |
| 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% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 13/50 (26%) | | | 3/50 (6%) | | | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 3/50 (6%) | Mean 6% | SD 0% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | |
| | | 7/50 (14%) | | | 2/50 (4%) | | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 2/50 (4%) | Mean 4% | SD 0% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 19/50 (38%) | | | 5/50 (10%) | | | |
| Overall Incidence | Total | 19/50 (38%) | Mean 38% | SD 0% | Total | 5/50 (10%) | Mean 10% | SD 0% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|----------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *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% |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| 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, 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% |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | | |
| 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% |
| | | | | | | | | | |
| #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% |

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

Version: Aug2016
 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 | | | |
|-------------------------------------------------------------------------|-------|-----------|---------|-------|--------|-----------|---------|-------|
| #Mammary Gland: Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Carcinoma or Adenoma | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: Fibroma, Fibroadenoma or Adenoma | | | | | | | | |
| 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 | | | | | | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/50 (2%) | Mean 2% | SD 0% |
| | | | | | | | | |
| #Mesentery: Hemangioma | | | | | | | | |
| 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: Aug2016
 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 | | | |
|---------------------------------------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| #Mesentery: | | | | | | | | | |
| 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% |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Lipoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *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: | | | | | | | | | |
| Polyp | | | | | | | | | |
| | | 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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 | | | |
|---------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #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%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Cystadenocarcinoma | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Cystadenoma | | | | | | | | |
| | | | | | | 1/50 | (2%) | |
| Overall Incidence | | | | | | Total | 1/50 | (2%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Benign | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |
| *Ovary: | | | | | | | | |
| Granulosa Cell Tumor Malignant | | | | | | | | |
| | | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | | Total | 0/50 | (0%) |
| | | | | | | | | |

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

Version: Aug2016
 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 |
|-----------------------------------------------------|-------|------|------|------------------|
| *Ovary: | | | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Granulosa-Theca Tumor Malignant | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Hemangiosarcoma | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Luteoma | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Sarcoma | | | | |
| | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% SD 0% |
| | | | | |
| *Ovary: | | | | |
| Tubulostromal Adenoma | | | | |
| | | 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: Aug2016
 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: 08/03/2016

| Male | | | | | Female | | | |
|-------------------------------------------------------------|-------|-----------|---------|-------|--------------------|------------|-------|--|
| *Ovary: | | | | | | | | |
| Yolk Sac Carcinoma | | | | | | | | |
| | | | | | 0/50 (0%) | | | |
| Overall Incidence | | | | | Total 0/50 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | |
| *Parathyroid Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/44 (0%) | | | |
| Overall Incidence | Total | 0/44 (0%) | Mean 0% | SD 0% | Total 0/45 (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% | Total 2/49 (4.08%) | Mean 4.08% | SD 0% | |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 0/49 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | | | | 0/50 (0%) | | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 2/49 (4.08%) | Mean 4.08% | SD 0% | |
| | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | | | | 0/50 (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
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Version: Aug2016
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 Species: MICE
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ORAL
 Vehicle: WATER

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| | | Male | | | Female | | |
|-------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| 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% |
| | | | | | | | |
| *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% |
| | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | |
| Schwannoma 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: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 | (0%) | | 0/48 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 (0%) |
| | | | | | | | Mean 0% |
| | | | | | | | SD 0% |

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

Version: Aug2016
 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: 123
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| | | Male | | | | Female | | | |
|----------------------------------------|-------|------|------|---------|-------|--------|------|------|---------------|
| *Salivary Glands: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/48 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (0%) | Mean 0% SD 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Myxosarcoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/48 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/48 | (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%) | | | 1/50 | (2%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 1/50 | (2%) | Mean 2% 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
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Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Skeletal Muscle: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/50 | (0%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 (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%) |
| | | | | | | | |
| #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%) |
| | | | | | | | |
| #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%) |
| | | | | | | | |
| #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% | Total | 0/50 (0%) |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | |
| | | 1/50 | (2%) | | 4/50 | (8%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 4/50 (8%) |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | Male | | | | Female | | | |
|--------------------------------------------------------------------|-------|------|------|---------|--------|-------|------|------|
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 1/50 | (2%) | | | 4/50 | (8%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 4/50 | (8%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 1/50 | (2%) | | | 3/50 | (6%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 3/50 | (6%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | Total | 0/50 | (0%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/50 | (2%) |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 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: Aug2016
 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: 08/03/2016

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

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|-----------------------------------------------------------------------------------------------------------|-------|------|------|---------|--------|-------|-----------|
| #Skin: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 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: | | | | | | | |
| 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 | | | | | | | |
| | | 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 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% |
| | | | | | | | |
| #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% |

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

Version: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|------------------------------------------------------|-------|------|------|---------|--------|---------|-----------|
| *Spleen: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 2/50 | (4%) | | 0/49 | (0%) | |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | Total | 0/49 (0%) |
| | | | | | | Mean 0% | SD 0% |
| *Spleen: | | | | | | | |
| 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% |
| #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%) | | 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 Papilloma | | | | | | | |
| | | 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, 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% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
 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: 08/03/2016

| | | Male | | | | Female | | | |
|------------------------------------------|-------|------|------|---------|-------|--------|------|---------|-------|
| #Stomach, Glandular: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | | | | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | | | | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Neoplasm NOS | | | | | | | | | |
| | | 0/45 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/45 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma Benign | | | | | | | | | |
| | | 0/45 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/45 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma NOS | | | | | | | | | |
| | | 0/45 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/45 | (0%) | Mean 0% | SD 0% | 0/50 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/45 | (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/45 | (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: Aug2016
 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: 08/03/2016

| | | Male | | | Female | | |
|---------------------------------------------------------------|-------|-----------|---------|-------|-----------|-----------|---------------|
| *Thyroid Gland: C-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% |
| | | | | | | | |
| *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 | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 0/49 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/49 (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% |

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

Version: Aug2016
 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 | | |
|-----------------------------------|-------|------|------|---------|--------|-----------|-----------|
| #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 | | | | | | | |
| | | 1/50 | (2%) | | 0/50 | (0%) | |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | 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% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Adenoma | | | | | | | |
| | | | | | 0/50 | (0%) | |
| Overall Incidence | | | | | Total | 0/50 (0%) | Mean 0% |
| | | | | | | | SD 0% |
| | | | | | | | |
| #Uterus: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | | | | 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: Aug2016
 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: 08/03/2016

| | Male | | Female | |
|-----------------------------------------------------|------|-------|-----------|---------------|
| #Uterus: Hemangioma | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Uterus: Hemangiosarcoma | | | | |
| Overall Incidence | | Total | 1/50 (2%) | Mean 2% SD 0% |
| #Uterus: Leiomyoma | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Uterus: Polyp Stromal | | | | |
| Overall Incidence | | Total | 4/50 (8%) | Mean 8% SD 0% |
| #Uterus: Sarcoma Stromal | | | | |
| Overall Incidence | | Total | 0/50 (0%) | Mean 0% SD 0% |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | |
| Overall Incidence | | Total | 4/50 (8%) | Mean 8% SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2016
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: 08/03/2016

| | Male | | | | Female | | | |
|--------------------------|-------|------|------|---------|--------|-------|------|---------|
| #Zymbal's 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% |
| | | | | | | | | |
| #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