

Version: Mar2010
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: 03/22/2010

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 | 058810504 | 05/09/02 | 728 | 50(1) | 39(688) | 56.7 | Isoeugenol |
| Battelle Columbus Laboratory | 052000706 | 08/24/04 | 730 | 50(1) | 34(689) | 56.4 | Kava kava extract |
| Battelle Columbus Laboratory | 059902304 | 04/11/02 | 728 | 50(1) | 34(692) | 56.2 | beta-Myrcene |
| Battelle Columbus Laboratory | 059902006 | 04/15/03 | 730 | 50(1) | 38(691) | 56.6 | Pulegone |
| Battelle Columbus Laboratory | 058814807 | 02/04/03 | 728 | 50(1) | 35(702) | 52.7 | 3,3',4,4'-Tetrachloroazobenzene |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 058810504 | 05/08/02 | 727 | 49(5) | 34(679) | 65.0 | Isoeugenol |
| Battelle Columbus Laboratory | 052000706 | 08/23/04 | 729 | 50(5) | 38(695) | 66.2 | Kava kava extract |
| Battelle Columbus Laboratory | 059902304 | 04/10/02 | 727 | 50(5) | 39(705) | 64.1 | beta-Myrcene |
| Battelle Columbus Laboratory | 059902006 | 04/14/03 | 729 | 49(5) | 35(705) | 64.9 | Pulegone |
| Battelle Columbus Laboratory | 058814807 | 02/03/03 | 731 | 50(5) | 35(675) | 63.2 | 3,3',4,4'-Tetrachloroazobenzene |

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|-----------------|-------------|-------------|-------|------------------|-------------|-------------|--|
| #All Organs: | | | | | | | | | |
| Benign Tumors | | | | | | | | | |
| | | 33/50 (66%) | 34/50 (68%) | 33/50 (66%) | | 20/49 (41%) | 26/50 (52%) | 21/50 (42%) | |
| | | 30/50 (60%) | 30/50 (60%) | | | 27/49 (55%) | 24/50 (48%) | | |
| Overall Incidence | Total | 160/250 (64%) | Mean 64% | SD 3.74% | Total | 118/248 (47.58%) | Mean 47.58% | SD 6.19% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Tumors | | | | | | | | | |
| | | 20/50 (40%) | 32/50 (64%) | 30/50 (60%) | | 21/49 (43%) | 19/50 (38%) | 14/50 (28%) | |
| | | 19/50 (38%) | 28/50 (56%) | | | 20/49 (41%) | 13/50 (26%) | | |
| Overall Incidence | Total | 129/250 (51.6%) | Mean 51.6% | SD 11.87% | Total | 87/248 (35.08%) | Mean 35.13% | SD 7.66% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant and Benign Tumors | | | | | | | | | |
| | | 43/50 (86%) | 47/50 (94%) | 43/50 (86%) | | 34/49 (69%) | 39/50 (78%) | 30/50 (60%) | |
| | | 38/50 (76%) | 41/50 (82%) | | | 40/49 (82%) | 29/50 (58%) | | |
| Overall Incidence | Total | 212/250 (84.8%) | Mean 84.8% | SD 6.57% | Total | 172/248 (69.35%) | Mean 69.4% | SD 10.51% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 1/50 (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 4/248 (1.61%) | Mean 1.61% | SD 1.68% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 3/50 (6%) | 6/50 (12%) | 7/50 (14%) | | 1/49 (2%) | 1/50 (2%) | 1/50 (2%) | |
| | | 3/50 (6%) | 3/50 (6%) | | | 3/49 (6%) | 0/50 (0%) | | |
| Overall Incidence | Total | 22/250 (8.8%) | Mean 8.8% | SD 3.9% | Total | 6/248 (2.42%) | Mean 2.43% | SD 2.24% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|---------------|------------|------------|-------|----------------|-------------|------------|--|
| #All Organs: | | | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | | | |
| | | 3/50 (6%) | 8/50 (16%) | 7/50 (14%) | | 1/49 (2%) | 1/50 (2%) | 3/50 (6%) | |
| | | 3/50 (6%) | 3/50 (6%) | | | 4/49 (8%) | 1/50 (2%) | | |
| Overall Incidence | Total | 24/250 (9.6%) | Mean 9.6% | SD 4.98% | Total | 10/248 (4.03%) | Mean 4.04% | SD 2.88% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Histiocytic Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 3/50 (6%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 3/49 (6%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 7/248 (2.82%) | Mean 2.82% | SD 3.07% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 1/50 (2%) | | 11/49 (22%) | 6/50 (12%) | 7/50 (14%) | |
| | | 1/50 (2%) | 1/50 (2%) | | | 6/49 (12%) | 2/50 (4%) | | |
| Overall Incidence | Total | 5/250 (2%) | Mean 2% | SD 1.41% | Total | 32/248 (12.9%) | Mean 12.94% | SD 6.57% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #All Organs: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| #All Organs: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 2/50 (4%) | | 0/48 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 1/50 (2%) | 3/50 (6%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 9/250 (3.6%) | Mean 3.6% | SD 2.61% | Total | 2/246 (0.81%) | Mean 0.81% | SD 1.11% | |
| | | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 8
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/246 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Complex | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/246 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 1/49 (2%) | 1/49 (2%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 2/246 (0.81%) | Mean 0.82% | SD 1.12% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/247 (0%) | Mean 0% | SD 0% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 9
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|--------------|------------|-----------|--|
| *Bone Marrow: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 1/247 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Bone Marrow: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Bone: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 10
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|--------------|------------|-----------|--|
| #Bone: | | | | | | | | | |
| Osteosarcoma or Osteoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Meningioma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Brain: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 11
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Clitoral/Preputial Gland: Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/241 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/241 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/241 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/241 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Clitoral/Preputial Gland: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/241 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 12
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|-----------------------------------|-------|----------------|------------|------------|-------|-----------------|-------------|-----------|--|
| *Clitoral/Preputial Gland: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/47 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/241 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Esophagus: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Eye: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 8/50 (16%) | 5/50 (10%) | 9/50 (18%) | | 3/49 (6%) | 5/50 (10%) | 4/50 (8%) | |
| | | 6/50 (12%) | 6/50 (12%) | | | 7/49 (14%) | 14/50 (28%) | | |
| Overall Incidence | Total | 34/250 (13.6%) | Mean 13.6% | SD 3.29% | Total | 33/248 (13.31%) | Mean 13.28% | SD 8.77% | |
| | | | | | | | | | |
| #Harderian Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 4/50 (8%) | 0/50 (0%) | 1/50 (2%) | | 1/49 (2%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 6/250 (2.4%) | Mean 2.4% | SD 3.29% | Total | 2/248 (0.81%) | Mean 0.82% | SD 1.12% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 13
 Report Date: 03/22/2010

| | | Male | | | Female | | | |
|---------------------------------|-------|----------------|------------|------------|------------|-----------------|------------|----------|
| #Harderian Gland: | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | |
| | | 12/50 (24%) | 5/50 (10%) | 9/50 (18%) | 4/49 (8%) | 5/50 (10%) | 4/50 (8%) | |
| | | 7/50 (14%) | 6/50 (12%) | | 8/49 (16%) | 14/50 (28%) | | |
| Overall Incidence | Total | 39/250 (15.6%) | Mean 15.6% | SD 5.55% | Total | 35/248 (14.11%) | Mean 14.1% | SD 8.48% |
| | | | | | | | | |
| #Harderian Gland: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Heart: | | | | | | | | |
| Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Heart: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Intestine Large: Cecum: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Cecum: | | | | | | | | | |
| Leiomyoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Large: Colon/Rectum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Intestine Small: Duodenum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Duodenum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Ileum: | | | | | | | | | |
| Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 16
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|-----------|-----------|--|
| #Intestine Small: Jejunum: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Jejunum: | | | | | | | | | |
| Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/49 (0%) | 2/50 (4%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 2/248 (0.81%) | Mean 0.8% | SD 1.79% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|---------------|-----------|-----------|--|
| #Intestine Small: Site Unspecified: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 3/50 (6%) | 0/50 (0%) | | 0/49 (0%) | 2/50 (4%) | 1/50 (2%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 5/250 (2%) | Mean 2% | SD 2.83% | Total | 3/248 (1.21%) | Mean 1.2% | SD 1.79% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Leiomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Intestine Small: Site Unspecified: Polyp Adenomatous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 18
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|-------------------------------|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Islets, Pancreatic: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/245 (0.82%) | Mean 0.81% | SD 1.11% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/49 (0%) | 1/49 (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 1/245 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 2/50 (4%) | | | 0/49 (0%) | 2/49 (4%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 3/245 (1.22%) | Mean 1.22% | SD 1.82% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 1/245 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 19
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.1% | Total | 1/245 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 20
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|-------------------------------|-------|-----------------|-------------|-------------|-------|----------------|-------------|------------|--|
| *Liver: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 5/50 (10%) | 5/50 (10%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 12/250 (4.8%) | Mean 4.8% | SD 4.82% | Total | 1/247 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatoblastoma | | | | | | | | | |
| | | 3/50 (6%) | 0/50 (0%) | 4/50 (8%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 2/50 (4%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 10/250 (4%) | Mean 4% | SD 3.16% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 24/50 (48%) | 27/50 (54%) | 26/50 (52%) | | 11/49 (22%) | 8/50 (16%) | 6/50 (12%) | |
| | | 22/50 (44%) | 22/50 (44%) | | | 13/49 (27%) | 3/49 (6%) | | |
| Overall Incidence | Total | 121/250 (48.4%) | Mean 48.4% | SD 4.56% | Total | 41/247 (16.6%) | Mean 16.62% | SD 8.13% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 21
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|-----------------|-------------|-------------|-------|-----------------|-------------|------------|--|
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma | | | | | | | | | |
| | | 8/50 (16%) | 20/50 (40%) | 14/50 (28%) | | 3/49 (6%) | 3/50 (6%) | 1/50 (2%) | |
| | | 13/50 (26%) | 17/50 (34%) | | | 5/49 (10%) | 2/49 (4%) | | |
| Overall Incidence | Total | 72/250 (28.8%) | Mean 28.8% | SD 9.01% | Total | 14/247 (5.67%) | Mean 5.68% | SD 3.04% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatoblastoma | | | | | | | | | |
| | | 11/50 (22%) | 20/50 (40%) | 16/50 (32%) | | 3/49 (6%) | 3/50 (6%) | 1/50 (2%) | |
| | | 13/50 (26%) | 19/50 (38%) | | | 5/49 (10%) | 2/49 (4%) | | |
| Overall Incidence | Total | 79/250 (31.6%) | Mean 31.6% | SD 7.67% | Total | 14/247 (5.67%) | Mean 5.68% | SD 3.04% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 28/50 (56%) | 38/50 (76%) | 33/50 (66%) | | 13/49 (27%) | 10/50 (20%) | 7/50 (14%) | |
| | | 29/50 (58%) | 34/50 (68%) | | | 17/49 (35%) | 4/49 (8%) | | |
| Overall Incidence | Total | 162/250 (64.8%) | Mean 64.8% | SD 8.07% | Total | 51/247 (20.65%) | Mean 20.68% | SD 10.4% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | | |
| | | 30/50 (60%) | 38/50 (76%) | 34/50 (68%) | | 13/49 (27%) | 10/50 (20%) | 7/50 (14%) | |
| | | 29/50 (58%) | 34/50 (68%) | | | 17/49 (35%) | 4/49 (8%) | | |
| Overall Incidence | Total | 165/250 (66%) | Mean 66% | SD 7.21% | Total | 51/247 (20.65%) | Mean 20.68% | SD 10.4% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocholangiocarcinoma | | | | | | | | | |
| | | 2/50 (4%) | 4/50 (8%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 7/250 (2.8%) | Mean 2.8% | SD 3.35% | Total | 0/247 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 22
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| *Liver: | | | | | | | | | |
| Hepatocholangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Ito Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Ito Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.79% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/247 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 23
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|----------------|-------------|-------------|-------|----------------|------------|------------|--|
| *Lung: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 6/50 (12%) | 9/50 (18%) | 8/50 (16%) | | 4/48 (8%) | 2/50 (4%) | 4/50 (8%) | |
| | | 6/50 (12%) | 5/50 (10%) | | | 1/49 (2%) | 3/49 (6%) | | |
| Overall Incidence | Total | 34/250 (13.6%) | Mean 13.6% | SD 3.29% | Total | 14/246 (5.69%) | Mean 5.7% | SD 2.68% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma | | | | | | | | | |
| | | 2/50 (4%) | 2/50 (4%) | 5/50 (10%) | | 0/48 (0%) | 2/50 (4%) | 2/50 (4%) | |
| | | 3/50 (6%) | 3/50 (6%) | | | 2/49 (4%) | 0/49 (0%) | | |
| Overall Incidence | Total | 15/250 (6%) | Mean 6% | SD 2.45% | Total | 6/246 (2.44%) | Mean 2.42% | SD 2.21% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | | |
| | | 7/50 (14%) | 11/50 (22%) | 13/50 (26%) | | 4/48 (8%) | 4/50 (8%) | 6/50 (12%) | |
| | | 9/50 (18%) | 7/50 (14%) | | | 3/49 (6%) | 3/49 (6%) | | |
| Overall Incidence | Total | 47/250 (18.8%) | Mean 18.8% | SD 5.22% | Total | 20/246 (8.13%) | Mean 8.12% | SD 2.4% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 24
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Lung: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Lung: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 25
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Lymph Node: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Bronchial: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 26
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Lymph Node, Mandibular: Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mandibular: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 27
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|--------------|------------|-----------|--|
| #Lymph Node, Mesenteric: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Lymph Node, Mesenteric: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: Adenoacanthoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| #Mammary Gland: Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 28
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|--------------|------------|-----------|--|
| #Mammary Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroadenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mammary Gland: | | | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|----------------------------------|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Mesentery: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Mesentery: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Nose: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/247 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 30
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|----------------|------------|-----------|--|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Papilloma Squamous or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): | | | | | | | | | |
| Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| *Ovary: | | | | | | | | | |
| Choriocarcinoma | | | | | | | | | |
| | | | | | | 0/48 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | | | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | | | | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| *Ovary: | | | | | | | | | |
| Cystadenoma | | | | | | | | | |
| | | | | | | 3/48 (6%) | 5/49 (10%) | 2/50 (4%) | |
| | | | | | | 1/49 (2%) | 2/49 (4%) | | |
| Overall Incidence | Total | | | | Total | 13/245 (5.31%) | Mean 5.32% | SD 3.11% | |

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

Version: Mar2010
 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: 31
 Report Date: 03/22/2010

| | Male | Female |
|---|---------------------|---------------------|
| *Ovary: | | |
| Fibrous Histiocytoma | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/245 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor Benign | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 1/49 (2%) | 0/50 (0%) |
| Overall Incidence | Total 1/245 (0.41%) | Mean 0.41% SD 0.91% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor Malignant | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/245 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Granulosa Cell Tumor: Benign, Malignant, NOS | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 1/49 (2%) | 0/50 (0%) |
| Overall Incidence | Total 1/245 (0.41%) | Mean 0.41% SD 0.91% |
| | | |
| *Ovary: | | |
| Hemangioma | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 1/49 (2%) | 1/49 (2%) |
| Overall Incidence | Total 2/245 (0.82%) | Mean 0.82% SD 1.12% |

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

Version: Mar2010
 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: 32
 Report Date: 03/22/2010

| | Male | Female |
|------------------------------------|---------------------|---------------------|
| *Ovary: | | |
| Hemangiosarcoma | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 1/49 (2%) | 0/49 (0%) |
| Overall Incidence | Total 1/245 (0.41%) | Mean 0.41% SD 0.91% |
| | | |
| *Ovary: | | |
| Leiomyosarcoma | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total 0/245 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Luteoma | | |
| | 0/48 (0%) | 1/49 (2%) |
| | 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total 2/245 (0.82%) | Mean 0.81% SD 1.11% |
| | | |
| *Ovary: | | |
| Plasma Cell Tumor Malignant | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 0/49 (0%) | 0/49 (0%) |
| Overall Incidence | Total 0/245 (0%) | Mean 0% SD 0% |
| | | |
| *Ovary: | | |
| Teratoma Benign | | |
| | 0/48 (0%) | 0/49 (0%) |
| | 0/49 (0%) | 1/49 (2%) |
| Overall Incidence | Total 1/245 (0.41%) | Mean 0.41% SD 0.91% |

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

Version: Mar2010
 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: 33
 Report Date: 03/22/2010

| | | Male | | | Female | | |
|------------------------------|-------|------------|-----------|-----------|------------------|-----------|-----------|
| *Ovary: | | | | | | | |
| Teratoma Malignant | | | | | | | |
| | | | | | 0/48 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | | | | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total 0/245 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Ovary: | | | | | | | |
| Tubulostromal Adenoma | | | | | | | |
| | | | | | 0/48 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | | | | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | | | | | Total 0/245 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total 0/244 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total 0/244 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/47 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total 0/244 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|------------|-----------|-------|----------------|------------|-----------|--|
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | 4/47 (9%) | 2/50 (4%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/49 (0%) | | | 2/49 (4%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/247 (0%) | Mean 0% | SD 0% | Total | 10/245 (4.08%) | Mean 4.13% | SD 2.65% | |
| ----- | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/247 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| ----- | | | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/49 (0%) | | 4/47 (9%) | 2/50 (4%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/49 (0%) | | | 2/49 (4%) | 1/49 (2%) | | |
| Overall Incidence | Total | 0/247 (0%) | Mean 0% | SD 0% | Total | 10/245 (4.08%) | Mean 4.13% | SD 2.65% | |
| ----- | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/49 (2%) | 0/49 (0%) | | 0/47 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/247 (0.4%) | Mean 0.41% | SD 0.91% | Total | 1/245 (0.41%) | Mean 0.4% | SD 0.89% | |
| ----- | | | | | | | | | |
| *Pituitary Gland: Pars Intermedia: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 1/49 (2%) | 0/49 (0%) | | 0/47 (0%) | 1/50 (2%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/49 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/247 (0.4%) | Mean 0.41% | SD 0.91% | Total | 1/245 (0.41%) | Mean 0.4% | SD 0.89% | |

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 35
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|-----------------------------|-------|-------|------|---------|------|--------|-------|-------|------|
| *Prostate: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/250 | (0%) | Mean 0% | | SD 0% | | | |
| | | | | | | | | | |
| *Prostate: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/250 | (0%) | Mean 0% | | SD 0% | | | |
| | | | | | | | | | |
| *Prostate: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | | |
| | | 0/50 | (0%) | 0/50 | (0%) | | | | |
| Overall Incidence | Total | 0/250 | (0%) | Mean 0% | | SD 0% | | | |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) |
| Overall Incidence | Total | 0/250 | (0%) | Mean 0% | | SD 0% | Total | 0/246 | (0%) |
| | | | | | | | Mean | 0% | SD |
| | | | | | | | | | 0% |
| | | | | | | | | | |
| *Salivary Glands: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 | (0%) | 0/50 | (0%) | 0/50 | (0%) | 0/49 | (0%) |
| | | 0/50 | (0%) | 0/50 | (0%) | | | 0/49 | (0%) |
| Overall Incidence | Total | 0/250 | (0%) | Mean 0% | | SD 0% | Total | 0/246 | (0%) |
| | | | | | | | Mean | 0% | SD |
| | | | | | | | | | 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 36
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|----------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| *Salivary Glands: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Seminal Vesicle: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | | | | | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | | | | | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Myxosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 37
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|-----------|-----------|--|
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 3/50 (6%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/49 (0%) | 2/50 (4%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 5/248 (2.02%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Rhabdomyosarcoma or Rhabdomyoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 3/50 (6%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/49 (0%) | 2/50 (4%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 5/248 (2.02%) | Mean 2% | SD 2.83% | |
| | | | | | | | | | |
| #Skeletal Muscle: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 38
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|---------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #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%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/248 (0.81%) | Mean 0.8% | SD 1.1% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Basosquamous Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 39
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 3/49 (6%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 2/49 (4%) | 1/50 (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 8/248 (3.23%) | Mean 3.24% | SD 2.33% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 1/49 (2%) | 1/50 (2%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 3/248 (1.21%) | Mean 1.21% | SD 1.1% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 3/49 (6%) | 0/50 (0%) | 2/50 (4%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 2/49 (4%) | 1/50 (2%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 8/248 (3.23%) | Mean 3.24% | SD 2.33% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.41% | SD 0.91% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 40
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|-----------------------------------|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 1/50 (2%) | 1/50 (2%) | 1/50 (2%) | | 1/49 (2%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 4/250 (1.6%) | Mean 1.6% | SD 0.89% | Total | 2/248 (0.81%) | Mean 0.81% | SD 1.11% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Liposarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Mast Cell Tumor Benign | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 41
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Myxosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 2/49 (4%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/248 (1.21%) | Mean 1.22% | SD 1.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 2/49 (4%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/248 (1.21%) | Mean 1.22% | SD 1.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Osteosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 3/49 (6%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 4/248 (1.61%) | Mean 1.62% | SD 2.66% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 42
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|---------------|------------|-----------|--|
| #Skin: | | | | | | | | | |
| Schwannoma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 2/49 (4%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 3/248 (1.21%) | Mean 1.22% | SD 1.82% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (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%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |

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

Version: Mar2010
 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: 43
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|------------|-----------|-----------|-------|--------------|-----------|-----------|--|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 1/50 (2%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 1/248 (0.4%) | Mean 0.4% | SD 0.89% | |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Trichoepithelioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 44
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| #Skin: Sebaceous Gland: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Spinal Cord: | | | | | | | | | |
| Meningioma Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/244 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/244 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 2/50 (4%) | 1/49 (2%) | | 1/48 (2%) | 0/49 (0%) | 0/49 (0%) | |
| | | 2/50 (4%) | 2/50 (4%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 7/249 (2.81%) | Mean 2.81% | SD 1.78% | Total | 2/244 (0.82%) | Mean 0.82% | SD 1.13% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 45
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|---------------|------------|-----------|-------|---------------|------------|-----------|--|
| *Spleen: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 1/49 (2%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 1/244 (0.41%) | Mean 0.41% | SD 0.91% | |
| | | | | | | | | | |
| *Spleen: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) | | 0/48 (0%) | 0/49 (0%) | 0/49 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/244 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Mast Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 1/50 (2%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 9/50 (18%) | 0/50 (0%) | | 1/49 (2%) | 3/50 (6%) | 1/50 (2%) | |
| | | 1/50 (2%) | 1/50 (2%) | | | 2/49 (4%) | 2/50 (4%) | | |
| Overall Incidence | Total | 11/250 (4.4%) | Mean 4.4% | SD 7.67% | Total | 9/248 (3.63%) | Mean 3.62% | SD 1.67% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 46
 Report Date: 03/22/2010

| | | Male | | | Female | | |
|--------------------------------|-------|--------------|------------|-----------|-----------|---------------|---------------------|
| #Stomach, Forestomach: | | | | | | | |
| Squamous Cell Papilloma | | | | | | | |
| | | 0/50 (0%) | 8/50 (16%) | 0/50 (0%) | 1/49 (2%) | 3/50 (6%) | 1/50 (2%) |
| | | 0/50 (0%) | 1/50 (2%) | | 2/49 (4%) | 2/50 (4%) | |
| Overall Incidence | Total | 9/250 (3.6%) | Mean 3.6% | SD 6.99% | Total | 9/248 (3.63%) | Mean 3.62% SD 1.67% |
| | | | | | | | |
| #Stomach, Glandular: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | 1/50 (2%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/248 (0.81%) | Mean 0.81% SD 1.11% |
| | | | | | | | |
| #Stomach, Glandular: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) | 1/50 (2%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/248 (0.81%) | Mean 0.81% SD 1.11% |
| | | | | | | | |
| *Testes: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 (4%) | 1/50 (2%) | 0/50 (0%) | | | |
| | | 0/50 (0%) | 0/50 (0%) | | | | |
| Overall Incidence | Total | 3/250 (1.2%) | Mean 1.2% | SD 1.79% | | | |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 0/48 (0%) | 0/48 (0%) | 0/47 (0%) | 0/47 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/49 (0%) | 0/41 (0%) | | 0/48 (0%) | 1/48 (2%) | |
| Overall Incidence | Total | 0/233 (0%) | Mean 0% | SD 0% | Total | 1/242 (0.41%) | Mean 0.42% SD 0.93% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 47
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|---|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Thymus: | | | | | | | | | |
| Thymoma Malignant | | | | | | | | | |
| | | 0/48 (0%) | 0/48 (0%) | 0/47 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/49 (0%) | |
| | | 0/49 (0%) | 0/41 (0%) | | | 0/48 (0%) | 0/48 (0%) | | |
| Overall Incidence | Total | 0/233 (0%) | Mean 0% | SD 0% | Total | 0/242 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thymus: | | | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | | | |
| | | 0/48 (0%) | 0/48 (0%) | 0/47 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/49 (0%) | |
| | | 0/49 (0%) | 0/41 (0%) | | | 0/48 (0%) | 1/48 (2%) | | |
| Overall Incidence | Total | 0/233 (0%) | Mean 0% | SD 0% | Total | 1/242 (0.41%) | Mean 0.42% | SD 0.93% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/246 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/48 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 2/246 (0.81%) | Mean 0.81% | SD 1.11% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 48
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|---------------|------------|-----------|--|
| *Thyroid Gland: Follicular Cell: Carcinoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 0/48 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 1/49 (2%) | 2/49 (4%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 3/246 (1.22%) | Mean 1.22% | SD 1.83% | |
| | | | | | | | | | |
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 1/50 (2%) | | 0/48 (0%) | 0/50 (0%) | 1/50 (2%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 2/49 (4%) | 2/49 (4%) | | |
| Overall Incidence | Total | 2/250 (0.8%) | Mean 0.8% | SD 1.1% | Total | 5/246 (2.03%) | Mean 2.03% | SD 2.04% | |
| | | | | | | | | | |
| #Tissue NOS: Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tissue NOS: Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 49
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|--|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Tissue NOS: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Fibroma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| #Tongue: | | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 0/250 (0%) | Mean 0% | SD 0% | Total | 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

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

Page: 50
 Report Date: 03/22/2010

| | | Male | | | | Female | | | |
|------------------------------------|-------|--------------|-----------|-----------|-------|------------|-----------|-----------|--|
| #Tooth: | | | | | | | | | |
| Odontoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 1/50 (2%) | | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | Total | 1/250 (0.4%) | Mean 0.4% | SD 0.89% | Total | 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangioma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Hemangiosarcoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Plasma Cell Tumor Malignant | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |
| | | | | | | | | | |
| *Urinary Bladder: | | | | | | | | | |
| Sarcoma | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/47 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/50 (0%) | 0/50 (0%) | | | 0/49 (0%) | 0/49 (0%) | | |
| Overall Incidence | Total | 0/249 (0%) | Mean 0% | SD 0% | Total | 0/245 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
 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: 51
 Report Date: 03/22/2010

| | Male | Female |
|--------------------------|------------------|---------------|
| #Uterus: | | |
| Adenoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: | | |
| Carcinoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: | | |
| Hemangioma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: | | |
| Hemangiosarcoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: | | |
| Leiomyoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |

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

Version: Mar2010
 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: 52
 Report Date: 03/22/2010

| | Male | Female |
|---|---------------------|---------------------|
| #Uterus: Leiomyosarcoma | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |
| | | |
| #Uterus: Polyp Stromal | | |
| | 0/49 (0%) | 2/50 (4%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 2/248 (0.81%) | Mean 0.8% SD 1.79% |
| | | |
| #Uterus: Sarcoma Stromal | | |
| | 1/49 (2%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 1/248 (0.4%) | Mean 0.41% SD 0.91% |
| | | |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | |
| | 1/49 (2%) | 2/50 (4%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 3/248 (1.21%) | Mean 1.21% SD 1.79% |
| | | |
| #Uterus: Schwannoma Malignant | | |
| | 0/49 (0%) | 0/50 (0%) |
| | 0/49 (0%) | 0/50 (0%) |
| Overall Incidence | Total 0/248 (0%) | Mean 0% SD 0% |

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

Version: Mar2010
 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: 53
 Report Date: 03/22/2010

| | Male | | Female | | |
|--------------------------------|------|------------------|-----------|-----------|--|
| #Vagina: | | | | | |
| Liposarcoma | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | | Total 0/248 (0%) | Mean 0% | SD 0% | |
| | | | | | |
| #Vagina: | | | | | |
| Squamous Cell Papilloma | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | |
| | | 0/49 (0%) | 0/50 (0%) | | |
| Overall Incidence | | Total 0/248 (0%) | Mean 0% | SD 0% | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied