Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1 Report Date: 05/04/2011

Page: 4

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|-----------------|------------------------|----------------------------------|---|--|--|---------------------------------|
| | | | | | Male | | |
| Battelle Columbus Laboratory | 059903104 | 03/17/05 | 726 | 50(1) | 34(687) | 54.6 | Ginkgo biloba extract |
| Battelle Columbus Laboratory | 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 | 052010704 | 10/26/04 | 730 | 50(1) | 34(665) | 55.7 | N,N-Dimethyl-p-toluidine |
| 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 | 059903104 | 03/18/05 | 727 | 50(5) | 31(628) | 64.5 | Ginkgo biloba extract |
| 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 | 052010704 | 10/25/04 | 729 | 50(5) | 43(715) | 66.6 | N,N-Dimethyl-p-toluidine |
| 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 |

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 5

| | | | Male | | | | Female | |
|-------------------------------------|-------|---------------------------------|-------------|-------------|-------|---------------------------------|-------------|-------------|
| #All Organs: Benign Tumors | | | | | | | | |
| | | 38/50 (76%) | 33/50 (66%) | 34/50 (68%) | | 25/50 (50%) | 20/49 (41%) | 26/50 (52%) |
| | | 33/50 (66%) | 36/50 (72%) | 30/50 (60%) | | 21/50 (42%) | 24/50 (48%) | 27/49 (55%) |
| Overall Incidence | Total | 30/50 (60%) 234/350 (66.86%) | Mean 66.86% | SD 5.87% | Total | 24/50 (48%) 167/348 (47.99%) | Mean 47.99% | SD 5.13% |
| #All Organs: Malignant Tumors | | | | | | | ••••• | |
| | | 35/50 (70%) | 20/50 (40%) | 32/50 (64%) | | 28/50 (56%) | 21/49 (43%) | 19/50 (38%) |
| | | 30/50 (60%) | 29/50 (58%) | 19/50 (38%) | | 14/50 (28%) | 21/50 (42%) | 20/49 (41%) |
| | | 28/50 (56%) | | | | 13/50 (26%) | | |
| Overall Incidence | Total | 193/350 (55.14%) | Mean 55.14% | SD 11.94% | Total | 136/348 (39.08%) | Mean 39.1% | SD 10.06% |
| #All Organs: Malignant and Benign 1 | | | | | | | | |
| | | 44/50 (88%) | 43/50 (86%) | 47/50 (94%) | | 35/50 (70%) | 34/49 (69%) | 39/50 (78%) |
| | | 43/50 (86%) | 45/50 (90%) | 38/50 (76%) | | 30/50 (60%) | 35/50 (70%) | 40/49 (82%) |
| | | 41/50 (82%) | | | | 29/50 (58%) | | |
| Overall Incidence | Total | 301/350 (86%) | Mean 86% | SD 5.77% | Total | 242/348 (69.54%) | Mean 69.57% | SD 8.59% |
| #All Organs: Hemangioma | | | | | | | | |
| J | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 1/50 (2%) | 1/49 (2%) |
| | | 0/50 (0%) | ` ' | , , | | 1/50 (2%) | , , | , , |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 1.51% | Total | 5/348 (1.44%) | Mean 1.43% | SD 1.51% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/04/2011

Page: 6

| | | | Male | | | | Female | |
|---------------------------------------|------------------|--------------------------|-------------------------|------------|-------|-------------------------|-------------|------------|
| #All Organs: Hemangiosarcoma | | | | | | | | |
| | | 9/50 (18%) | 3/50 (6%) | 6/50 (12%) | | 2/50 (4%) | 1/49 (2%) | 1/50 (2%) |
| | | 7/50 (14%) 3/50 (6%) | 8/50 (16%) | 3/50 (6%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 3/49 (6%) |
| Overall Incidence | Total | 39/350 (11.14%) | Mean 11.14% | SD 5.15% | Total | 8/348 (2.3%) | Mean 2.31% | SD 2.17% |
| #All Organs: Hemangiosarcoma or H | | | | | | | | ••••• |
| | | 9/50 (18%) | 3/50 (6%) | 8/50 (16%) | | 2/50 (4%) | 1/49 (2%) | 1/50 (2%) |
| | | 7/50 (14%) 3/50 (6%) | 8/50 (16%) | 3/50 (6%) | | 3/50 (6%) 1/50 (2%) | 1/50 (2%) | 4/49 (8%) |
| Overall Incidence | Total | 41/350 (11.71%) | Mean 11.71% | SD 5.47% | Total | 13/348 (3.74%) | Mean 3.74% | SD 2.47% |
| #All Organs: Histiocytic Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (0%) | 3/50 (6%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) | 3/49 (6%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 8/348 (2.3%) | Mean 2.3% | SD 2.72% |
| #All Organs: Malignant Lymphoma: F | listiocytic, Lyn | nphocytic, Mixed, NOS, o | r Undifferentiated Cell | Туре | | | | ••••• |
| | | 1/50 (2%) | 0/50 (0%) | 2/50 (4%) | | 11/50 (22%) | 11/49 (22%) | 6/50 (12%) |
| | | 1/50 (2%) 1/50 (2%) | 4/50 (8%) | 1/50 (2%) | | 7/50 (14%) 2/50 (4%) | 15/50 (30%) | 6/49 (12%) |
| Overall Incidence | Total | 10/350 (2.86%) | Mean 2.86% | SD 2.54% | Total | 58/348 (16.67%) | Mean 16.67% | SD 8.65% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

.....

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #All Organs: Mesothelioma: Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/49 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0% #All Organs: Mesothelioma: Malignant 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) SD 0% Mean 0% **#All Organs:** Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0%

Page: 7

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 8

Report Date: 05/04/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Mean 0.29% SD 0.77% **Overall Incidence** Total 1/350 (0.29%) SD 0.76% Total 1/348 (0.29%) Mean 0.29% #All Organs: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/49 (2%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 1/350 (0.29%) Mean 0.29% SD 0.76% Total 1/348 (0.29%) Mean 0.29% SD 0.77% *Adrenal Cortex: Adenoma 0/50 0/50 1/50 (2%)3/50 (6%)(0%)0/50 (0%)0/48 (0%)(0%)2/50 (4%)3/50 (6%)1/50 (2%)1/50 (2%)0/50 (0%)1/49 (2%)3/50 (6%)0/49 (0%)**Overall Incidence** Total 13/350 (3.71%) SD 2.43% 2/346 (0.58%) Mean 0.58% SD 0.99% Mean 3.71% Total *Adrenal Cortex: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)

SD 0%

.....

0/49

0/346 (0%)

Total

(0%)

Mean 0%

SD 0%

Total

0/50

0/350 (0%)

(0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 9

| | | | Male | | | | Female | |
|--|-----------|---------------|------------|-------------|-------|---------------|------------|-----------|
| *Adrenal Medulla: Pheochromocytoma Be | enign | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 2/50 (4%) | 1/49 (2%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 3/346 (0.87%) | Mean 0.86% | SD 1.58% |
| *Adrenal Medulla: Pheochromocytoma Ma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/346 (0.29%) | Mean 0.29% | SD 0.77% |
| *Adrenal Medulla: Pheochromocytoma: B | | | | | | | | |
| | og, cop.o | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 2/50 (4%) | 1/49 (2%) |
| | | 0/50 (0%) | , | , | | 1/49 (2%) | , | , |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 4/346 (1.16%) | Mean 1.15% | SD 1.58% |
| *Bone Marrow: Hemangioma | ••••• | ••••• | | ••••• | | | | |
| J | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/48 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | () | · · · · · · | | 0/50 (0%) | ` ' | ` , |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/347 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 10

Report Date: 05/04/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** *Bone Marrow: Hemangiosarcoma 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)0/50 (0%)Mean 0.57% **Overall Incidence** Total 2/350 (0.57%) SD 1.51% Total 1/347 (0.29%) Mean 0.29% SD 0.77% *Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/347 (0%) Mean 0% SD 0% #Bone: Hemangiosarcoma 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% 0/348 (0%) SD 0% Total Mean 0% #Bone: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0%

.....

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

ups Report Date: 05/04/2011

Page: 11

| | | | Male | | | | Female | |
|----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|
| #Bone: Osteosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.77% |
| #Bone: Osteosarcoma or Osteom | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.77% |
| *Brain: Meningioma Benign | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Brain: Meningioma Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 1/50 (2%) | , , | , , | | 0/49 (0%) | , , | , |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/347 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 12

| | | | Male | | | | Female | |
|------------------------------------|-----------------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Brain: Meningioma: Benign, Ma | alignant, NOS | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Brain: Oligodendroglioma Mali | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Brain: Oligodendroglioma, Glio | oma, or Astrocy | /toma | | | | | | |
| | , | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Brain: Schwannoma Malignant | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 13

| | | | Male | | | | Female | |
|---|-------|------------|-----------|-----------|-------|---------------|------------|-----------|
| *Clitoral/Preputial Gland: Adenoma | | | | | | | | |
| | | 0/50 (0%) | 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%) | 0/50 (0%) | 0/47 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/341 (0%) | Mean 0% | SD 0% |
| *Clitoral/Preputial Gland: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 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%) | 0/50 (0%) | 0/47 (0%) |
| | | 0/50 (0%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/341 (0.29%) | Mean 0.29% | SD 0.77% |
| Clitoral/Preputial Gland: | | | | | | | | |
| | | 0/50 (0%) | 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%) | 0/50 (0%) | 0/47 (0%) |
| | | 0/50 (0%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/341 (0.29%) | Mean 0.29% | SD 0.77% |
| Clitoral/Preputial Gland: | | | | | | | | |
| - | | 0/50 (0%) | 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%) | 0/50 (0%) | 0/47 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/341 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 14

| | | | Male | | | | Female | |
|---|-------|---------------------------------------|---------------------------|--------------------------|-------|--|------------------------|--------------------------|
| *Clitoral/Preputial Gland: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/47 (0%) 0/50 (0%) | 0/49 (0%) 0/47 (0%) |
| Overall Incidence | Total | 0/50 (0%) 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/49 (0%) 0/341 (0%) | Mean 0% | SD 0% |
| #Esophagus: Squamous Cell Carcinoma | | ••••• | | | | ••••• | | |
| - | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Eye: Sarcoma | | | | | | ••••• | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Harderian Gland: Adenoma | | | | | | | | |
| | | 4/50 (8%) 9/50 (18%) 6/50 (12%) | 8/50 (16%) 11/50 (22%) | 5/50 (10%) 6/50 (12%) | | 5/50 (10%) 4/50 (8%) 14/50 (28%) | 3/49 (6%) 1/50 (2%) | 5/50 (10%) 7/49 (14%) |
| Overall Incidence | Total | 49/350 (14%) | Mean 14% | SD 4.9% | Total | 39/348 (11.21%) | Mean 11.2% | SD 8.32% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 15

| | | | Male | | | | Female | |
|---|-------|--------------------------|------------------------|------------------------|-------|--------------------------|------------------------|------------------------|
| #Harderian Gland: Carcinoma | | | | | | | | |
| | | 3/50 (6%) 1/50 (2%) | 4/50 (8%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | | 1/50 (2%) 0/50 (0%) | 1/49 (2%) 0/50 (0%) | 0/50 (0%) 1/49 (2%) |
| | | 0/50 (2%) | 0/50 (0%) | 1/30 (2%) | | 0/50 (0%) | 0/30 (0%) | 1/49 (2%) |
| Overall Incidence | Total | 9/350 (2.57%) | Mean 2.57% | SD 3.21% | Total | 3/348 (0.86%) | Mean 0.87% | SD 1.08% |
| #Harderian Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 7/50 (14%) | 12/50 (24%) | 5/50 (10%) | | 6/50 (12%) | 4/49 (8%) | 5/50 (10%) |
| | | 9/50 (18%) 6/50 (12%) | 11/50 (22%) | 7/50 (14%) | | 4/50 (8%) 14/50 (28%) | 1/50 (2%) | 8/49 (16%) |
| Overall Incidence | Total | 57/350 (16.29%) | Mean 16.29% | SD 5.22% | Total | 42/348 (12.07%) | Mean 12.07% | SD 8.26% |
| #Harderian Gland: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| Heart: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/347 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 16

| | | | Male | | | | Female | |
|--|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Intestine Large: Cecum: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Cecum: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Cecum: Carcinoma or Adenoma | | ••••• | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Large: Cecum: Leiomyoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 17

| | | | Male | | | | Female | |
|--|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Intestine Large: Colon/Rect Leiomyosarcoma | um: | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Duodenum: Adenoma | | ••••• | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 1/50 (2%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Intestine Small: Duodenum: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Duodenum: Leiomyosarcoma | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 18

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Intestine Small: Duodenum Polyp Adenomatous | : | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Ileum: Carcinoma | | | | | | | ••••• | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Ileum: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Ileum: Polyp Adenomatous | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 19

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Intestine Small: Jejunum: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 1/50 (2%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Intestine Small: Jejunum: Carcinoma | | | | ••••• | | | | |
| | | 1/50 (2%) 0/50 (0%) 2/50 (4%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.57% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Intestine Small: Jejunum: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Intestine Small: Jejunum: Leiomyosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 20

| | | | Male | | | | Female | |
|---|------------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Intestine Small: Site Uns | specified: | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 2/50 (4%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 2/50 (4%) 0/49 (0%) |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 1.51% | Total | 2/348 (0.57%) | Mean 0.57% | SD 1.51% |
| #Intestine Small: Site Uns Carcinoma | specified: | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) 2/50 (4%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.57% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Intestine Small: Site Uns | • | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) 2/50 (4%) | 0/50 (0%) 0/50 (0%) | 3/50 (6%) 0/50 (0%) | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 2/50 (4%) 0/49 (0%) |
| Overall Incidence | Total | 6/350 (1.71%) | Mean 1.71% | SD 2.43% | Total | 3/348 (0.86%) | Mean 0.86% | SD 1.57% |
| #Intestine Small: Site Uns Hemangiosarcoma | | | | | | | | |
| . . | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 21 Report Date: 05/04/2011

| | | | Male | | | | Female | |
|---|-----------|-------------------------|------------|-----------|-------|-------------------------|------------|-----------|
| #Intestine Small: Site Uns Leiomyosarcoma | pecified: | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |
| | | ` , | | | | | | |
| #Intestine Small: Site Uns Polyp Adenomatous | pecified: | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | 00.007 | | 0/50 (0%) | | 05 00/ |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| Islets, Pancreatic: Adenoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 1/50 (2%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total | 2/345 (0.58%) | Mean 0.58% | SD 0.99% |
| *Islets, Pancreatic: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 2/50 (4%) | | | | 1/49 (2%) | | |
| Overall Incidence | Total | 3/350 (0.86%) | Mean 0.86% | SD 1.57% | Total | 1/345 (0.29%) | Mean 0.29% | SD 0.77% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 22

| | | | Male | | | | Female | |
|--|-------|---------------|------------|-----------|-------|---------------|------------|-----------|
| *Islets, Pancreatic: Carcinoma or Adenoma | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 1/50 (2%) |
| | | 0/50 (0%) | 2/50 (4%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 2/50 (4%) | | | | 2/49 (4%) | | |
| Overall Incidence | Total | 5/350 (1.43%) | Mean 1.43% | SD 1.9% | Total | 3/345 (0.87%) | Mean 0.87% | SD 1.6% |
| *Kidney: Renal Tubule: Adenoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.07% | Total | 1/345 (0.29%) | Mean 0.29% | SD 0.77% |
| *Kidney: Renal Tubule: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 1/50 (2%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.07% | Total | 1/345 (0.29%) | Mean 0.29% | SD 0.77% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 23

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Kidney: Renal Tubule: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Plasma Cell Tumor Malig | nant | | | | | | | |
| _ | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Kidney: Renal Tubule: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

Page: 24

| | | | Male | | | | Female | |
|---------------------------------|-------|-------------------------|------------|------------|-------|------------------------|------------|-----------|
| *Liver: Fibrous Histiocytoma | | | | | | | | |
| • | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Liver: Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 1/50 (2%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/347 (0.29%) | Mean 0.29% | SD 0.76% |
| *Liver: Hemangiosarcoma | | | | | | | | |
| _ | | 9/50 (18%) | 1/50 (2%) | 5/50 (10%) | | 0/50 (0%) | 0/49 (0%) | 1/50 (2%) |
| | | 5/50 (10%) 1/50 (2%) | 6/50 (12%) | 0/50 (0%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 27/350 (7.71%) | Mean 7.71% | SD 6.58% | Total | 1/347 (0.29%) | Mean 0.29% | SD 0.76% |
| *Liver: Hepatoblastoma | | | | | | | | |
| • | | 3/50 (6%) | 3/50 (6%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) |
| | | 4/50 (8%) 2/50 (4%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) 0/49 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 14/350 (4%) | Mean 4% | SD 2.83% | Total | 1/347 (0.29%) | Mean 0.29% | SD 0.76% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 25

| | | | Male | | | | Female | |
|---------------------------------------|------------|---|----------------------------|----------------------------|-------|--|----------------------------|----------------------------|
| *Liver: Hepatocellular Adenoma | | | | | | | | |
| | | 31/50 (62%) 26/50 (52%) 22/50 (44%) | 24/50 (48%) 29/50 (58%) | 27/50 (54%) 22/50 (44%) | | 17/50 (34%) 6/50 (12%) 3/49 (6%) | 11/49 (22%) 17/50 (34%) | 8/50 (16%) 13/49 (27%) |
| Overall Incidence | Total | 181/350 (51.71%) | Mean 51.71% | SD 6.87% | Total | 75/347 (21.61%) | Mean 21.59% | SD 10.77% |
| *Liver: Hepatocellular Carcinoma | | | | | | | | |
| - | | 22/50 (44%) 14/50 (28%) 17/50 (34%) | 8/50 (16%) 22/50 (44%) | 20/50 (40%) 13/50 (26%) | | 9/50 (18%) 1/50 (2%) 2/49 (4%) | 3/49 (6%) 6/50 (12%) | 3/50 (6%) 5/49 (10%) |
| Overall Incidence | Total | 116/350 (33.14%) | Mean 33.14% | SD 10.45% | Total | 29/347 (8.36%) | Mean 8.34% | SD 5.46% |
| *Liver: Hepatocellular Carcinoma | or Hepatob | olastoma | | | | | | |
| ., | ., | 24/50 (48%) 16/50 (32%) 19/50 (38%) | 11/50 (22%) 22/50 (44%) | 20/50 (40%) 13/50 (26%) | | 10/50 (20%) 1/50 (2%) 2/49 (4%) | 3/49 (6%) 6/50 (12%) | 3/50 (6%) 5/49 (10%) |
| Overall Incidence | Total | 125/350 (35.71%) | Mean 35.71% | SD 9.48% | Total | 30/347 (8.65%) | Mean 8.63% | SD 6.07% |
| *Liver: Hepatocellular Carcinoma | | | | | | | | |
| · · · · · · · · · · · · · · · · · · · | | 39/50 (78%) 33/50 (66%) 34/50 (68%) | 28/50 (56%) 38/50 (76%) | 38/50 (76%) 29/50 (58%) | | 20/50 (40%) 7/50 (14%) 4/49 (8%) | 13/49 (27%) 20/50 (40%) | 10/50 (20%) 17/49 (35%) |
| Overall Incidence | Total | 239/350 (68.29%) | Mean 68.29% | SD 8.9% | Total | 91/347 (26.22%) | Mean 26.2% | SD 12.69% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Control Animal Groups Report Date: 05/04/2011
AGE

Page: 26

| | | | Male | | | Female | |
|------------------------------------|---------------|---|----------------------------|----------------------------|---|------------------------------------|----------------------------|
| *Liver: Hepatocellular Carcinom | a, Hepatocell | lular Adenoma, or Hepato | blastoma | | | | |
| • | | 39/50 (78%) 34/50 (68%) 34/50 (68%) | 30/50 (60%) 38/50 (76%) | 38/50 (76%) 29/50 (58%) | 20/50 (40 ^o 7/50 (14 ^o 4/49 (8 ^o | %) 20/50 (40%) | 10/50 (20%) 17/49 (35%) |
| Overall Incidence | Total | 242/350 (69.14%) | Mean 69.14% | SD 7.99% | Total 91/347 (26.22% | Mean 26.2% | SD 12.69% |
| *Liver: Hepatocholangiocarcino | ma | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 1/50 (2%) | 2/50 (4%) 0/50 (0%) | 4/50 (8%) 0/50 (0%) | 0/50 (0' 0/50 (0' 0/49 (0' | , , , | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 7/350 (2%) | Mean 2% | SD 3.06% | Total 0/347 (0%) | Mean 0% | SD 0% |
| *Liver: Hepatocholangioma | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | , | %) 0/49 (0%) %) 0/50 (0%) %) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total 0/347 (0%) | Mean 0% | SD 0% |
| *Liver: Ito Cell Tumor Benign | | | | | | | |
| v | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0' 0/50 (0' 0/49 (0' | , , , | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total 0/347 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 27

Report Date: 05/04/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

| | | | Male | | | | Female | |
|-------------------------------------|-------|--|---------------------------|--------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Liver: Ito Cell Tumor Malignant | t | | | | | | | |
| | | 0/50 (0%) 2/50 (4%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 1.51% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Liver: Plasma Cell Tumor Malig | | | | | | | | |
| • | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% |
| *Liver: Sarcoma | | | | | | | ••••• | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 1/50 (2%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/347 (0.29%) | Mean 0.29% | SD 0.76% |
| *Lung: Alveolar/Bronchiolar Ade | | | | | | | ••••• | |
| | | 8/50 (16%) 8/50 (16%) 5/50 (10%) | 6/50 (12%) 11/50 (22%) | 9/50 (18%) 6/50 (12%) | | 0/50 (0%) 4/50 (8%) 3/49 (6%) | 4/48 (8%) 2/50 (4%) | 2/50 (4%) 1/49 (2%) |
| Overall Incidence | Total | 53/350 (15.14%) | Mean 15.14% | SD 4.14% | Total | 16/346 (4.62%) | Mean 4.64% | SD 3.06% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 28

| | | | Male | | | | Female | | | | | |
|--|-------|--|---------------------------|---------------------------|-------|--------------------------------------|------------------------|------------------------|--|--|--|--|
| *Lung: Alveolar/Bronchiolar Carcinoma 11/50 (22%) 2/50 (4%) 2/50 (4%) 1/50 (2%) 0/48 (0%) 2/50 (4%) | | | | | | | | | | | | |
| | | 11/50 (22%) 5/50 (10%) 3/50 (6%) | 2/50 (4%) 2/50 (4%) | 2/50 (4%) 3/50 (6%) | | 1/50 (2%) 2/50 (4%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 2/50 (4%) 2/49 (4%) | | | | |
| Overall Incidence | Total | 28/350 (8%) | Mean 8% | SD 6.53% | Total | 7/346 (2.02%) | Mean 2.01% | SD 2.01% | | | | |
| *Lung: | | reolar/Bronchiolar Adenor | | ••••• | | | | | | | | |
| | | 17/50 (34%) 13/50 (26%) 7/50 (14%) | 7/50 (14%) 13/50 (26%) | 11/50 (22%) 9/50 (18%) | | 1/50 (2%) 6/50 (12%) 3/49 (6%) | 4/48 (8%) 2/50 (4%) | 4/50 (8%) 3/49 (6%) | | | | |
| Overall Incidence | Total | 77/350 (22%) | Mean 22% | SD 7.3% | Total | 23/346 (6.65%) | Mean 6.65% | SD 3.23% | | | | |
| *Lung: Fibrosarcoma | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/346 (0%) | Mean 0% | SD 0% | | | | |
| *Lung: Fibrous Histiocytoma | | | | | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) | Mean 0% | SD 0% | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 29

| | | | Male | | | | Female | |
|--------------------------------------|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Lung: Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total | 0/346 (0%) | Mean 0% | SD 0% |
| *Lung: Plasma Cell Tumor Malig | ynant | ••••• | | | | | ••••• | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/346 (0%) | Mean 0% | SD 0% |
| *Lung: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/346 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 30

| | | | Male | | | | Female | |
|--|--------|------------|-----------|-----------|-------|------------|-----------|-----------|
| #Lymph Node: Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Plasma Cell Tumor Mali | ignant | | | | | | | |
| | _ | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female #Lymph Node, Bronchial:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0% **#Lymph Node, Mandibular: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/49 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0% #Lymph Node, Mandibular: Hemangiosarcoma 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) SD 0% Mean 0% #Lymph Node, Mandibular: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0%

Page: 31

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 32

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Lymph Node, Mandibular: Plasma Cell Tumor Maligna | ant | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node, Mesenteric: Fibrous Histiocytoma | | | | ••••• | | | | |
| · | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node, Mesenteric: Hemangioma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Lymph Node, Mesenteric: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 33

Report Date: 05/04/2011

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Lymph Node, Mesenterio Plasma Cell Tumor Mali | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Adenoacanthoma | | | | | | | | ••••• |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 1/49 (2%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.77% |
| #Mammary Gland: Adenoma | | | | | | | | ••••• |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Carcinoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 1/50 (2%) | 0/50 (0%) 1/49 (2%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.58% | SD 0.99% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 34 Report Date: 05/04/2011

| | | | Male | | | | Female | |
|--|-------|------------|-----------|-----------|-------|---------------|------------|-----------|
| #Mammary Gland: Carcinoma or Adenoma | 1 | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 1/49 (2%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.58% | SD 0.99% |
| #Mammary Gland: Fibroadenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Fibroma, Fibroadenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mammary Gland: Fibroma, Fibroadenoma | | | | | | | | |
| • | , | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 1/49 (2%) |
| | | | | | | | (/ | (/ |
| | | 0/50 (0%) | ` , | | | 0/50 (0%) | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

Page: 35

| | | | Male | | | | | Female | |
|--------------------------------|-------|------------|-----------|-------|------|-------|---------------|------------|-----------|
| #Mesentery: Fibrosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mesentery: Hemangioma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Mesentery: Hemangiosarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Mesentery: Sarcoma | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | , , | | | | 0/50 (0%) | , , | , , |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 36

| | | | Male | | | Female | | | | | |
|---|------------------|---|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|--|--|--|
| *Nose: Hemangiosarcoma | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/349 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% | | | |
| *Nose: Mast Cell Tumor Malig | nant | | ••••• | | | | | | | | |
| _ | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/48 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/349 (0%) | Mean 0% | SD 0% | Total | 0/347 (0%) | Mean 0% | SD 0% | | | |
| #Oral Cavity (Oral Mucos Squamous Cell Carcine | sa, Tongue, Phar | | | | | | | | | | |
| | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |
| #Oral Cavity (Oral Mucos | sa, Tongue, Phar | ynx, Tooth, Gingiva): Squamous, or Papilloma | | | | | | | | | |
| | , , | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 37

| | | | Mal | е | | | | Female | |
|--|-------|------------------------|----------|---------|------|-------|------------------------|------------|------------|
| #Oral Mucosa: Squamous Cell Carcinoma | 1 | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0 | , | (0%) | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (09 | %) 0/50 | (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| *Ovary: Choriocarcinoma | | | | ••••• | | | | | |
| | | | | | | | 1/50 (2%) | 0/48 (0%) | 0/49 (0%) |
| | | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | | | | | 0/49 (0%) | | |
| Overall Incidence | | | | | | Total | 1/345 (0.29%) | Mean 0.29% | SD 0.76% |
| *Ovary: Cystadenocarcinoma | | | | | | | | | |
| | | | | | | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) |
| | | | | | | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | | | | | | 0/49 (0%) | | |
| Overall Incidence | | | | | | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Ovary: Cystadenoma | | | | | | | | | |
| - | | | | | | | 2/50 (4%) | 3/48 (6%) | 5/49 (10%) |
| | | | | | | | 2/50 (4%) | 1/50 (2%) | 1/49 (2%) |
| | | | | | | | 2/49 (4%) | | |
| Overall Incidence | | | | | | Total | 16/345 (4.64%) | Mean 4.65% | SD 2.84% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 38

Report Date: 05/04/2011

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Fibrous Histiocytoma** 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/49 (0%)Mean 0% **Overall Incidence** Total 0/345 (0%) SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/48 (0%)0/49 (0%)(0%)0/50 0/50 (0%)(2%)0/49 (0%)**Overall Incidence** Total 1/345 (0.29%) Mean 0.29% SD 0.77% **Granulosa Cell Tumor Malignant** 0/50 0/49 (0%)0/48 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/49 **Overall Incidence** Total 0/345 (0%) Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/48 0/49 (0%)(0%)0/50 (0%)0/50 (0%)1/49 (2%)0/49 (0%)**Overall Incidence** 1/345 (0.29%) Total Mean 0.29% SD 0.77%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 39

Report Date: 05/04/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Hemangioma 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(2%)1/49 (2%)**Overall Incidence** Total 2/345 (0.58%) Mean 0.58% SD 1% *Ovary: Hemangiosarcoma 1/50 (2%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/49 (2%)(0%)0/49 **Overall Incidence** Total 2/345 (0.58%) Mean 0.58% SD 0.99% *Ovary: Luteoma 0/50 0/48 (2%)(0%)(0%)1/49 1/50 (2%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** 2/345 (0.58%) Mean 0.58% SD 0.99% Total *Ovary: **Plasma Cell Tumor Malignant** 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/345 (0%) Mean 0% SD 0%

.....

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Overall Incidence

Overall Incidence

*Pancreas: Adenoma

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 40

Mean 0.29%

Mean 0%

(0%)

(0%)

0/47

0/50

SD 0.76%

SD 0%

(0%)

(0%)

0/49

0/49

Report Date: 05/04/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Teratoma Benign 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)1/49 (2%)**Overall Incidence** Total 1/345 (0.29%) Mean 0.29% SD 0.77% *Ovary: **Teratoma Malignant** 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/345 (0%) Mean 0% SD 0% **Tubulostromal Adenoma** 0/50 0/49 (0%)0/48 (0%)(0%)0/50 (0%)1/50 (2%)0/49 (0%)0/49 (0%)

0/50

0/50

SD 0%

(0%)

(0%)

1/345 (0.29%)

0/50

0/50

0/49

0/344 (0%)

(0%)

(0%)

(0%)

Total

Total

Total

0/50

0/50

0/50

0/350 (0%)

(0%)

(0%)

(0%)

0/50

0/50

Mean 0%

.....

(0%)

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 41

Report Date: 05/04/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/344 (0%) Mean 0% SD 0% *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/49 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)(0%)0/50 0/49 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/344 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 0/49 2/50 (0%)0/50 (0%)(0%)4/50 (8%)4/47 (9%)(4%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/48 (0%)2/49 (4%)0/49 (0%)(2%)1/49 **Overall Incidence** Total 0/346 (0%) Mean 0% SD 0% Total 14/343 (4.08%) Mean 4.09% SD 3.17% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/47 0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/346 (0%) Mean 0% SD 0% Total 0/343 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 42

| | | | Male | | | | Female | | | | |
|---|-----------|------------------------|-------------|-----------|-------|----------------|------------|-----------|--|--|--|
| *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma | | | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/49 (0%) | | 4/50 (8%) | 4/47 (9%) | 2/50 (4%) | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/48 (0%) | 2/49 (4%) | | | |
| | | 0/49 (0%) | | | | 1/49 (2%) | | | | | |
| Overall Incidence | Total | 0/346 (0%) | Mean 0% | SD 0% | Total | 14/343 (4.08%) | Mean 4.09% | SD 3.17% | | | |
| Pituitary Gland: Pars Int Adenoma | | | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 1/49 (2%) | | 1/50 (2%) | 0/47 (0%) | 1/50 (2%) | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) | | | |
| | | 0/49 (0%) | | | | 0/49 (0%) | | | | | |
| Overall Incidence | Total | 1/346 (0.29%) | Mean 0.29% | SD 0.77% | Total | 2/343 (0.58%) | Mean 0.57% | SD 0.98% | | | |
| Pituitary Gland: Pars Int Carcinoma or Adenom | termedia: | | | | | | | | | | |
| | | 0/49 (0%) | 0/50 (0%) | 1/49 (2%) | | 1/50 (2%) | 0/47 (0%) | 1/50 (2%) | | | |
| | | 0/49 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) | | | |
| | | 0/49 (0%) | | | | 0/49 (0%) | | | | | |
| Overall Incidence | Total | 1/346 (0.29%) | Mean 0.29% | SD 0.77% | Total | 2/343 (0.58%) | Mean 0.57% | SD 0.98% | | | |
| *Prostate: Adenoma | | | | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | | | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | | | | | | |
| Sverail Illicidence | i Ulai | 0/330 (0/6) | IVICALI U/0 | 30 0% | | | | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 43

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Prostate: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | | | |
| *Prostate: Hemangioma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | | | |
| *Salivary Glands: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 1/50 (2%) | 0/49 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/346 (0.29%) | Mean 0.29% | SD 0.76% |
| *Salivary Glands: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 1/50 (2%) | 0/49 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/49 (0%) 1/346 (0.29%) | Mean 0.29% | SD 0.76% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 44

| | | | Male | | | | Female | |
|--|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Salivary Glands: Mast Cell Tumor Malignant | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/49 (0%) | 0/49 (0%) 0/50 (0%) | 0/49 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/346 (0%) | Mean 0% | SD 0% |
| #Seminal Vesicle: Adenoma | | | | | ••••• | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | | | | |
| #Skeletal Muscle: Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skeletal Muscle: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/50 (0%) 1/348 (0.29%) | Mean 0.29% | SD 0.76% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 45

| | | | Male | | | | Female | |
|--|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Skeletal Muscle: Myxosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skeletal Muscle: Rhabdomyosarcoma | | | | ••••• | | | | |
| · | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | | 0/50 (0%) 0/50 (0%) 2/50 (4%) | 0/49 (0%) 0/50 (0%) | 3/50 (6%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 5/348 (1.44%) | Mean 1.43% | SD 2.51% |
| #Skeletal Muscle: Rhabdomyosarcoma or | | | | ••••• | | | | |
| | - | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | | 0/50 (0%) 0/50 (0%) 2/50 (4%) | 0/49 (0%) 0/50 (0%) | 3/50 (6%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 5/348 (1.44%) | Mean 1.43% | SD 2.51% |
| #Skeletal Muscle: Sarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 46

| | | | Male | | | | Female | | | | |
|---|----------------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|--|--|--|
| #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign | | | | | | | | | | | |
| | · | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |
| #Skin: | | umor Benign, or Trichoer | | | | | | | | | |
| | 1 | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 1/50 (2%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |
| #Skin: Basal Cell Carcinoma | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |
| #Skin: Basal Cell Carcinoma | or Basosquamou | s Tumor (malignant or N | OS) | ••••• | | | | | | | |
| | · | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 47

| | | | ı | Vlale | | | | | | F | emale | | |
|--|------------------------------------|--|-----------------------------------|--------------|--------------|--------------|-------|----------------------|----------------------|--------------|--------------|--------------|--------------|
| #Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli | | oma, Basosquamous T | Tumor (benign, | malignan | t or | , | | | | | | | |
| , . | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 0/50 | (0%) (0%) | 0/50 0/50 | (0%) (0%) | | 1/50 1/50 0/50 | (2%) (2%) (0%) | 0/49 0/50 | (0%) (0%) | 0/50 0/49 | (0%) (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0 | | SD 0% | | Total | 2/348 (0. | 57%) | | 0.57% | SD 0. | 98% |
| #Skin: | | | | | | | | | | | | | |
| Basal or Sq. Cell Carcir Adenoma, Papilloma, S | noma, Carcinom iq Papilloma, Ke | a, Basosq. Tumor (M o ratoacanthoma, Tricho | or B), Basal Cell pepithelioma | Adenom | a, | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 0/50 | (0%) (0%) | 0/50 0/50 | (0%) (0%) | | 1/50 1/50 1/50 | (2%) (2%) (2%) | 0/49 1/50 | (0%) (2%) | 0/50 0/49 | (0%) (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0 | | SD 0% | | Total | 4/348 (1. | 15%) | | 1.14% | SD 1. | 07% |
| #Skin: Basosquamous Tumor | | | | | | | | | | | | | |
| · | - | 0/50 (0%) | 0/50 | (0%) | 0/50 | (0%) | | 0/50 | (0%) | 0/49 | (0%) | 0/50 | (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 | (0%) | 0/50 | (0%) | | 1/50 0/50 | (2%) (0%) | 0/50 | (0%) | 0/49 | (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0 | | SD 0% | | Total | 1/348 (0. | , | | 0.29% | SD 0. | |
| #Skin: Fibroma | | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 0/50 | (0%) (0%) | 0/50 0/50 | (0%) (0%) | | 0/50 1/50 0/50 | (0%) (2%) (0%) | 0/49 0/50 | (0%) (0%) | 0/50 0/49 | (0%) (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0 | 1% | SD 0% | | Total | 1/348 (0. | ` , | Mean | 0.29% | SD 0. | 76% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

| | | | Male | | | | Female | |
|--------------------------------|-----------------|---------------------------|---------------------|------------|--------|------------------------|-------------|------------|
| #Skin: | | | | , | | | | |
| Fibroma, Fibrosarcoma | a, Sarcoma, Myx | coma, Myxosarcoma, or F | ibrous Histiocytoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 3/50 (6%) | 3/49 (6%) | 0/50 (0%) |
| | | 1/50 (2%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) 1/50 (2%) | 2/50 (4%) | 2/49 (4%) |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total | 13/348 (3.74%) | Mean 3.74% | SD 2.16% |
| #Skin: Fibrosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 2/50 (4%) | 1/49 (2%) |
| | | 1/50 (2%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 5/348 (1.44%) | Mean 1.43% | SD 1.51% |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcom | na, Myxosarcom | a, or Fibrous Histiocytom | a | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 3/50 (6%) | 3/49 (6%) | 0/50 (0%) |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 2/50 (4%) | 2/50 (4%) | 2/49 (4%) |
| | | 1/50 (2%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total | 13/348 (3.74%) | Mean 3.74% | SD 2.16% |
| #Skin: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 1/49 (2%) |
| | | 0/50 (0%) | 0/00 (0/0) | 0/00 (0/0) | | 0/50 (0%) | 3/30 (0/0) | 1,40 (270) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.77% |
| Overall illelidelide | i Ulai | 0/330 (0/0) | IVICALI U/0 | 30 0/0 | i Otai | 1/340 (0.23/0) | MEAN 0.23/0 | GD 0.7770 |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/04/2011

| | | | Male | | | | Female | |
|-----------------------------------|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Skin: Granular Cell Tumor Bei | nian | | | | | | | |
| | 3 | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Hemangioma | ••••• | | | | | | | |
| _ | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Skin: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) | 1/50 (2%) | 1/50 (2%) | | 0/50 (0%) | 1/49 (2%) | 0/50 (0%) |
| | | 1/50 (2%) 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.07% | Total | 2/348 (0.57%) | Mean 0.58% | SD 0.99% |
| #Skin: Keratoacanthoma | ••••• | | | | | | | ••••• |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 1/50 (2%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 50

| | | Male | | | | Female | |
|-------|-------------------------------------|--|---|---|---|--|--|
| | | | | | | | |
| | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| | | ••••• | | | ••••• | | |
| | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| | | | | | ••••• | | |
| | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |
| | Total t | 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/350 (0.29%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/350 (0.29%) Mean 0.29% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% t 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0.29% SD 0.76% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 | 0/50 (0%) 0/50 | 0/50 (0%) 0/50 |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

VAGE DRN OII

Page: 51

| | | | Male | | | | Female | |
|----------------------------------|-------|---------------|------------|-----------|-------|---------------|------------|-----------|
| #Skin: Melanoma Malignant | | | | | | | | |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Skin: Myxosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Neural Crest Tumor | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Neurofibroma or Schwan | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | ` ' | ` ' | | 0/50 (0%) | ` ' | , , |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

| | | | Male | | | | Female | |
|------------------------|-----------------|------------------------|------------------|-----------|--------|----------------|---------------|------------|
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or | Schwannoma (n | nalignant or NOS) | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 2/49 (4%) |
| | | 0/50 (0%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 3/348 (0.86%) | Mean 0.87% | SD 1.6% |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, N | eurofibroma, or | Schwannoma (benign, ma | alignant or NOS) | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 2/49 (4%) |
| | | 0/50 (0%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 3/348 (0.86%) | Mean 0.87% | SD 1.6% |
| #Skin: Osteosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 3/50 (6%) | 3/49 (6%) | 0/50 (0%) |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 1/50 (2%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | 3,33 (3,70) | (0.00) | | 0/50 (0%) | 5,00 (0,0) | ·· (0 / 0) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 7/348 (2.01%) | Mean 2.02% | SD 2.86% |
| Jacian includence | I Olai | 1/330 (0.2970) | WIGGIT 0.2370 | GD 0.7078 | i Otai | 77546 (2.0176) | WICAII 2.02/0 | GD 2.00% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

0/50

0/50

0/50

0/350 (0%)

(0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #Skin: Schwannoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/348 (0%) Mean 0% SD 0% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/49 (4%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 3/348 (0.86%) Mean 0.87% SD 1.6% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)Mean 0.29% Overall Incidence Total 0/350 (0%) Mean 0% SD 0% Total 1/348 (0.29%) SD 0.76% #Skin: **Squamous Cell Papilloma**

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

1/50

1/348 (0.29%)

Total

(0%)

(0%)

(2%)

0/49

0/50

(0%)

(0%)

Mean 0.29%

Total

Overall Incidence

Page: 53

Report Date: 05/04/2011

0/50

0/49

SD 0.76%

(0%)

(0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

| | | | Male | | | | Female | |
|----------------------------------|------------------|----------------------|-----------------------|---------------|-------|---------------|------------|-----------|
| #Skin: Squamous Cell Papillor | na or Papilloma | | | | | | | |
| | • | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 1/348 (0.29%) | Mean 0.29% | SD 0.76% |
| #Skin: | | | | | | ••••• | | |
| Squamous Cell Papillor | na, Papilloma, S | quamous Cell Carcino | ma or Keratoacanthoma | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.57% | SD 0.98% |
| #Skin: | | | | | | | | |
| Squamous Cell Papillor | na, Papilloma, o | r Keratoacanthoma | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 1/50 (2%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 1/50 (2%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.57% | SD 0.98% |
| #Skin: Trichoepithelioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | (-,0) | 2, 2 2 (2, 0) | | 0/50 (0%) | (-,-) | (-,-) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 55

Report Date: 05/04/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

| | | | Male | | | | Female | |
|---|-------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| #Skin: Sebaceous Gland: Adenoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Sebaceous Gland: Carcinoma | | | | | | | ••••• | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Skin: Sebaceous Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Spinal Cord: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/49 (0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |

......

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/04/2011

| | | | Male | | | | Female | |
|---------------------------------------|-------|----------------|-----------|-----------|-------|---------------|------------|-----------|
| #Spinal Cord: Meningioma Malignant | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| *Spleen: Fibrous Histiocytoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/347 (0%) | Mean 0% | SD 0% | Total | 0/343 (0%) | Mean 0% | SD 0% |
| *Spleen: Hemangioma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/48 (0%) | 0/49 (0%) |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | | 0/49 (0%) | 0/49 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/347 (0%) | Mean 0% | SD 0% | Total | 0/343 (0%) | Mean 0% | SD 0% |
| *Spleen: Hemangiosarcoma | | | | | | | | |
| - | | 0/50 (0%) | 0/50 (0%) | 2/50 (4%) | | 1/50 (2%) | 1/48 (2%) | 0/49 (0%) |
| | | 1/49 (2%) | 3/48 (6%) | 2/50 (4%) | | 0/49 (0%) | 0/49 (0%) | 1/49 (2%) |
| | | 2/50 (4%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 10/347 (2.88%) | Mean 2.9% | SD 2.32% | Total | 3/343 (0.87%) | Mean 0.87% | SD 1.09% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

control Animal Groups Report Date: 05/04/2011

| | | | Male | | | | Female | |
|--|-------|---------------|------------|-----------|---------------|------|------------|-----------|
| *Spleen: Mast Cell Tumor Malignar | nt | | | | | | | |
| · · | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | 0/48 (0%) | 1/49 (2%) |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | 0/49 | (0%) | 0/49 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/347 (0%) | Mean 0% | SD 0% | Total 1/343 (| | Mean 0.29% | SD 0.77% |
| *Spleen: Plasma Cell Tumor Maligr | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | 0/48 (0%) | 0/49 (0%) |
| | | 0/49 (0%) | 0/48 (0%) | 0/50 (0%) | 0/49 | (0%) | 0/49 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | 0/49 | (0%) | | |
| Overall Incidence | Total | 0/347 (0%) | Mean 0% | SD 0% | Total 0/343 | (0%) | Mean 0% | SD 0% |
| #Stomach, Forestomach: Mast Cell Tumor Malignar | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | 0/50 | (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total 0/348 | ` ' | Mean 0% | SD 0% |
| #Stomach, Forestomach: Squamous Cell Carcinom | | | | | | | | |
| • | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 | (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 1/50 (2%) | 0/50 | (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | 0/50 | (0%) | | |
| Overall Incidence | Total | 2/350 (0.57%) | Mean 0.57% | SD 0.98% | Total 0/348 | (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 58

| | | | Male | | | | Female | | | | | | |
|--|-------|-------------------------------------|------------------------|-------------------------|-------|-------------------------------------|------------------------|------------------------|--|--|--|--|--|
| #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 1/50 (2%) | 9/50 (18%) 1/50 (2%) | | 2/50 (4%) 1/50 (2%) | 1/49 (2%) 1/50 (2%) | 3/50 (6%) 2/49 (4%) | | | | | |
| Overall Incidence | Total | 1/50 (2%) 12/350 (3.43%) | Mean 3.43% | SD 6.5% | Total | 2/50 (4%) 12/348 (3.45%) | Mean 3.45% | SD 1.51% | | | | | |
| #Stomach, Forestomach: Squamous Cell Papilloma | | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 1/50 (2%) | 0/50 (0%) 1/50 (2%) | 8/50 (16%) 0/50 (0%) | | 2/50 (4%) 1/50 (2%) 2/50 (4%) | 1/49 (2%) 1/50 (2%) | 3/50 (6%) 2/49 (4%) | | | | | |
| Overall Incidence | Total | 10/350 (2.86%) | Mean 2.86% | SD 5.87% | Total | 12/348 (3.45%) | Mean 3.45% | SD 1.51% | | | | | |
| #Stomach, Glandular: Adenoma | | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 1/49 (2%) 0/50 (0%) | 1/50 (2%) 0/49 (0%) | | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.58% | SD 0.99% | | | | | |
| #Stomach, Glandular: Carcinoma or Adenoma | | | | | | | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 1/49 (2%) 0/50 (0%) | 1/50 (2%) 0/49 (0%) | | | | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 2/348 (0.57%) | Mean 0.58% | SD 0.99% | | | | | |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 59

| | | | Male | | | | Female | |
|-------------------------------------|----------|-------------------------------------|------------------------|------------------------|-------|-------------------------------------|------------------------|------------------------|
| *Testes: Adenoma | | | | | | | | |
| | | 1/50 (2%) 0/50 (0%) 0/50 (0%) | 2/50 (4%) 0/50 (0%) | 1/50 (2%) 0/50 (0%) | | | | |
| Overall Incidence | Total | 4/350 (1.14%) | Mean 1.14% | SD 1.57% | | | | |
| *Thymus: Thymoma Benign | | | | | ••••• | | | |
| | | 0/50 (0%) 0/47 (0%) 0/41 (0%) | 0/48 (0%) 0/48 (0%) | 0/48 (0%) 0/49 (0%) | | 0/50 (0%) 0/49 (0%) 1/48 (2%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/48 (0%) |
| Overall Incidence | Total | 0/331 (0%) | Mean 0% | SD 0% | Total | 1/342 (0.29%) | Mean 0.3% | SD 0.79% |
| *Thymus: Thymoma Malignant | | | | | | | | |
| | | 0/50 (0%) 0/47 (0%) 0/41 (0%) | 0/48 (0%) 0/48 (0%) | 0/48 (0%) 0/49 (0%) | | 0/50 (0%) 0/49 (0%) 0/48 (0%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/48 (0%) |
| Overall Incidence | Total | 0/331 (0%) | Mean 0% | SD 0% | Total | 0/342 (0%) | Mean 0% | SD 0% |
| *Thymus: Thymoma: Benign, Malign | ant, NOS | | | | ••••• | | | |
| | | 0/50 (0%) 0/47 (0%) 0/41 (0%) | 0/48 (0%) 0/48 (0%) | 0/48 (0%) 0/49 (0%) | | 0/50 (0%) 0/49 (0%) 1/48 (2%) | 0/47 (0%) 0/50 (0%) | 0/50 (0%) 0/48 (0%) |
| Overall Incidence | Total | 0/331 (0%) | Mean 0% | SD 0% | Total | 1/342 (0.29%) | Mean 0.3% | SD 0.79% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 60

Report Date: 05/04/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

0/49

0/50

1/50

1/349 (0.29%)

0/49

0/50

0/50

1/349 (0.29%)

(0%)

(0%)

(2%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

1/50

Mean 0.29%

Mean 0.29%

(0%)

(0%)

(0%)

(2%)

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** *Thyroid Gland: C-Cell: Carcinoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/349 (0.29%) Mean 0.29% SD 0.76% Total 0/345 (0%) Mean 0% SD 0%

0/50

0/50

SD 0.76%

0/50

0/50

SD 0.76%

.....

(0%)

(0%)

(0%)

(0%)

0/49

0/50

0/49

0/49

1/50

0/49

2/345 (0.58%)

0/345 (0%)

Total

Total

(0%)

(0%)

(0%)

(0%)

(2%)

(0%)

0/48

0/50

0/48

0/50

(0%)

(0%)

(0%)

(0%)

Mean 0%

Mean 0.58%

0/50

0/49

0/50

1/49

SD 0%

SD 0.99%

(0%)

(0%)

(0%)

(2%)

| *Thyroid | Gland: | Follicular | Cell: |
|----------|--------|------------|-------|
| Adana | ma | | |

*Thyroid Gland: C-Cell: Carcinoma or Adenoma

| Au | IIIa | |
|----|------|--|
| | | |
| | | |
| | | |

Overall Incidence

Overall Incidence

| *Thyroid Gland: Follicular Carcinoma | Cell: | | | | | | | | | | | | |
|---|-------|---------------|--------|-------|----------|------|-------|-----------|------|------|-------|-------|------|
| | | 0/49 (0%) | 1/50 | (2%) | 0/50 | (0%) | | 0/49 | (0%) | 0/48 | (0%) | 0/50 | (0%) |
| | | 1/50 (2%) | 0/50 | (0%) | 0/50 | (0%) | | 0/50 | (0%) | 0/50 | (0%) | 1/49 | (2%) |
| | | 0/50 (0%) | 1 | | | | | 2/49 | (4%) | | | | |
| Overall Incidence | Total | 2/349 (0.57%) | Mean (| 0.57% | SD 0.989 | % | Total | 3/345 (0. | 87%) | Mean | 0.87% | SD 1. | 61% |

.....

Total

Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 61

| | | | Male | | | Female | |
|--|-------|-------------------------------------|------------------------|------------------------|--------------------|---------------------------------------|------------------------|
| *Thyroid Gland: Follicular Cel Carcinoma or Adenoma | II: | | | | | | |
| | | 0/49 (0%) 1/50 (2%) 0/50 (0%) | 1/50 (2%) 1/50 (2%) | 0/50 (0%) 0/50 (0%) | 1/50 (2 | 9%) 0/48 (0%) 9%) 0/50 (0%) 9%) | 0/50 (0%) 2/49 (4%) |
| Overall Incidence | Total | 3/349 (0.86%) | Mean 0.86% | SD 1.07% | Total 5/345 (1.45% | Mean 1.45% | SD 1.94% |
| #Tissue NOS: Fibrosarcoma | | •••••• | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0 | 0%) 0/49 (0%) 0%) 0/50 (0%) 0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total 0/348 (0%) | Mean 0% | SD 0% |
| #Tissue NOS: Hemangiosarcoma | | | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0 | 9%) 0/49 (0%) 9%) 0/50 (0%) 9%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total 0/348 (0%) | Mean 0% | SD 0% |
| #Tissue NOS: Plasma Cell Tumor Maligna | | •••••• | | | | | |
| | | 0/50 (0%) 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0%) 0/50 (0%) | 0/50 (0 | 0%) 0/49 (0%) 0%) 0/50 (0%) | 0/50 (0%) 0/49 (0%) |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 62

| | | | Male | | | | Female | |
|-----------------------------------|-------|-------------------------|------------|-----------|-------|-------------------------|-----------|-----------|
| #Tissue NOS: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 0/50 (0%) 0/350 (0%) | Mean 0% | SD 0% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |
| #Tongue: Fibroma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 0/350 (0%) | Mean 0% | SD 0% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Tongue: Squamous Cell Carcino | | | | | | | | |
| - | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Tongue: Squamous Cell Carcino | | | | | | | | |
| | • | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 1/50 (2%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/50 (0%) | | |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 63

| | | | Male | | | | Female | |
|---|-------|----------------------------|------------|-----------|-------|-------------------------|-----------|-----------|
| #Tooth: Odontoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 5/50 (10%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| Overall Incidence | Total | 1/50 (2%) 6/350 (1.71%) | Mean 1.71% | SD 3.73% | Total | 0/50 (0%) 0/348 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Urinary Bladder: Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/349 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Urinary Bladder: Plasma Cell Tumor Mali | | | | | | | | |
| | _ | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/349 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |
| *Urinary Bladder: Sarcoma | | | | | | | | |
| | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/47 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | | | | 0/49 (0%) | | |
| Overall Incidence | Total | 0/349 (0%) | Mean 0% | SD 0% | Total | 0/345 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 64

Report Date: 05/04/2011

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female #Uterus:** Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% #Uterus: Hemangiosarcoma 0/50 0/49 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% **#Uterus:** Leiomyoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 65

Report Date: 05/04/2011

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female #Uterus:** Leiomyosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/348 (0%) SD 0% #Uterus: **Polyp Stromal** 1/50 (2%)0/49 (0%)2/50 (4%)0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 3/348 (0.86%) Mean 0.86% SD 1.57% #Uterus: Sarcoma 0/50 0/49 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% **#Uterus:** Sarcoma Stromal 1/50 (2%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 2/348 (0.57%) Mean 0.58% SD 0.99%

.....

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 66

Report Date: 05/04/2011

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Sarcoma Stromal or Polyp Stromal 2/50 (4%)1/49 (2%)2/50 (4%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)**Overall Incidence** 5/348 (1.44%) Mean 1.43% Total SD 1.9% #Uterus: **Schwannoma Malignant** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% #Vagina: Liposarcoma 0/50 0/49 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% #Vagina: **Squamous Cell Papilloma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/348 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 67 Report Date: 05/04/2011

| | | | Male | | | | Female | |
|--|-------|---------------|------------|-----------|-------|------------|-----------|-----------|
| #Zymbal's Gland: Carcinoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | , | , | | 0/50 (0%) | , | , |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |
| #Zymbal's Gland: Carcinoma or Adenoma | | | | | | | | |
| | | 0/50 (0%) | 0/50 (0%) | 0/50 (0%) | | 0/50 (0%) | 0/49 (0%) | 0/50 (0%) |
| | | 0/50 (0%) | 1/50 (2%) | 0/50 (0%) | | 0/50 (0%) | 0/50 (0%) | 0/49 (0%) |
| | | 0/50 (0%) | (=77) | (1,1) | | 0/50 (0%) | (473) | (575) |
| Overall Incidence | Total | 1/350 (0.29%) | Mean 0.29% | SD 0.76% | Total | 0/348 (0%) | Mean 0% | SD 0% |

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied