Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 4

Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903104	03/17/05	726	50(1)	34(687)	54.6	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/24/04	730	50(1)	34(689)	56.4	Kava kava extract
Battelle Columbus Laboratory	052010704	10/26/04	730	50(1)	34(665)	55.7	N,N-Dimethyl-p-toluidine
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					Female		
Battelle Columbus Laboratory	059903104	03/18/05	727	50(5)	31(628)	64.5	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/23/04	729	50(5)	38(695)	66.2	Kava kava extract
Battelle Columbus Laboratory	052010704	10/25/04	729	50(5)	43(715)	66.6	N,N-Dimethyl-p-toluidine
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Page: 5

Mean 1.33%

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #All Organs: **Benign Tumors** 38/50 (76%)33/50 (66%)34/50 (68%)25/50 (50%)17/50 (34%)26/50 (52%)36/50 (72%)30/50 (60%)38/50 (76%)24/50 (48%)24/50 (48%)22/50 (44%)Overall Incidence Total 209/300 (69.67%) Mean 69.67% SD 6.25% Total 138/300 (46%) Mean 46% SD 6.45% #All Organs: **Malignant Tumors** 35/50 (70%)27/50 (54%)32/50 (64%)28/50 (56%)19/50 (38%)19/50 (38%)29/50 (58%)27/50 (54%)21/50 (42%)21/50 (42%)16/50 (32%)18/50 (36%)Mean 57% **Overall Incidence** Total 171/300 (57%) SD 9.61% Total 121/300 (40.33%) Mean 40.33% SD 8.33% #All Organs: **Malignant and Benign Tumors** 44/50 (88%)48/50 (96%)47/50 (94%)35/50 (70%)30/50 (60%)39/50 (78%)32/50 45/50 (90%)40/50 (80%)47/50 (94%)35/50 (70%)34/50 (68%)(64%)**Overall Incidence** Total 271/300 (90.33%) Mean 90.33% SD 5.85% 205/300 (68.33%) Mean 68.33% SD 6.12% Total **#All Organs:** Hemangioma 2/50 0/50 (0%)0/50 (0%)(4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/300 (1.33%) Mean 1.33% SD 2.07% Total 4/300 (1.33%) Mean 1.33% SD 1.03% #All Organs: Hemangiosarcoma 9/50 (18%)4/50 (8%)6/50 (12%)2/50 (4%)0/50 (0%)1/50 (2%)8/50 (16%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)

SD 6.86%

Total

4/300 (1.33%)

Total

29/300 (9.67%)

.....

Mean 9.67%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 6

Report Date: 11/11/2014

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 9/50 (18%)4/50 (8%)8/50 (16%)2/50 (4%)1/50 (2%)1/50 (2%)8/50 (16%)1/50 (2%)3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)8/300 (2.67%) **Overall Incidence** Total 33/300 (11%) Mean 11% SD 6.54% Total Mean 2.67% SD 1.03% #All Organs: **Histiocytic Sarcoma** (2%)0/50 (0%)2/50 (4%)0/50 (0%)1/50 1/50 (2%)3/50 (6%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% Total 7/300 (2.33%) Mean 2.33% SD 1.97% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 1/50 (2%)3/50 (6%)2/50 (4%)11/50 (22%)6/50 (12%)6/50 (12%)3/50 9/50 4/50 (8%)5/50 (10%)(6%)15/50 (30%)7/50 (14%)(18%)**Overall Incidence** Total 18/300 (6%) Mean 6% SD 2.83% Total 54/300 (18%) Mean 18% SD 7.04% **#All Organs:** Mesothelioma: Benign 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Benign, Malignant, NOS

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

0/300 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

0/300 (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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/49 (4%)	0/50 (0%)
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%

^{*:} 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: 11/11/2014

Page: 8

			Male				Female	
Adrenal Medulla: Pheochromocytoma B	enign							
		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%)		2/50 (4%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/298 (1.01%)	Mean 1%	SD 1.67%
Adrenal Medulla: Pheochromocytoma M	alignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Pheochromocytoma: E	Benign, Complex		- / / / / / / / / / /					
·	Benign, Complex Total	x, Malignant, NOS 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 2/50 (4%) 3/298 (1.01%)	0/49 (0%) 0/49 (0%) Mean 1%	0/50 (0%) 1/50 (2%) SD 1.67%
Pheochromocytoma: E Overall Incidence #Blood Vessel: Hemangioma		0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33%	0/50 (0%)		2/50 (4%) 3/298 (1.01%)	0/49 (0%)	1/50 (2%)
Overall Incidence #Blood Vessel:		0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%)	1/50 (2%) SD 1.67% 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma		0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%)	1/50 (2%) SD 1.67% 0/50 (0%)
Overall Incidence #Blood Vessel:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma Overall Incidence *Bone Marrow:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%) SD 0.82%
Overall Incidence #Blood Vessel: Hemangioma Overall Incidence *Bone Marrow:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 0%		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%) Mean 0.33%	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%) SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 9

Mean 0%

SD 0%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** *Bone Marrow: Hemangiosarcoma 0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 0/50 (0%)0/299 (0%) **Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% Total Mean 0% SD 0% *Bone Marrow: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% *Bone Marrow: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% #Bone: **Fibroma** 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

0/300 (0%)

Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteo	oma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Be	nign							
	•	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, W	lalignant, NOS							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mal								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gli	oma, or Astrocy	rtoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 12 Report Date: 11/11/2014

			Male				Female	
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		4/50 (8%)	6/50 (12%)	5/50 (10%)		5/50 (10%)	3/50 (6%)	5/50 (10%)
		11/50 (22%)	5/50 (10%)	7/50 (14%)		1/50 (2%)	9/50 (18%)	2/50 (4%)
Overall Incidence	Total	38/300 (12.67%)	Mean 12.67%	SD 5.01%	Total	25/300 (8.33%)	Mean 8.33%	SD 5.72%

^{*:} 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

Control Animal Groups /AGE **Page:** 13

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma								
		3/50 (6%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 2.19%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	7/50 (14%)	5/50 (10%)		6/50 (12%)	3/50 (6%)	5/50 (10%)
		11/50 (22%)	6/50 (12%)	8/50 (16%)		1/50 (2%)	10/50 (20%)	3/50 (6%)
Overall Incidence	Total	44/300 (14.67%)	Mean 14.67%	SD 4.13%	Total	28/300 (9.33%)	Mean 9.33%	SD 6.28%
Heart: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 15

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #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%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Small: Jejunum: Adenoma (0%)0/50 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Jejunum: Carcinoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Site Unspecified: Adenoma 2/50 0/50 (0%)3/50 (6%)(4%)0/50 (0%)0/50 (0%)2/50 (4%)

1/50

SD 2.53%

(2%)

0/50

3/300 (1%)

Total

(0%)

0/50

(0%)

Mean 1%

1/50

(2%)

Total

0/50

6/300 (2%)

(0%)

0/50

Mean 2%

(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

Control Animal Groups Report Date: 11/11/2014 AGE

Page: 16

			Male				Female	
Intestine Small: Site Uns Carcinoma	pecified:							
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Carcinoma or Adenoma	pecified:							
		1/50 (2%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.76%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Intestine Small: Site Uns Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
'Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Manaç

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Page: 17

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** *Islets, Pancreatic: Carcinoma or Adenoma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/300 (0.67%) **Overall Incidence** Total 5/300 (1.67%) Mean 1.67% SD 1.51% Total Mean 0.67% SD 1.03% *Kidney: Pelvis and Transitional Epithelium: Carcinoma (0%) (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

0/50

0/300 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

......

0/50

0/300 (0%)

(0%)

0/50

Mean 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: 18

Report Date: 11/11/2014

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2/300 (0.67%)			10tai	0/300 (0%)		3D 0%
Kidney: Renal Tubule: Hemangioma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hemangiosarcoma								
		9/50 (18%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		6/50 (12%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	24/300 (8%)	Mean 8%	SD 7.04%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

d Control Animal Groups Report Date: 11/11/2014
AVAGE

Page: 19

			Male				Female	
*Liver: Hepatoblastoma								
		3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/300 (3.33%)	Mean 3.33%	SD 2.42%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hepatocellular Adenom	a							
		31/50 (62%)	26/50 (52%)	27/50 (54%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
		29/50 (58%)	23/50 (46%)	32/50 (64%)		17/50 (34%)	5/50 (10%)	13/50 (26%)
Overall Incidence	Total	168/300 (56%)	Mean 56%	SD 6.69%	Total	67/300 (22.33%)	Mean 22.33%	SD 10.46%
Liver: Hepatocellular Carcinor								
		22/50 (44%)	12/50 (24%)	20/50 (40%)		9/50 (18%)	6/50 (12%)	3/50 (6%)
		22/50 (44%)	18/50 (36%)	11/50 (22%)		6/50 (12%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	105/300 (35%)	Mean 35%	SD 9.78%	Total	30/300 (10%)	Mean 10%	SD 5.06%
Liver: Hepatocellular Carcinor	ma or Hepatob	lastoma						
•	•	24/50 (48%)	15/50 (30%)	20/50 (40%)		10/50 (20%)	6/50 (12%)	3/50 (6%)
		22/50 (44%)	18/50 (36%)	12/50 (24%)		6/50 (12%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	111/300 (37%)	Mean 37%	SD 8.92%	Total	31/300 (10.33%)	Mean 10.33%	SD 5.72%
Liver: Hepatocellular Carcinor	ma or Hepatoc	ellular Adenoma						
		39/50 (78%)	35/50 (70%)	38/50 (76%)		20/50 (40%)	12/50 (24%)	10/50 (20%)
		38/50 (76%)	31/50 (62%)	39/50 (78%)		20/50 (40%)	8/50 (16%)	15/50 (30%)
Overall Incidence	Total	220/300 (73.33%)	Mean 73.33%	SD 6.28%	Total	85/300 (28.33%)	Mean 28.33%	SD 10.15%

^{*:} 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

Page: 20

Report Date: 11/11/2014

Length of Study: CHRONIC

			Male				Female	
Liver:								
Hepatocellular Carcinor	ma, Hepatocel	lular Adenoma, or Hepato	blastoma					
		39/50 (78%)	36/50 (72%)	38/50 (76%)		20/50 (40%)	12/50 (24%)	10/50 (20%)
		38/50 (76%)	31/50 (62%)	39/50 (78%)		20/50 (40%)	8/50 (16%)	15/50 (30%)
Overall Incidence	Total	221/300 (73.67%)	Mean 73.67%	SD 6.12%	Total	85/300 (28.33%)	Mean 28.33%	SD 10.15%
Liver: Hepatocholangiocarcine	oma							
ricpatoonolarigioodiom	Oma	0/50 (0%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 3.27%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign			•••••					
•		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Mast Cell Tumor Malign	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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

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: 21

			Male				Female	
Lung: Alveolar/Bronchiolar Ad	denoma							
		8/50 (16%)	4/50 (8%)	9/50 (18%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		11/50 (22%)	5/50 (10%)	6/50 (12%)		2/50 (4%)	1/50 (2%)	5/50 (10%)
Overall Incidence	Total	43/300 (14.33%)	Mean 14.33%	SD 5.28%	Total	11/300 (3.67%)	Mean 3.67%	SD 3.44%
Lung: Alveolar/Bronchiolar Ca	arcinoma							
		11/50 (22%)	4/50 (8%)	2/50 (4%)		1/50 (2%)	2/50 (4%)	2/50 (4%)
		2/50 (4%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	28/300 (9.33%)	Mean 9.33%	SD 6.65%	Total	6/300 (2%)	Mean 2%	SD 1.79%
Overall Incidence	Total	17/50 (34%) 13/50 (26%) 69/300 (23%)	8/50 (16%) 10/50 (20%) Mean 23%	11/50 (22%) 10/50 (20%) SD 6.29%	Total	1/50 (2%) 2/50 (4%) 17/300 (5.67%)	3/50 (6%) 1/50 (2%) Mean 5.67%	4/50 (8%) 6/50 (12%) SD 3.88%
*Lung: Hemangiosarcoma								
_		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma Overall Incidence	Total	1/50 (2%) 2/300 (0.67%)	\ /	` '	Total	` ,	` '	` ,
Hemangiosarcoma Overall Incidence	r:	1/50 (2%) 2/300 (0.67%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma Overall Incidence #Lymph Node, Mandibula	r:	1/50 (2%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 0/50 (0%)	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)
Hemangiosarcoma Overall Incidence #Lymph Node, Mandibula	r:	1/50 (2%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 22

Mean 1%

SD 1.1%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female #Lymph Node, Mediastinal: Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Lymph Node, Mesenteric: Hemangiosarcoma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% **#Mammary Gland:** Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 3/300 (1%) Mean 1% SD 1.1% Total **#Mammary Gland:** Carcinoma or Adenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 3/300 (1%) Mean 1% SD 1.1% #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)

SD 0%

Total

3/300 (1%)

Total

0/300 (0%)

Mean 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: 23

			Male				Female	
#Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Report Date: 11/11/2014

Page: 24

			Male				Female	
Nose: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous		ynx, Tooth, Gingiva):						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%

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

^{#:} Denominator is number of animals necropsied

*Ovary:

*Ovary:

*Ovary:

*Ovary:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Choriocarcinoma

Cystadenocarcinoma

Overall Incidence

Overall Incidence

Cystadenoma

Overall Incidence

Overall Incidence

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL Male **Female** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Total 1/297 (0.34%) Mean 0.33% SD 0.82% 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Total 0/297 (0%) Mean 0% SD 0% 2/50 (4%)1/50 (2%)5/49 (10%)(2%)1/50 2/48 (4%)2/50 (4%)Total 13/297 (4.38%) Mean 4.4% SD 3.02%

0/50

0/50

1/297 (0.34%)

Total

(0%)

(0%)

0/50

1/48

(0%)

(2%)

Mean 0.35%

0/49

0/50

SD 0.85%

(0%)

(0%)

Page: 25

Report Date: 11/11/2014

*Ovary:					
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)	1/48 (2%)	0/50 (0%)	
Overall Incidence	Total	1/297 (0.34%)	Mean 0.35%	SD 0.85%	

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

Granulosa Cell Tumor Benign

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 26

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% *Ovary: Hemangiosarcoma (0%) 1/50 (2%)0/50 0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% *Ovary: Luteoma 0/50 (0%)0/50 (0%)1/49 (2%)(0%) 0/50 (0%)0/48 0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.34% SD 0.83% *Ovary: Sarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 0/50 (0%)1/50 0/49 (0%)1/50 (2%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 2/297 (0.67%) Mean 0.67%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Tumor Incidence for Selected Control Animal Groups

Page: 27

Mean 5.02%

SD 3.75%

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** *Ovary: Yolk Sac Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/297 (0%) **Overall Incidence** Total Mean 0% SD 0% *Pancreas: Carcinoma (0%) (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 0/49 (0%)0/50 (0%)(0%)4/50 (8%)3/49 (6%)2/50 (4%)0/50 (0%)0/47 (0%)0/50 (0%)0/48 (0%)5/50 (10%)1/50 (2%)**Overall Incidence** Total 0/295 (0%) Mean 0% SD 0% Total 15/297 (5.05%) Mean 5.02% SD 3.75% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/49 (0%)4/50 (8%)3/49 (6%)2/50 (4%)0/50 (0%)0/47 (0%)0/50 (0%)(0%)5/50 (10%)1/50 (2%)

SD 0%

Total

15/297 (5.05%)

Total

......

0/295 (0%)

Mean 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
Pituitary Gland: Pars Interm Adenoma	edia:							
		0/49 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/49 (2%)	1/50 (2%)
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.34%	SD 0.83%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
Pituitary Gland: Pars Interm Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/49 (2%)	1/50 (2%)
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.34%	SD 0.83%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
Salivary Glands: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 29

Report Date: 11/11/2014

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: B6C3F1 Vehicle: CORN OIL

			Male				Female	
Salivary Glands:								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skeletal Muscle: Rhabdomyosarcoma or F								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

ontrol Animal Groups GE **Page:** 30

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Skin:								,
Basal Cell Carcinoma			- / / / /				- / / /	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin: Basal Cell Carcinoma (or Basosquamou	us Tumor (malignant or N	OS)					
Buoui oui oui oiiioiiia (or Baccoquanie	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin:	Danal Call Adam	oma Basosauamous Tur	nor (honian maliana	nt or				
, ,	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
verall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.03%
verall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom bithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 2/300 (0.67%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.03%
verall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom bithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total Total	0/50 (0%) 2/300 (0.67%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.03%
NOS), or Trichoepithelicoverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, Soverall Incidence	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli overall Incidence Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, Soverall Incidence	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli overall Incidence Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, Soverall Incidence	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%) 1/300 (0.33%) oma, Myxosarcoma, or Fi	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%) SD 0.82%		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%) 3/300 (1%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%) SD 1.1%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 31

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Skin: **Fibrosarcoma** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 4/300 (1.33%) Mean 1.33% SD 1.63% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (0%)0/50 1/50 (2%)0/50 (0%)3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)1/50 (2%)Mean 0.67% **Overall Incidence** Total 2/300 (0.67%) SD 1.03% Total 8/300 (2.67%) Mean 2.67% SD 2.07% #Skin: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin: **Granular Cell Tumor Benign** (0%) 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

Total

0/50

1/300 (0.33%)

(0%)

0/50

(0%)

Mean 0.33%

1/50

SD 0.82%

(2%)

Total

0/50

0/300 (0%)

(0%)

0/50

Mean 0%

(0%)

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 32

Mean 0%

SD 0%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Skin:								
Hemangiosarcoma		0/50 (00/)	0/50 (00/)	4/50 (00	//	0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2% 0/50 (0%	,	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Keratoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (29	<u>(</u>	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
∜Skin: Mast Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

0/300 (0%)

Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 33

			Male				Female	
#Skin: Mast Cell Tumor Malignan	t							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwann	noma benign							
	3	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

for Selected Control Animal Groups

Route: GAVAGE

Page: 34

Report Date: 11/11/2014

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: CORN OIL

			Male				Female	
#Skin:								
Neurofibrosarcoma or \$	Schwannoma (n	nalignant or NOS)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin:								
Neurofibrosarcoma, Ne	urofibroma, or	Schwannoma (benign, ma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		•••••		•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skin: Schwannoma Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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: 35

Report Date: 11/11/2014

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant c	or NOS),				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Skin: Squamous Cell Papilloma	a	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a or Papilloma						•••••	•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthoma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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

ontrol Animal Groups

Page: 36

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Squamous Cell Papilloma, F	Papilloma,	or Keratoacanthoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Spinal Cord: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
		3/48 (6%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	8/298 (2.68%)	Mean 2.71%	SD 2.15%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.03%
Spleen: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 37

Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female			
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous										
1		0/50 (0%) 1/50 (2%)	2/50 (4%) 2/50 (4%)	9/50 (18%) 5/50 (10%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)		
Overall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 6.62%	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%		
#Stomach, Forestomach: Squamous Cell Papilloma										
		0/50 (0%) 1/50 (2%)	1/50 (2%)	8/50 (16%) 5/50 (10%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)		
Overall Incidence	Total	17/300 (5.67%)	2/50 (4%) Mean 5.67%	5/50 (10%) SD 6.12%	Total	1/50 (2%) 7/300 (2.33%)	0/50 (0%) Mean 2.33%	0/50 (0%) SD 2.34%		
≠Stomach, Glandular: Adenoma					• • • • • • • • • • • • • • • • • • • •					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%		
Stomach, Glandular: Carcinoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Stomach, Glandular: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%		
						` ,				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 38

			Male			Female	
*Testes: Adenoma							
		1/50 (2%)	` ,	(2%)			
		0/50 (0%)	` '	(0%)			
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33% SD 1.63%				
*Testes: Hemangioma							
		0/50 (0%)	` ,	(0%)			
		0/50 (0%)	, ,	(0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%				
*Thymus: Neoplasm NOS							
-		0/50 (0%)	0/49 (0%) 0/48	(0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	` ,	(0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/282 (0%)	Mean 0% SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign							
		0/50 (0%)	` ,	(0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	` '	(0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	1/282 (0.35%)	Mean 0.34% SD 0.83%	Total	0/297 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant							
		0/50 (0%)	` ,	(0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	` '	(0%)	0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/282 (0%)	Mean 0% SD 0%	Total	0/297 (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: 39

			Male				Female	
Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/50 (0%) 0/48 (0%)	1/49 (2%) 0/40 (0%)	0/48 (0%) 0/47 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/282 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/297 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/299 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
		0/299 (0%)				` ,		SD 0.62%
*Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Thyroid Gland: Follicular Ce Adenoma	H:							
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 40

Mean 0.33%

SD 0.82%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/299 (0.67%) **Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total Mean 0.67% SD 1.03% **#Tissue NOS: Fibrosarcoma** (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% **#Tissue NOS:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Tongue: Squamous Cell Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)

SD 0%

Total

1/300 (0.33%)

Total

0/300 (0%)

Mean 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 41

Report Date: 11/11/2014

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Tooth: Odontoma								
		0/50 (0%) 5/50 (10%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 4.08%	Total	0/300 (0%)	Mean 0%	SD 0%
Urethra: Hemangiosarcoma	•••••							
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Irinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)

Total

0/300 (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: 42

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female			
Uterus:							
Hemangioma			0/50 (00/)	0/50 (00/)	0/50 (00/)		
			0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		
verall Incidence		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%		
Jterus: Hemangiosarcoma							
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%		
Uterus: Leiomyoma							
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%		
Uterus: Polyp Stromal							
, , , , , , , , , , , , , , , , , , ,			1/50 (2%)	0/50 (0%)	2/50 (4%)		
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence		Total	3/300 (1%)	Mean 1%	SD 1.67%		
Uterus: Sarcoma							
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#Zymbal's Gland:

Overall Incidence

Carcinoma or Adenoma

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

Length of Study: CHRONIC

Male **Female #Uterus:** Sarcoma Stromal 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% #Uterus: Sarcoma Stromal or Polyp Stromal 2/50 (4%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 6/300 (2%) Mean 2% SD 2.19% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0%

0/50

0/50

SD 1.03%

(0%)

(0%)

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

Total

0/50

1/50

2/300 (0.67%)

(0%)

(2%)

0/50

1/50

Mean 0.67%

(0%)

(2%)

Page: 43

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

^{#:} Denominator is number of animals necropsied