

NTP Historical Controls Report

All Routes and Vehicles

MICE

August 2016

REPORT DESCRIPTION

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

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
М3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male			Female	
M1	M2	М3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 3

Report Date: 08/03/2016

Species: MICE Strain: B6C3F1 Route: ALL ROUTES
Vehicle: ALL VEHICLES

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 Northwest	052060104	10/06/08	729	50(5)	38(708)	52.1	Antimony trioxide
Battelle Northwest	052072504	08/31/09	729	50(5)	35(697)	51.1	2,3-Butanedione
Battelle Northwest	056031106	05/15/06	729	50(5)	39(715)	54.3	Cobalt
Battelle Columbus Laboratory	052020304	07/10/07	730	50(1)	33(694)	52.6	Green Tea Extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	729	50(5)	39(709)	52.6	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	729	50(5)	38(692)	52.4	Metal Working Fluids: TRIM® VX
Battelle Northwest	051047204	01/31/11	729	50(5)	40(705)	52.7	p-Chloro-a,a,a-trifluorotoluene
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
Battelle Columbus Laboratory	059601406	09/26/06	730	50(1)	25(660)	55.9	Water disinfection byproducts (Bromodichloroacetic Acid
					Female		
Battelle Northwest	052060104	10/06/08	731	50(5)	36(692)	54.1	Antimony trioxide
Battelle Northwest	052072504	08/31/09	731	50(5)	36(697)	51.0	2,3-Butanedione
Battelle Northwest	056031106	05/15/06	731	50(5)	36(686)	66.7	Cobalt
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green Tea Extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	731	50(5)	39(696)	59.2	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	731	50(5)	35(692)	57.9	Metal Working Fluids: TRIM® VX
Battelle Northwest	051047204	01/31/11	731	50(5)	38(700)	55.9	p-Chloro-a,a,a-trifluorotoluene
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A
Battelle Columbus Laboratory	059601406	09/25/06	729	50(5)	30(680)	63.5	Water disinfection byproducts (Bromodichloroacetic Acid

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 4

Report Date: 08/03/2016

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

43/50 (86%) 33/50 (66%) 39/50 (78%) 2	25/50 (50%) 15/50 (30%) 29/50 (58%) 20/50 (40%) 17/50 (34%) 26/50 (52%) 23/50 (46%) 24/50 (48%) 24/50 (48%)
43/50 (86%) 33/50 (66%) 39/50 (78%) 2	20/50 (40%) 17/50 (34%) 26/50 (52%)
	()
32/50 (64%) 32/50 (64%) 30/50 (60%) 2	23/50 (46%) 24/50 (48%) 24/50 (48%)
38/50 (76%) 43/50 (86%) 2	22/50 (44%) 36/50 (72%)
Overall Incidence Total 384/550 (69.82%) Mean 69.82% SD 12.21% Total 261/9	1/550 (47.45%) Mean 47.45% SD 11.39%
#All Organs: Malignant Tumors	
25/50 (50%) 27/50 (54%) 36/50 (72%) 2	25/50 (50%) 24/50 (48%) 31/50 (62%)
28/50 (56%) 27/50 (54%) 26/50 (52%) 1	18/50 (36%) 19/50 (38%) 30/50 (60%)
32/50 (64%) 25/50 (50%) 27/50 (54%) 2	27/50 (54%) 24/50 (48%) 16/50 (32%)
21/50 (42%) 30/50 (60%) 1	18/50 (36%) 31/50 (62%)
Overall Incidence Total 304/550 (55.27%) Mean 55.27% SD 7.91% Total 263/5	3/550 (47.82%) Mean 47.82% SD 11.04%
#All Organs: Malignant and Benign Tumors	
45/50 (90%) 37/50 (74%) 45/50 (90%) 3	35/50 (70%) 34/50 (68%) 40/50 (80%)
49/50 (98%) 48/50 (96%) 46/50 (92%) 2	29/50 (58%) 30/50 (60%) 41/50 (82%)
42/50 (84%) 44/50 (88%) 40/50 (80%) 3	38/50 (76%) 38/50 (76%) 34/50 (68%)
47/50 (94%) 48/50 (96%) 3	32/50 (64%) 45/50 (90%)
	96/550 (72%) Mean 72% SD 9.8%
łAll Organs: Hemangioma	
	0/50 (0%) 0/50 (0%) 0/50 (0%)
2/50 (4%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
	1/50 (2%) 0/50 (0%) 1/50 (2%)
2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
	/550 (0.73%) Mean 0.73% SD 1.01%

^{*:} 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: 5

Report Date: 08/03/2016

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Hemangiosarcoma								
		2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	0/50 (0%)	3/50 (6%)
		5/50 (10%)	4/50 (8%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	3/50 (6%)	0/50 (0%)
		1/50 (2%)	5/50 (10%)			1/50 (2%)	6/50 (12%)	
Overall Incidence	Total	29/550 (5.27%)	Mean 5.27%	SD 4.5%	Total	24/550 (4.36%)	Mean 4.36%	SD 3.78%
All Organs: Hemangiosarcoma or He	(emangioma							
nemangiosarcoma or m	cinangionia	2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	0/50 (0%)	3/50 (6%)
		7/50 (14%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		3/50 (6%)	3/50 (6%)	1/50 (2%)
		3/50 (6%)	5/50 (10%)	1750 (270)		2/50 (4%)	6/50 (12%)	1750 (270)
Overall Incidence	Total	34/550 (6.18%)	Mean 6.18%	SD 4.77%	Total	28/550 (5.09%)	Mean 5.09%	SD 3.27%
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)	
verall Incidence	Total	7/550 (1.27%)	Mean 1.27%	SD 1.35%	Total	18/550 (3.27%)	Mean 3.27%	SD 2.24%
All Organs:		nphocytic, Mixed, NOS, o						
- , ,		4/50 (8%)	6/50 (12%)	4/50 (8%)		7/50 (14%)	9/50 (18%)	14/50 (28%)
		4/50 (8%)	3/50 (6%)	3/50 (6%)		7/50 (14%)	6/50 (12%)	18/50 (36%)
		7/50 (0/0)						
		6/50 (12%)	6/50 (12%)	5/50 (10%)		10/50 (20%)	9/50 (18%)	7/50 (14%)
		(/	` ,	` '		10/50 (20%) 9/50 (18%)	9/50 (18%) 6/50 (12%)	7/50 (14%)

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
All Organs:								
Mesothelioma: Benign, Mal	ignant, NOS							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (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%)
		0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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%)	()

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

Page: 6

^{#:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Male **Female** *Adrenal Cortex: Adenoma 4/49 (8%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/49 (2%)0/50 (0%)9/49 (18%)0/49(0%)2/49 (4%)0/49 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/49 (0%)**Overall Incidence** 23/547 (4.2%) Mean 4.23% SD 5.36% 4/546 (0.73%) Mean 0.73% SD 1.37% Total Total *Adrenal Medulla: Pheochromocytoma Benign 0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)1/50 (2%)(0%)(0%)(2%)0/49 0/50 1/48 0/49 (0%)0/49 (0%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)(2%)(0%)1/50 0/50 **Overall Incidence** 2/546 (0.37%) Mean 0.37% SD 0.83% 7/546 (1.28%) Mean 1.28% SD 1.35% Total Total *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/50 0/50 (0%)(0%)1/50 (2%)0/49 (0%)(0%)0/50 1/50 (2%)0/49 (0%)(0%)(2%)(0%)0/50 1/48 0/49 0/49 (0%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%) 1/50 (2%)0/50 (0%)Overall Incidence 2/546 (0.37%) Mean 0.37% SD 0.83% 7/546 (1.28%) Mean 1.28% SD 1.35% Total Total #Blood Vessel: Hemangioma (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% Total 1/550 (0.18%) Mean 0.18% SD 0.6%

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Blood Vessel: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total *Bone Marrow: Hemangiosarcoma (2%)0/50 0/49 (0%)0/48 (0%)1/50 0/50 (0%)0/50 (0%)(0%)(2%)(2%)(0%)1/50 1/50 0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** 3/547 (0.55%) Mean 0.55% SD 0.93% 1/548 (0.18%) Mean 0.18% SD 0.6% Total Total *Bone Marrow: **Mast Cell Tumor Malignant** 0/49 (0%)(2%)0/50 (0%)(0%)0/50 1/50 (2%)1/48 0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)Overall Incidence 2/547 (0.37%) Mean 0.37% SD 0.83% 1/548 (0.18%) Mean 0.18% SD 0.6% Total Total *Bone Marrow: Sarcoma 0/49 0/48 (0%)0/50 (0%) 0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/547 (0%) Mean 0% SD 0% Total 1/548 (0.18%) Mean 0.18% SD 0.6%

Page: 8

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Bone: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05 00/		1/50 (2%)	0/50 (0%)	05 000
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	1/50 (2%)	05 000
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Bone: Osteosarcoma or Osteom	na							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#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%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%

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

Page: 9

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 10

Report Date: 08/03/2016

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** *Brain: **Granular Cell Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) Mean 0% SD 0% Total *Brain: Meningioma Malignant 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)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%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) SD 0% Total Total Mean 0% *Brain: Meningioma: Benign, Malignant, NOS (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 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%)1/50 (2%) 0/50 (0%)0/49 (0%)Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) Mean 0% SD 0% Total Total **#Coagulating Gland: Granular Cell Tumor** 0/50 0/50 (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(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 0/50 0/50 0/50 (0%)0/50 (0%)(0%)(0%)(0%)

SD 0.6%

0/50

0/550 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

1/50

1/550 (0.18%)

(2%)

0/50

Mean 0.18%

(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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Coagulating Gland: Sarcoma								
		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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		6/50 (12%)	3/50 (6%)	6/50 (12%)		3/50 (6%)	3/50 (6%)	3/50 (6%)
		7/50 (14%)	6/50 (12%)	7/50 (14%)		2/50 (4%)	3/50 (6%)	2/50 (4%)
		4/50 (8%)	5/50 (10%)	5/50 (10%)		1/50 (2%)	2/50 (4%)	9/50 (18%)
		7/50 (14%)	6/50 (12%)			2/50 (4%)	5/50 (10%)	
Overall Incidence	Total	62/550 (11.27%)	Mean 11.27%	SD 2.57%	Total	35/550 (6.36%)	Mean 6.36%	SD 4.37%
#Harderian Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	2/50 (4%)		4/50 (8%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	` '		1/50 (2%)	0/50 (0%)	` ,
Overall Incidence	Total	15/550 (2.73%)	Mean 2.73%	SD 2.72%	Total	12/550 (2.18%)	Mean 2.18%	SD 2.75%

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

Page: 11

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Harderian Gland: Carcinoma or Adenoma 7/50 (14%)3/50 (6%)8/50 (16%)7/50 (14%)4/50 (8%)3/50 (6%)8/50 (16%)7/50 (14%)12/50 (24%)4/50 (8%)3/50 (6%)2/50 (4%)6/50 (12%)6/50 (12%)6/50 (12%)4/50 (8%)2/50 (4%)10/50 (20%)8/50 (16%)6/50 (12%)3/50 (6%)5/50 (10%)Overall Incidence Total 77/550 (14%) Mean 14% SD 4.38% 47/550 (8.55%) Mean 8.55% SD 4.74% Total *Heart: Hemangiosarcoma (2%)0/50 0/50 (0%)1/50 (2%)1/50 0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 **Overall Incidence** 2/550 (0.36%) Mean 0.36% SD 0.81% 0/550 (0%) SD 0% Total Total Mean 0% #Intestine Large: Cecum: Carcinoma 0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 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%)(2%) 0/50 (0%)0/50 (0%)1/50 Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total Total #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(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 0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% Total 0/550 (0%) Mean 0% SD 0%

Page: 12

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 13

Report Date: 08/03/2016

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

					Male						F	emale		
Intestine Large: Cecum: Leiomyosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	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%)		
verall Incidence	Total	0/550 (0%		Mean		SD 0%		Total	1/550 (0.	,		0.18%	SD 0	0.6%
Intestine Small: Duodenum: Adenoma														
		2/50	(4%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)				1/50	(2%)	0/50	(0%)		
verall Incidence	Total	9/550 (1.64	,	Mean 1		SD 1.759		Total	2/550 (0.			0.36%	SD 0	.81%
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%)
		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%)		
verall Incidence	Total	1/550 (0.18	3%)	Mean 0		SD 0.6%		Total	0/550 (0%)	Mea	n 0%	SD	0%
Intestine Small: Duodenum: Polyp Adenomatous														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(00/)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/30	(0/0)	0/30	(0 /0)		0/30	(0 /0)	0/30	(0 /0)	0/30	(0 /0)
		0/50 0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)

SD 0.6%

Total

0/550 (0%)

Mean 0%

SD 0%

Total

1/550 (0.18%)

Mean 0.18%

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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female			
Intestine Small: Ileum: Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	
Intestine Small: Ileum: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	
Intestine Small: Jejunum: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	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%)	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	0/550 (0%)	Mean 0%	SD 0%	
Intestine Small: Jejunum: Carcinoma				•••••					
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	` '		0/50 (0%)	0/50 (0%)	, ,	
		`/	, , - /			` -/	` '		

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

Page: 14

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Jejunui Leiomyosarcoma	m:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%
Intestine Small: Site Un Adenoma	specified:					•••••		•••••
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
verall Incidence	Total	12/550 (2.18%)	Mean 2.18%	SD 2.09%	Total	3/550 (0.55%)	Mean 0.55%	SD 0.93%
Intestine Small: Site Un Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	7/550 (1.27%)	Mean 1.27%	SD 1.62%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Intestine Small: Site Un Carcinoma or Adenom	specified:							
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	3/50 (6%)	1/50 (2%)		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%)
		2/50 (4%)	3/50 (6%)	0,00 (0,0)		1/50 (2%)	0/50 (0%)	5.50 (0.0)
verall Incidence	Total	(,	` '	SD 221%	Total	` '	, ,	SD 1.01%
Overall Incidence	Total	19/550 (3.45%)	Mean 3.45%	SD 2.21%	Total	4/550 (0.73%)	Mean 0.73%	SD 1.01%

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

Page: 15

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Site Unsp Leiomyosarcoma	pecified:							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%
fintestine Small: Site Unsp Polyp Adenomatous								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (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%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	6/546 (1.1%)	Mean 1.09%	SD 1.38%	Total	3/548 (0.55%)	Mean 0.55%	SD 0.93%
Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/48 (0%)	0/49 (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%)	0/50 (0%)
		0/50 (0%)	0/50 (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%)	` '

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

Page: 16

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Islets, Pancreatic: Carcinoma or Adenoma								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (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%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	7/546 (1.28%)	Mean 1.27%	SD 1.62%	Total	3/548 (0.55%)	Mean 0.55%	SD 0.93%
Kidney: Pelvis and Transi Carcinoma	itional Epitheli	ium:						
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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	0/549 (0%)	Mean 0%	SD 0%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
Kidney: Pelvis and Transi Carcinoma or Adenoma	itional Epitheli							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)	
verall Incidence	Total	0/549 (0%)	Mean 0%	SD 0%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
Kidney: Renal Tubule: Adenoma				•••••				
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (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%)
		0/50 (0%)	2/50 (4%)	()		0/50 (0%)	0/50 (0%)	(-,-)
verall Incidence	Total	3/549 (0.55%)	Mean 0.55%	SD 1.29%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
veran incluence	i Ulai	3/343 (0.33/0)	WEATT 0.5576	OD 1.23/0	i Otai	1/343 (0.10/0)	WEAT 0.1070	OD 0.070

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

Page: 17

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/549 (0.36%)	Mean 0.36%	SD 1.21%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		3/50 (6%)	0/50 (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%)
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/549 (0.91%)	Mean 0.91%	SD 2.07%	Total	2/549 (0.36%)	Mean 0.36%	SD 0.81%
*Liver: Cholangiocarcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (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	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
3 2 2		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	` '		0/50 (0%)	0/49 (0%)	, ,
Overall Incidence	Total	4/550 (0.73%)	Mean 0.73%	SD 1.62%	Total	0/549 (0%)	Mean 0%	SD 0%

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

Page: 18

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 19

Report Date: 08/03/2016

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Liver: Hemangiosarcoma 0/50 (0%)0/50 (0%)4/50 (8%)0/50 (0%)0/50 (0%)2/50 (4%)3/50 (6%)4/50 (8%)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%)1/50 (2%)0/50 (0%)2/49 (4%)Overall Incidence 12/550 (2.18%) Mean 2.18% SD 3.4% 5/549 (0.91%) Mean 0.92% SD 1.66% Total Total *Liver: Hepatoblastoma 2/50 1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)(4%)2/50 (4%)(0%)3/50 (6%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)4/50 (8%)0/50 (0%)(0%)0/49 **Overall Incidence** 18/550 (3.27%) Mean 3.27% SD 2.41% 3/549 (0.55%) Mean 0.55% SD 0.93% Total Total *Liver: Hepatocellular Adenoma (60%)28/50 (22%)(38%)30/50 17/50 (34%)(56%)11/50 6/50 (12%)19/50 (52%)(48%)35/50 (70%)26/50 24/50 12/50 (24%)7/50 (14%)14/50 (28%)23/50 (46%)25/50 (50%)23/50 (46%)9/50 (18%)12/50 (24%)5/50 (10%)32/50 (64%)39/50 (78%)13/50 (26%)33/49 (67%)Overall Incidence 302/550 (54.91%) Mean 54.91% SD 12.44% 141/549 (25.68%) Mean 25.76% SD 15.94% Total Total *Liver: **Hepatocellular Carcinoma** (30%)(50%)15/50 17/50 (34%)25/50 6/50 (12%)5/50 (10%)10/50 (20%)15/50 (30%)12/50 (24%)11/50 (22%)5/50 (10%)6/50 (12%)10/50 (20%)8/50 (16%)4/50 21/50 (42%)18/50 (36%)7/50 (14%)7/50 (14%)(8%)

SD 9.96%

2/50

71/549 (12.93%)

Total

(4%)

9/49

(18%)

SD 5.05%

Mean 12.94%

Total

11/50

165/550 (30%)

(22%)

12/50

Mean 30%

(24%)

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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: Hepatocellular Carcinoma or Hepatoblastoma 16/50 (32%)18/50 (36%)27/50 (54%)6/50 (12%)6/50 (12%)10/50 (20%)17/50 (34%)15/50 (30%)11/50 (22%)5/50 (10%)6/50 (12%)10/50 (20%)21/50 (42%)9/50 (18%)18/50 (36%)7/50 (14%)7/50 (14%)4/50 (8%)12/50 (24%)15/50 (30%)2/50 (4%)9/49 (18%)Overall Incidence 179/550 (32.55%) Mean 32.55% SD 9.92% 72/549 (13.11%) SD 4.97% Total Total Mean 13.12% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 39/50 (78%)31/50 (62%)38/50 (76%)14/50 (28%)(22%)25/50 11/50 (50%)40/50 (80%)35/50 (70%)32/50 (64%)14/50 (28%)12/50 (24%)20/50 (40%)34/50 (68%)30/50 (60%)31/50 (62%)15/50 (30%)18/50 (36%)8/50 (16%)(78%)42/50 (84%)(30%)36/49 39/50 15/50 (73%)391/550 (71.09%) Mean 71.09% 188/549 (34.24%) Mean 34.32% **Overall Incidence** Total SD 8.46% Total SD 15.89% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 39/50 (78%)32/50 (64%)39/50 (78%)14/50 (28%)12/50 (24%)25/50 (50%)40/50 (80%)36/50 (72%)32/50 (64%)14/50 (28%)12/50 (24%)20/50 (40%)34/50 (68%)31/50 (62%)31/50 (62%)15/50 (30%)18/50 (36%)8/50 (16%)(78%)(84%)(30%)39/50 42/50 15/50 36/49 (73%)395/550 (71.82%) Overall Incidence Mean 71.82% SD 8.12% 189/549 (34.43%) Mean 34.5% SD 15.75% Total Total *Liver: Hepatocholangiocarcinoma 1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 5/550 (0.91%) Mean 0.91% SD 1.87% Total 1/549 (0.18%) Mean 0.18% SD 0.6%

Page: 20

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (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 0/550 (0%) Mean 0% SD 0% 1/549 (0.18%) Mean 0.18% SD 0.6% Total Total *Lung: Alveolar/Bronchiolar Adenoma 10/50 (20%)5/50 (10%)7/50 (14%)(2%)3/50 (6%)3/49 (6%)1/50 12/50 (24%)4/50 (8%)5/50 (10%)5/50 (10%)1/50 (2%)1/50 (2%)6/50 (12%)11/50 (22%)5/50 (10%)4/50 (8%)5/50 (10%)1/50 (2%)(10%)6/50 (12%)13/50 (26%)5/50 3/50 (6%)**Overall Incidence** 84/550 (15.27%) Mean 15.27% SD 6.47% 32/549 (5.83%) Mean 5.83% SD 3.4% Total Total *Lung: Alveolar/Bronchiolar Carcinoma (10%)11/50 (22%)(4%)4/50 (8%)5/50 2/50 3/50 (6%)5/49 (10%)(4%)(16%)(2%)2/50 4/50 (8%) 8/50 1/50 2/50 (4%)4/50 (8%)10/50 (20%)6/50 (12%)5/50 (10%)5/50 (10%)0/50 (0%)0/50 (0%)(8%)(14%)(4%)4/50 7/50 1/50 (2%)2/50 Overall Incidence 66/550 (12%) Mean 12% SD 5.51% 25/549 (4.55%) Mean 4.56% SD 3.62% Total Total *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma (32%)13/50 (26%)9/50 (18%)16/50 3/50 (6%)6/50 (12%)8/49 (16%)14/50 (28%)8/50 (16%)13/50 (26%)6/50 (12%)3/50 (6%)4/50 (8%)5/50 14/50 (28%)17/50 (34%)10/50 (20%)9/50 (18%)(10%)1/50 (2%)10/50 (20%)19/50 (38%)6/50 (12%)5/50 (10%)Overall Incidence Total 143/550 (26%) Mean 26% SD 6.99% Total 56/549 (10.2%) Mean 10.21% SD 4.64%

Page: 21

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) Mean 0% SD 0% Total **#Lymph Node:** Hemangiosarcoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 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%)0/50 **Overall Incidence** 0/550 (0%) Mean 0% SD 0% 2/550 (0.36%) Mean 0.36% SD 0.81% Total Total #Lymph Node, Mandibular: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 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%)0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Lymph Node, Mediastinal: **Mast Cell Tumor Malignant** 0/50 0/50 (0%) 0/50 0/50 (0%)(0%)0/50 (0%)(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 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% Total 1/550 (0.18%) Mean 0.18% SD 0.6%

Page: 22

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Lymph Node, Mesenteric:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Lymph Node, Mesenteric: Hemangiosarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	,		0/50 (0%)	1/50 (2%)	,
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	7/550 (1.27%)	Mean 1.27%	SD 1.35%

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

Page: 23

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Mammary Gland: Carcinoma or Adenoma	a							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		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%)	1/50 (2%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	8/550 (1.45%)	Mean 1.45%	SD 1.29%
Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	,		0/50 (0%)	0/50 (0%)	, ,
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		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%)	1/50 (2%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	8/550 (1.45%)	Mean 1.45%	SD 1.29%
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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		` '	` ,	` '/		` '	` ,	` '
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

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

Page: 24

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%
#Mesentery: Lipoma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Nose: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/48 (2%)	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%)	0/50 (0%)	
Overall Incidence	Total	0/548 (0%)	Mean 0%	SD 0%	Total	1/548 (0.18%)	Mean 0.19%	SD 0.63%
Nose: Polyp								
7 F		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (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%)	0,00 (0,0)		0/50 (0%)	0/50 (0%)	2.30 (0.0)
Overall Incidence	Total	1/548 (0.18%)	Mean 0.19%	SD 0.62%	Total	0/548 (0%)	Mean 0%	SD 0%
verali ilicidelice	i Otal	1/340 (0.1070)	WCaii 0.1970	OD 0.0270	iolai	0/040 (070)	Wicaii 070	OD 070

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

Page: 25

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)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%)(0%)1/50 0/50 **Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma (0%)0/50 0/50 (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 (0%)0/50 0/50 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%) 2/50 (4%)0/50 (0%)Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 2/550 (0.36%) Mean 0.36% SD 1.21% Total Total **#Oral Mucosa: Squamous Cell Carcinoma** (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% Total 1/550 (0.18%) Mean 0.18% SD 0.6%

Page: 26

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Cystadenocarcinoma 0/50 (0%)0/49 (0%)0/48 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/545 (0.18%) Mean 0.18% SD 0.6% *Ovary: Cystadenoma 1/50 (2%)0/49 (0%)1/48 (2%)2/50 (4%)3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)2/48 (4%)2/50 (4%)(2%)1/50 **Overall Incidence** 16/545 (2.94%) Mean 2.93% SD 1.65% Total *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/49 0/48 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/48 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** 3/545 (0.55%) Mean 0.55% SD 0.95% Total *Ovary: **Granulosa Cell Tumor Malignant** (2%)0/49 0/48 (0%)1/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/48 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/545 (0.18%) Mean 0.18% SD 0.6%

Page: 27

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/48 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 4/545 (0.73%) Mean 0.73% SD 1.02% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)1/49 (2%)0/48 (0%)(0%)0/50 0/50 0/50 (0%)(0%)0/50 (0%)1/50 (2%)0/48 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** 2/545 (0.37%) Mean 0.37% SD 0.82% Total *Ovary: Hemangiosarcoma (2%)0/49 0/48 (0%)1/50 (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%)**Overall Incidence** 1/545 (0.18%) Mean 0.18% SD 0.6% Total *Ovary: Luteoma 0/50 (0%)0/49 0/48 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)(0%)2/50 0/48 0/50 (4%)(0%)0/50 (0%)0/50 (0%)Mean 0.55% **Overall Incidence** Total 3/545 (0.55%) SD 1.29%

Page: 28

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male				Female	
Ovary: Sarcoma							
					0/50 (0%)	0/49 (0%)	0/48 (0%)
					1/50 (2%)	0/50 (0%)	0/50 (0%)
					0/50 (0%)	0/50 (0%)	0/48 (0%)
					0/50 (0%)	0/50 (0%)	
Overall Incidence				Total	1/545 (0.18%)	Mean 0.18%	SD 0.6%
Ovary: Tubulostromal Adenoma							
					0/50 (0%)	0/49 (0%)	0/48 (0%)
					0/50 (0%)	1/50 (2%)	0/50 (0%)
					0/50 (0%)	0/50 (0%)	0/48 (0%)
					0/50 (0%)	0/50 (0%)	
Overall Incidence				Total	1/545 (0.18%)	Mean 0.18%	SD 0.6%
Ovary: Yolk Sac Carcinoma							
					0/50 (0%)	0/49 (0%)	1/48 (2%)
					0/50 (0%)	0/50 (0%)	0/50 (0%)
					0/50 (0%)	0/50 (0%)	0/48 (0%)
					0/50 (0%)	0/50 (0%)	
Overall Incidence				Total	1/545 (0.18%)	Mean 0.19%	SD 0.63%
Parathyroid Gland: Adenoma	 						
	0/27 (0%)	0/40 (0%)	0/29 (0%)		0/27 (0%)	0/38 (0%)	0/28 (0%)
	0/41 (0%)	0/48 (0%)	0/34 (0%)		0/35 (0%)	0/43 (0%)	0/26 (0%)
	0/28 (0%)	0/36 (0%)	0/48 (0%)		1/35 (3%)	0/36 (0%)	0/44 (0%)
	0/45 (0%)	0/44 (0%)	` ,		0/34 (0%)	0/45 (0%)	, ,
	` '	` '			` '	` '	

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

Page: 29

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 30

Report Date: 08/03/2016

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male			Female	
*Pituitary Gland: Pars Di	stalis or Unspec	cified Site:					
		0/49 (0%)	0/50 (0%)	0/47 (0%)	9/49 (18	3%) 2/49 (4%)	3/47 (6%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0	0%) 3/49 (6%)	5/50 (10%)
		1/50 (2%)	0/50 (0%)	0/47 (0%)	8/48 (17	7%) 4/50 (8%)	5/50 (10%)
		0/50 (0%)	0/50 (0%)		1/50 (2	2%) 2/49 (4%)	
Overall Incidence	Total	2/542 (0.37%)	Mean 0.37%	SD 0.82%	Total 42/541 (7.76°	%) Mean 7.79%	SD 5.72%
Pituitary Gland: Pars Di Carcinoma							
		0/49 (0%)	0/50 (0%)	0/47 (0%)	0/49 (0	0%) 0/49 (0%)	0/47 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0	0%) 0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/47 (0%)	3/48 (6	6%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0	0%) 0/49 (0%)	
Overall Incidence	Total	0/542 (0%)	Mean 0%	SD 0%	Total 3/541 (0.55%	%) Mean 0.57%	SD 1.88%
Pituitary Gland: Pars Di Carcinoma or Adenom	stalis or Unspec						
		0/49 (0%)	0/50 (0%)	0/47 (0%)	9/49 (18	3%) 2/49 (4%)	3/47 (6%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0	0%) 3/49 (6%)	5/50 (10%)
		1/50 (2%)	0/50 (0%)	0/47 (0%)	11/48 (23	3%) 4/50 (8%)	5/50 (10%)
		0/50 (0%)	0/50 (0%)		1/50 (2	2%) 2/49 (4%)	
Overall Incidence	Total	2/542 (0.37%)	Mean 0.37%	SD 0.82%	Total 45/541 (8.32°	′	SD 6.88%
Pituitary Gland: Pars Int Adenoma							
		0/49 (0%)	0/50 (0%)	0/47 (0%)	0/49 (0	0%) 0/49 (0%)	0/47 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)	`	0%) 1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/47 (0%)	,	0%) 0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	··· (-,-)	(0%) 0/49 (0%)	(-,-/
Overall Incidence	Total	0/542 (0%)	Mean 0%	SD 0%	Total 1/541 (0.18%	, , ,	SD 0.62%
, voi all illolacilos	iotal	0/072 (0/0)	WCair 070	35 070	15141 (0.107	o, wican 0.1970	OD 0.0270

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pituitary Gland: Pars Intermedia: Carcinoma 0/49 (0%)0/50 (0%)0/47 (0%)0/49 (0%)1/49 (2%)0/47 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence 0/542 (0%) Mean 0% SD 0% 1/541 (0.18%) Mean 0.19% SD 0.62% Total Total *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma (0%)0/49 (0%)0/50 (0%)0/47 0/49 (0%)1/49 (2%)0/47 (0%)0/49 (0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)1/49 (2%)(0%)0/50 (0%)0/50 (0%)0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** 0/542 (0%) Mean 0% SD 0% 2/541 (0.37%) Mean 0.37% SD 0.83% Total Total *Pituitary Gland: Pars Intermedia: **Schwannoma Malignant** 0/49 (0%)0/50 (0%)0/47 (0%)(0%)0/49 0/47 (0%)0/49 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/49 (0%)**Overall Incidence** 1/542 (0.18%) Mean 0.18% SD 0.6% 0/541 (0%) Mean 0% SD 0% Total Total *Salivary Glands: Adenoma 0/50 (0%)0/50 (0%) 0/49 0/50 (0%)(0%)0/50 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 0/50 0/50 0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/547 (0%) Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% Total 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/48 (0%)	
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/547 (0.18%)	Mean 0.18%	SD 0.6%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	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%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/547 (0.18%)	Mean 0.18%	SD 0.6%
Salivary Glands: Hemangiosarcoma								
		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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/547 (0%)	Mean 0%	SD 0%
Salivary Glands: Myxosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	` '		0/50 (0%)	0/48 (0%)	, ,
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/547 (0.18%)	Mean 0.18%	SD 0.6%

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

Page: 32

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Seminal Vesicle: Adenoma								
		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%)					
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%				
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Skeletal Muscle: Rhabdomyosarcoma								
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	5/550 (0.91%)	Mean 0.91%	SD 1.64%
Skeletal Muscle: Rhabdomyosarcoma or I								
,		0/50 (0%)	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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	(')		0/50 (0%)	0/50 (0%)	, ,
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	5/550 (0.91%)	Mean 0.91%	SD 1.64%

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

Page: 33

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#Skeletal Muscle: Sarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 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	0/550 (0%)	Mean 0% SD 0%	Total 1/550 (0.18%) Mean 0.18% SD 0.6%
#Skin: Basal Cell Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/550 (0%)	Mean 0% SD 0%	Total 2/550 (0.36%) Mean 0.36% SD 0.81%
#Skin:		s Tumor (malignant or NO		
	•	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/550 (0%)	Mean 0% SD 0%	Total 2/550 (0.36%) Mean 0.36% SD 0.81%
#Skin:	esal Cell Aden	oma, Basosquamous Tum	or (banian malianant or	
NOS), or Trichoepithelion		Jilia, Dasosqualilous Tulli	or (benign, manghant or	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/550 (0%)	Mean 0% SD 0%	Total 2/550 (0.36%) Mean 0.36% SD 0.81%

......

Page: 34

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin:								,
Basal or Sq. Cell Carcin Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	ia, Basosq. Tumor (M o eratoacanthoma, Tricho	r B), Basal Cell Adenor epithelioma	na,				
		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%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	3/550 (0.55%)	Mean 0.55%	SD 0.93%
Skin:		•••••				•••••		
Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or	Fibrous Histiocytoma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	5/550 (0.91%)	Mean 0.91%	SD 1.04%	Total	12/550 (2.18%)	Mean 2.18%	SD 2.44%
Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	3/550 (0.55%)	Mean 0.55%	SD 0.93%
#Skin:	•••••							
Fibrosarcoma, Sarcom	a, Myxosarcoma	a, or Fibrous Histiocyto	ma					
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	, ,		1/50 (2%)	4/50 (8%)	` '
Overall Incidence	Total	5/550 (0.91%)	Mean 0.91%	SD 1.04%	Total	12/550 (2.18%)	Mean 2.18%	SD 2.44%

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

Page: 35

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 36

Report Date: 08/03/2016

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)1/50 (2%)0/50 (0%)3/50 (6%)Overall Incidence Total 2/550 (0.36%) Mean 0.36% SD 0.81% 4/550 (0.73%) Mean 0.73% SD 1.85% Total #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)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%)(0%)1/50 0/50 **Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Skin: Hemangiosarcoma 0/50 (0%)0/50 0/50 (0%)(2%)0/50 0/50 (0%)(0%)1/50 (0%)0/50 (0%)(0%)(0%)(0%)2/50 (4%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 1/50 (2%)(2%)1/50 1/50 Overall Incidence 3/550 (0.55%) Mean 0.55% SD 1.29% 5/550 (0.91%) Mean 0.91% SD 1.38% Total Total #Skin: Keratoacanthoma 0/50 0/50 (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(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 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.6%

......

Total

0/550 (0%)

Mean 0%

SD 0%

Total

1/550 (0.18%)

Mean 0.18%

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

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Lipoma				- ()		- / / / / / / / / / /		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/550 (0.55%)	1/50 (2%) Mean 0.55%	SD 1.29%	Total	0/50 (0%) 0/550 (0%)	0/50 (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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Skin:								
Neurofibrosarcoma or S	chwannoma (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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)		` '		` ,	` ,	` '
		0/30 (0%)	0/50 (0%)			1/50 (2%)	3/50 (6%)	

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

Page: 37

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male			·	Female	
#Skin:								
Neurofibrosarcoma, Neu	ırofibroma, or S	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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T	0/50 (0%)	0/50 (0%)	OD 00/	.	1/50 (2%)	3/50 (6%)	05 4 050/
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	4/550 (0.73%)	Mean 0.73%	SD 1.85%
#Skin: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	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%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	5/550 (0.91%)	Mean 0.91%	SD 1.38%
#Skin: Schwannoma Malignant								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	3/50 (6%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	4/550 (0.73%)	Mean 0.73%	SD 1.85%
#Skin: Squamous Cell Carcino	ma, Basal Cell	Carcinoma, Basosquamoı	us Tumor (malignant o	or NOS),				
or Carcinoma	•	•	` •	•				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%

......

Page: 38

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

					Male						F	emale		
Skin:									,					
Squamous Cell Papillo	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%)
		0/50	(0%)	0/50	(0%)	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	0/550 (0%		Mean	0%	SD 0%		Total	1/550 (0.	18%)	Mean	0.18%	SD 0	.6%
Skin:														
Squamous Cell Papillo	ma or Papilloma	l												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	0/550 (0%	,	Mean		SD 0%		Total	1/550 (0.	,		0.18%	SD 0	
Skin:														
•	Danillania C	Squamous Cell (Carcinom	a or Keratoa	canthoma	1								
Squamous Cell Papillo	ıma, Papılloma, S						(00/)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Squamous Cell Papillo	oma, Papilloma, S	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50		0/30			
Squamous Cell Papillo	oma, Papilloma, S	-	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Squamous Cell Papillo	ота, Раршота, з	0/50	` ,		` ,		` '			` '		(0%) (0%)		(2%) (0%)
Squamous Cell Papillo	ота, Раршота, з	0/50 0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	` '	1/50	` ,
	ma, Papilloma, S Total	0/50 0/50 0/50	(0%) (0%) (2%)	0/50 0/50	(0%) (0%) (0%)	0/50	(0%) (0%)	Total	0/50 0/50	(0%) (0%) (0%)	0/50 0/50 0/50	(0%)	1/50	(0%)
Overall Incidence		0/50 0/50 0/50 1/50 1/550 (0.189	(0%) (0%) (2%)	0/50 0/50 0/50 Mean 0	(0%) (0%) (0%)	0/50 0/50	(0%) (0%)	Total	0/50 0/50 0/50	(0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%)	1/50 0/50	(0%)
Overall Incidence Skin:	Total	0/50 0/50 0/50 1/50 1/550 (0.18	(0%) (0%) (2%) %)	0/50 0/50 0/50 Mean 0	(0%) (0%) (0%)	0/50 0/50	(0%) (0%)	Total	0/50 0/50 0/50	(0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%)	1/50 0/50	(0%)
Overall Incidence	Total	0/50 0/50 0/50 1/50 1/550 (0.189	(0%) (0%) (2%) %) oma	0/50 0/50 0/50 0/50 Mean 0.	(0%) (0%) (0%) 18%	0/50 0/50 SD 0.6%	(0%) (0%)	Total	0/50 0/50 0/50 1/550 (0.	(0%) (0%) (0%) 18%)	0/50 0/50 0/50 Mean	(0%) (0%) 0.18%	1/50 0/50 SD 0	(0%) .6%
Overall Incidence	Total	0/50 0/50 0/50 1/50 1/550 (0.18°	(0%) (0%) (2%) %) oma (0%)	0/50 0/50 0/50 0/50 Mean 0.	(0%) (0%) (0%) 18% 	0/50 0/50 SD 0.6% 0/50	(0%) (0%) 	Total	0/50 0/50 0/50 1/550 (0.	(0%) (0%) (0%) 18%) 	0/50 0/50 0/50 Mean 0/50	(0%) (0%) 0.18%	1/50 0/50 SD 0	(0%)
Overall Incidence #Skin:	Total	0/50 0/50 0/50 1/50 1/550 (0.189	(0%) (0%) (2%) %) oma	0/50 0/50 0/50 0/50 Mean 0.	(0%) (0%) (0%) 18%	0/50 0/50 SD 0.6%	(0%) (0%)	Total	0/50 0/50 0/50 1/550 (0.	(0%) (0%) (0%) 18%)	0/50 0/50 0/50 Mean	(0%) (0%) 0.18%	1/50 0/50 SD 0	(0%) .6%

SD 0.6%

Total

1/550 (0.18%)

Mean 0.18%

Total

1/550 (0.18%)

Overall Incidence

Page: 39

Mean 0.18%

SD 0.6%

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

	Male					Female			
*Spleen:									
Hemangiosarcoma		2/49 (4%)	0/48 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/49 (4%)	
		2/49 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)	2/50 (4%)	1/30 (2/0)		1/50 (2%)	0/49 (0%)	0/30 (0/0)	
Overall Incidence	Total	13/546 (2.38%)	Mean 2.37%	SD 1.97%	Total	5/548 (0.91%)	Mean 0.92%	SD 1.39%	
*Spleen:			•••••			•••••			
Mast Cell Tumor Malignant									
J		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (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	0/546 (0%)	Mean 0%	SD 0%	Total	1/548 (0.18%)	Mean 0.19%	SD 0.62%	
#Stomach, Forestomach: Squamous Cell Carcinoma									
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	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%)	, ,		0/50 (0%)	0/50 (0%)	, ,	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	
#Stomach, Forestomach:									
Squamous Cell Carcinoma	or Papillom	na Squamous							
•	•	1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
			` '						
		5/50 (10%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		

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

Page: 40

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
#Stomach, Forestomach: Squamous Cell Papilloma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%) 1/50 (2%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%) 0/50 (0%)	
		1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%) 0/50 (0%)	
		5/50 (10%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	11/550 (2%)	Mean 2%	SD 2.97%	Total 7/550 (1.27%)	Mean 1.27% SD 1.01%	
#Stomach, Glandular: Carcinoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total 0/550 (0%)	Mean 0% SD 0%	
#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%)	1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total 0/550 (0%)	Mean 0% SD 0%	
*Testes:							
7.000		0/49 (0%)	0/49 (0%)	1/50 (2%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	2/50 (4%)			
		0/50 (0%)	1/50 (2%)	()			
Overall Incidence	Total	5/548 (0.91%)	Mean 0.91%	SD 1.38%			
		0 . 0 (0.0 . 70)					

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

Page: 41

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Thymus: **Neoplasm NOS** 0/41 (0%)0/43 (0%)0/42 (0%)0/47 (0%)0/47 (0%)1/46 (2%)(0%)0/44(0%)0/49(0%)0/41 (0%)0/47 0/49 (0%)0/44 (0%)0/44 (0%)0/48 (0%)0/40 (0%)0/48 (0%)0/50 (0%)0/48 (0%)(0%)0/47 (0%)0/45 0/50 (0%)0/50 (0%)Overall Incidence Total 0/484 (0%) Mean 0% SD 0% 1/526 (0.19%) Mean 0.2% SD 0.66% Total *Thymus: **Thymoma Benign** (0%)0/41 (0%)0/43 (0%)0/42 0/47 (0%)0/47 (0%)0/46 (0%)0/44 (0%)1/49 (2%)(0%)0/44 (0%)0/41 0/47 (0%)0/49 (0%)0/48 0/44 (0%)0/48 (0%)0/40 (0%)(0%)0/50 (0%)0/48 (0%)0/47 (0%)0/45 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/484 (0.21%) Mean 0.19% SD 0.62% 0/526 (0%) Mean 0% SD 0% Total Total *Thymus: **Thymoma NOS** 0/41 (0%)0/43 (0%)0/42 (0%)(2%)0/47 0/46 (0%)1/47 (0%)0/44 (0%)0/49 (0%)(0%)0/47 (0%)0/49 0/44 (0%)0/41 (0%)0/44 (0%)0/48 (0%)0/40 (0%)0/48 (0%)0/50 (0%)0/48 (0%)0/47 (0%)0/45 (0%) 0/50 (0%)0/50 (0%)Overall Incidence Total 0/484 (0%) Mean 0% SD 0% 1/526 (0.19%) Mean 0.19% SD 0.64% Total *Thymus: Thymoma: Benign, Malignant, NOS 0/41 (0%)0/43 (0%)0/42 (0%) (2%)0/47 0/46 (0%)1/47 (0%)0/44(0%)1/49 (2%)0/41 (0%)0/47 (0%)0/49 (0%)0/44 (0%)0/44 (0%)(0%)0/50 0/48 0/48 0/40 (0%)0/48 (0%)(0%)(0%)(0%)0/47 0/45 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/484 (0.21%) Mean 0.19% SD 0.62% Total 1/526 (0.19%) Mean 0.19% SD 0.64%

......

Page: 42

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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%)	
Overall Incidence	Total	0/548 (0%)	Mean 0%	SD 0%	Total	1/547 (0.18%)	Mean 0.18%	SD 0.6%
Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		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%)	
Overall Incidence	Total	0/548 (0%)	Mean 0%	SD 0%	Total	2/547 (0.37%)	Mean 0.36%	SD 0.81%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
	Total	0/548 (0%)	Mean 0%	SD 0%	Total	3/547 (0.55%)	Mean 0.55%	SD 0.93%
Thyroid Gland: Follicular Cell: Adenoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	(/		0/50 (0%)	0/49 (0%)	(/
Overall Incidence	Total	3/548 (0.55%)	Mean 0.55%	SD 0.93%	Total	4/547 (0.73%)	Mean 0.73%	SD 1.01%

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

Page: 43

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male				Female						
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma												
		0/49 (0%)	0/50 (0%)	0/49 (0%)	0/48 (0%	(a) 1/50 (2%) 1	1/50 (2%)					
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%	%) 1/50 (2%) (0/50 (0%)					
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%	6) 0/50 (0%)	1/50 (2%)					
		0/50 (0%)	1/50 (2%)		0/50 (0%	6) 0/49 (0%)						
Overall Incidence	Total	3/548 (0.55%)	Mean 0.55%	SD 0.93%	Total 4/547 (0.73%)	Mean 0.73%	SD 1.01%					
#Tongue:												
Squamous Cell Carcine	oma or Papillom	na Squamous										
		0/50 (0%)	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%)	0/50 (0%	%) 0/50 (0%) 0	0/50 (0%)					
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%	6) 0/50 (0%) 0	0/50 (0%)					
		0/50 (0%)	0/50 (0%)		1/50 (2%	%) 0/50 (0%)						
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total 1/550 (0.18%)	Mean 0.18%	SD 0.6%					
#Tongue: Squamous Cell Papillo												
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%	6) 0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%	6) 0/50 (0%)	0/50 (0%)					
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%	6) 0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)		1/50 (2%	%) 0/50 (0%)						
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total 1/550 (0.18%)	Mean 0.18%	SD 0.6%					
#Tooth: Odontoma			•••••	•••••			•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%	6) 0/50 (0%) (0/50 (0%)					
		0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)		0/50 (0%	, , ,	()					
Overall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 1.21%	Total 0/550 (0%)	Mean 0%	SD 0%					
O TOTALI IIIOIGOTIOO	iotai	2,000 (0.0070)	1,10411 0.0070	35 1.2170	10101 07000 (070)	Wicaii 070	CD 0/0					

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

Page: 44

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Urethra: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total *Urinary Bladder: Hemangiosarcoma (0%)0/50 (0%)0/49 (0%)0/48 0/50 (0%)0/50 (0%)0/49 (0%)(0%)(0%)(2%)0/50 0/50 0/50 1/50 0/50 (0%)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%)(0%)(0%)0/50 0/50 **Overall Incidence** 1/547 (0.18%) Mean 0.18% SD 0.6% 0/548 (0%) SD 0% Total Total Mean 0% #Uterus: Adenoma 0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% Total #Uterus: **Granular Cell Tumor Benign** 0/50 0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/550 (0.18%) Mean 0.18% SD 0.6%

Page: 45

^{*:} 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: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

	Male		Female	
tUterus:				
Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (00/)
		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%)
n canall In aidem as	Tatal	0/50 (0%)	0/50 (0%)	CD 0 C0/
verall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Uterus:				
Hemangiosarcoma				
·		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	, ,
Overall Incidence	Total	5/550 (0.91%)	Mean 0.91%	SD 1.04%
Uterus:				
Leiomyoma				
Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Uterus:				
Polyp Stromal		4/EO (00/)	0/50 (00/)	0/50 (40/)
		4/50 (8%)	0/50 (0%)	2/50 (4%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	4/50 (8%)	00.000/
overall Incidence	Total	13/550 (2.36%)	Mean 2.36%	SD 3.2%

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

Page: 46

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male					Female	
#Uterus: Sarcoma Stromal									
							0/50 (0%)	0/50 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
							2/50 (4%)	0/50 (0%)	
Overall Incidence						Total	2/550 (0.36%)	Mean 0.36%	SD 1.21%
Uterus: Sarcoma Stromal or Poly	p Stromal								
							4/50 (8%)	0/50 (0%)	2/50 (4%)
							2/50 (4%)	0/50 (0%)	0/50 (0%)
							1/50 (2%)	0/50 (0%)	0/50 (0%)
							2/50 (4%)	4/50 (8%)	
Overall Incidence						Total	15/550 (2.73%)	Mean 2.73%	SD 3.13%
‡Zymbal's Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50	(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	, D	Total	0/550 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		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%)	

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

Page: 47

^{#:} Denominator is number of animals necropsied