

NTP Historical Controls Report

All Routes and Vehicles

MICE

November 2019

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: 11/01/2019

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

Length of Study: CHRONIC

Study Summary

					ay Sammary		
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 Columbus Laboratory	051098702	08/17/10	730	50(1)	44(722)	48.9	Dibutyl Phthalate
Battelle Columbus Laboratory	052020304	07/10/07	730	50(1)	33(694)	52.6	Green Tea Extract
Battelle Columbus Laboratory	051026002	07/16/10	727	49(1)	34(691)	47.6	2-Hydroxy-4-methoxybenzophenone
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 (Technica Grade)]
I. I. T. Research Institute	052010578	06/18/12	729	90(1)	66(687)	51.5	Radiofrequency Radiation
Battelle Columbus Laboratory	050303804	01/17/12	730	50(1)	26(683)	54.6	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					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 Columbus Laboratory	051098702	08/16/10	729	50(4)	42(713)	51.5	Dibutyl Phthalate
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green Tea Extract
Battelle Columbus Laboratory	051026002	07/15/10	726	50(4)	42(716)	54.7	2-Hydroxy-4-methoxybenzophenone
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 (Technica Grade)]
I. I. T. Research Institute	052010578	06/18/12	739	90(1)	67(704)	62.6	Radiofrequency Radiation
Battelle Columbus Laboratory	050303804	01/16/12	729	50(4)	38(700)	61.6	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Species: MICE

Strain: B6C3F1/N

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					
#All Organs: Benign Tumors											
		37/50 (74%)	22/50 (44%)	26/50 (52%)		25/50 (50%)	15/50 (30%)	13/50 (26%)			
		43/50 (86%)	28/49 (57%)	33/50 (66%)		20/50 (40%)	17/50 (34%)	17/50 (34%)			
		39/50 (78%)	32/50 (64%)	32/50 (64%)		26/50 (52%)	23/50 (46%)	24/50 (48%)			
		30/50 (60%)	61/90 (68%)	31/50 (62%)		24/50 (48%)	36/90 (40%)	20/50 (40%)			
		38/50 (76%)				22/50 (44%)					
Overall Incidence	Total	452/689 (65.6%)	Mean 65.46%	SD 11.28%	Total	282/690 (40.87%)	Mean 40.92%	SD 8.07%			
#All Organs: Malignant Tumors											
		25/50 (50%)	27/50 (54%)	19/50 (38%)		25/50 (50%)	24/50 (48%)	19/50 (38%)			
		28/50 (56%)	19/49 (39%)	27/50 (54%)		18/50 (36%)	11/50 (22%)	19/50 (38%)			
		26/50 (52%)	32/50 (64%)	25/50 (50%)		30/50 (60%)	27/50 (54%)	24/50 (48%)			
		27/50 (54%)	49/90 (54%)	30/50 (60%)		16/50 (32%)	33/90 (37%)	15/50 (30%)			
		21/50 (42%)				18/50 (36%)					
Overall Incidence	Total	355/689 (51.52%)	Mean 51.32%	SD 7.72%	Total	279/690 (40.43%)	Mean 40.67%	SD 10.64%			
#All Organs: Malignant and Benign ⁻	Tumors			20/20 (200:)				20/20 /25:			
		45/50 (90%)	` ,	33/50 (66%)		35/50 (70%)	34/50 (68%)	28/50 (56%)			
		49/50 (98%)	37/49 (76%)	48/50 (96%)		29/50 (58%)	25/50 (50%)	30/50 (60%)			
		46/50 (92%)	42/50 (84%)	44/50 (88%)		41/50 (82%)	38/50 (76%)	38/50 (76%)			
		40/50 (80%)	79/90 (88%)	42/50 (84%)		34/50 (68%)	59/90 (66%)	32/50 (64%)			
	_	47/50 (94%)			_	32/50 (64%)					
Overall Incidence	Total	589/689 (85.49%)	Mean 85.33%	SD 9.4%	Total	455/690 (65.94%)	Mean 65.97%	SD 8.87%			
#All Organs: Hemangioma											
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		2/50 (4%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	1/90 (1%)	1/50 (2%)		1/50 (2%)	4/90 (4%)	0/50 (0%)			
		2/50 (4%)	, ,	, ,		1/50 (2%)	, ,	, ,			
Overall Incidence	Total	8/689 (1.16%)	Mean 1.17%	SD 1.52%	Total	11/690 (1.59%)	Mean 1.42%	SD 1.57%			

Page: 4

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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					
#All Organs: Hemangiosarcoma											
		2/50 (4%)	1/50 (2%)	3/50 (6%)		4/50 (8%)	0/50 (0%)	3/50 (6%)			
		5/50 (10%)	1/49 (2%)	4/50 (8%)		2/50 (4%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	2/50 (4%)	3/50 (6%)			
		1/50 (2%) 1/50 (2%)	2/90 (2%)	5/50 (10%)		0/50 (0%) 1/50 (2%)	2/90 (2%)	1/50 (2%)			
Overall Incidence	Total	28/689 (4.06%)	Mean 4.17%	SD 3.3%		21/690 (3.04%)	Mean 3.09%	SD 2.78%			
#All Organs: Hemangiosarcoma or He											
G	J	2/50 (4%)	1/50 (2%)	3/50 (6%)		4/50 (8%)	0/50 (0%)	4/50 (8%)			
		7/50 (14%)	2/49 (4%)	4/50 (8%)		2/50 (4%)	2/50 (4%)	1/50 (2%)			
		2/50 (4%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	3/50 (6%)	3/50 (6%)			
		1/50 (2%)	3/90 (3%)	6/50 (12%)		1/50 (2%)	6/90 (7%)	1/50 (2%)			
		3/50 (6%)				2/50 (4%)					
Overall Incidence	Total	36/689 (5.22%)	Mean 5.34%	SD 3.97%	Total	32/690 (4.64%)	Mean 4.51%	SD 2.51%			
#All Organs: Histiocytic Sarcoma											
-		1/50 (2%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	1/50 (2%)	1/50 (2%)			
		0/50 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	4/50 (8%)	2/50 (4%)			
		1/50 (2%)	0/90 (0%)	1/50 (2%)		1/50 (2%)	8/90 (9%)	2/50 (4%)			
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	8/689 (1.16%)	Mean 1.23%	SD 1.54%		27/690 (3.91%)	Mean 3.61%	SD 2.61%			
#All Organs:											
Malignant Lymphoma: H	listiocytic, Lyn	nphocytic, Mixed, NOS, o	r Undifferentiated Cell	l Type							
		4/50 (8%)	6/50 (12%)	4/50 (8%)		7/50 (14%)	9/50 (18%)	11/50 (22%)			
		4/50 (8%)	3/49 (6%)	3/50 (6%)		7/50 (14%)	5/50 (10%)	6/50 (12%)			
		3/50 (6%)	6/50 (12%)	6/50 (12%)		18/50 (36%)	10/50 (20%)	9/50 (18%)			
		5/50 (10%)	6/90 (7%)	5/50 (10%)		7/50 (14%)	2/90 (2%)	4/50 (8%)			
		3/50 (6%)				9/50 (18%)					

Page: 5

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

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** #All Organs: **Malignant Schwannoma** 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%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/90 (0%)1/50 (2%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 2/689 (0.29%) Mean 0.31% SD 0.75% Total 1/690 (0.14%) Mean 0.15% SD 0.55% **#All Organs:** Osteosarcoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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 0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)3/90 (3%)(0%)(0%) 0/50 0/50 (0%)**Overall Incidence** Total 0/689 (0%) Mean 0% SD 0% Total 3/690 (0.43%) Mean 0.26% SD 0.92% **#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%)0/49 (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%)0/90 (0%) 0/50 (0%)3/90 0/50 0/50 (0%)(3%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/689 (0%) Mean 0% SD 0% Total 3/690 (0.43%) Mean 0.26% SD 0.92% *Adrenal Cortex: Adenoma 4/49 (8%)2/50 (4%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/49 (2%)1/48 (2%)0/50 (0%)0/49 (0%)0/50 (0%)2/49 (4%)0/50 9/49 (18%)3/50 (6%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/90 (0%)1/50 (2%)0/50 (0%)1/84 (1%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 22/685 (3.21%) Mean 3.43% SD 5.16% Total 5/681 (0.73%) Mean 0.71% SD 1.27%

Page: 6

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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					
Adrenal Medulla: Pheochromocytoma B	enign													
•	_	0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/49	(0%)
		0/49	(0%)	1/48	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
			(2%)	0/50	(0%)	0/50	(0%)		1/49	(2%)	2/50	(4%)	1/50	(2%)
			(2%) (0%)	0/90	(0%)	0/49	(0%)		0/49 1/50	(0%) (2%)	0/83	(0%)	0/50	(0%)
Overall Incidence	Total	3/683 (0.44%	b)	Mean 0	.47%	SD 0.9%		Total	6/678 (0	.88%)	Mean	0.93%	SD 1.	.32%
Adrenal Medulla: Pheochromocytoma M	lalignant													
•		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/48	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/49	(0%)		0/49	(0%)	2/83	(2%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/683 (0%)		Mean	0%	SD 0%		Total	2/678 (0	.29%)	Mean	0.19%	SD 0.	.67%
Adrenal Medulla: Pheochromocytoma: E	Benign, Complex	0/49 0/49 1/48 1/50	(0%) (0%) (2%) (2%) (2%) (0%)	0/50 1/48 0/50 0/90	(0%) (2%) (0%) (0%)	0/50 0/50 0/50 0/49	(0%) (0%) (0%) (0%)		0/50 0/49 1/49 0/49 1/50	(0%) (0%) (2%) (0%) (2%)	1/50 0/50 2/50 2/83	(2%) (0%) (4%) (2%)	0/49 0/49 1/50 0/50	(0%) (0%) (2%) (0%)
Overall Incidence	Total	3/683 (0.44%	,	Mean 0		SD 0.9%		Total	8/678 (1	,		1.11%	SD 1.	.35%
#Blood Vessel: Hemangioma														
-		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(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%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
		0/689 (0%)		Mean		SD 0%		Total	1/690 (0	4.40()		0.15%	SD 0.	/

Page: 7

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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											
3		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%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)			0/50 (0%)						
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total 1/690 (0.14%)	Mean 0.15%	SD 0.55%				
*Bone Marrow: Hemangiosarcoma											
		0/49 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	0/47 (0%)	1/50 (2%)	1/50 (2%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	2/50 (4%)	0/49 (0%)	0/90 (0%)	0/48 (0%)				
		0/50 (0%)			0/50 (0%)						
Overall Incidence	Total	4/684 (0.58%)	Mean 0.62%	SD 1.26%	Total 1/685 (0.15%)	Mean 0.15%	SD 0.55%				
*Bone Marrow: Mast Cell Tumor Malignant											
_		0/49 (0%)	1/48 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	1/47 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	1/50 (2%)	0/49 (0%)	0/90 (0%)	0/48 (0%)				
		0/50 (0%)			0/50 (0%)						
Overall Incidence	Total	4/684 (0.58%)	Mean 0.63%	SD 0.99%	Total 0/685 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Sarcoma											
		0/49 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/47 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)	0/49 (0%)	0/90 (0%)	0/48 (0%)				
		0/50 (0%)			0/50 (0%)						
Overall Incidence	Total	0/684 (0%)	Mean 0%	SD 0%	Total 1/685 (0.15%)	Mean 0.15%	SD 0.55%				

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

Page: 8

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Sele

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 9

			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%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%		
#Bone:										
Hemangioma										
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%		
#Bone: Hemangiosarcoma										
G		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	. ,	. ,		0/50 (0%)	, ,	. ,		
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%		
#Bone:										
Osteosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		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%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)		
O	T-1-1	0/50 (0%)	Maran 00/	OD 00/	T-1-1	0/50 (0%)	M 0.000′	00 0040/		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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						
#Bone:														
Osteosarcoma or Osteom	а													
		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/689 (0%	,	Mean	0%	SD 0%		Total	1/690 (0.	.14%)	Mean	0.09%	SD 0	.31%
Bone: Sarcoma														
		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%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/689 (0%	6)	Mean	0%	SD 0%		Total	1/690 (0.	14%)	Mean	0.15%	SD 0	.55%
Clitoral/Preputial Gland: Mast Cell Tumor														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/47	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/44	(0%)	0/46	(0%)	0/48	(0%)
		0/50	(0%)	1/89	(1%)	0/49	(0%)		0/49	(0%)	0/82	(0%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/686 (0.15		Mean 0	.09%	SD 0.319	%	Total	0/661 (0%)	Mea	ın 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%)	0/49	(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%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)		` ,		` '		0/50	(0%)		` '		` '
Overall Incidence	Total	1/689 (0.15	5%)	Mean 0	15%	SD 0.55%	%	Total	0/690 (0%)	Mea	ın 0%	SD	0%

Page: 10

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

			Male		Female					
Coagulating Gland:										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
verall Incidence	Total	0/50 (0%) 1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/50 (0%) 0/690 (0%)	Mean 0%	SD 0%		
		1/009 (0.15%)						JD 0%		
Epididymis: Mast Cell Tumor										
		0/50 (0%)	0/49 (0%)	0/50 (0%)						
		0/50 (0%)	0/49 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%)	1/90 (1%)	0/50 (0%)						
	T-1-1	0/50 (0%)	M 0.000/	OD 0.040/						
verall Incidence	Total	1/688 (0.15%)	Mean 0.09%	SD 0.31%						
Harderian Gland: Adenoma										
		6/50 (12%)	3/50 (6%)	3/50 (6%)		3/50 (6%)	3/50 (6%)	3/50 (6%)		
		7/50 (14%)	6/49 (12%)	6/50 (12%)		2/50 (4%)	1/50 (2%)	3/50 (6%)		
		7/50 (14%)	4/50 (8%)	5/50 (10%)		2/50 (4%)	1/50 (2%)	2/50 (4%)		
		5/50 (10%)	6/90 (7%)	2/50 (4%)		9/50 (18%)	4/90 (4%)	1/50 (2%)		
verall Incidence	Total	7/50 (14%)	Mean 9.92%	SD 3.46%	Total	2/50 (4%)	Mean 5.26%	SD 4.12%		
	Total	67/689 (9.72%)			Total	36/690 (5.22%)		SD 4.12%		
Harderian Gland: Carcinoma										
		1/50 (2%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	0/50 (0%)		
		1/50 (2%)	1/49 (2%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)		
		5/50 (10%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	3/50 (6%)	0/50 (0%)		
		1/50 (2%)	3/90 (3%)	1/50 (2%)		1/50 (2%)	0/90 (0%)	0/50 (0%)		
		1/50 (2%)				1/50 (2%)				
verall Incidence	Total	19/689 (2.76%)	Mean 2.72%	SD 2.36%	Total	13/690 (1.88%)	Mean 2%	SD 2.58%		

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

Page: 11

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Harderian Gland: Carcinoma or Adenoma 7/50 (14%)3/50 (6%)4/50 (8%)7/50 (14%)4/50 (8%)3/50 (6%)8/50 (16%)7/49 (14%)7/50 (14%)4/50 (8%)2/50 (4%)3/50 (6%)12/50 (24%)6/50 (12%)6/50 (12%)2/50 (4%)4/50 (8%)2/50 (4%)6/50 (12%)9/90 (10%)3/50 (6%)(20%)4/90 (4%)1/50 (2%)10/50 8/50 (16%)3/50 (6%)**Overall Incidence** Total 86/689 (12.48%) Mean 12.64% SD 4.8% Total 49/690 (7.1%) Mean 7.26% SD 4.84% #Harderian Gland: **Mast Cell Tumor** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(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 0/50 (0%)1/90 (1%)0/50 (0%)0/50 (0%)0/90 (0%)(0%)(0%) 0/50 0/50 (0%)SD 0.31% **Overall Incidence** Total 1/689 (0.15%) Mean 0.09% Total 0/690 (0%) Mean 0% SD 0% *Heart: Hemangiosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/90 0/50 (0%)0/90 0/50 0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/689 (0.15%) Mean 0.15% SD 0.55% Total 0/690 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Leiomvosarcoma 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%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

1/690 (0.14%)

Mean 0.15%

SD 0.55%

Total

0/689 (0%)

Mean 0%

Overall Incidence

Page: 12

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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: Duodenum Adenoma	ո։									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	7/689 (1.02%)	Mean 1.08%	SD 1.75%	Total	2/690 (0.29%)	Mean 0.31%	SD 0.75%		
Intestine Small: Duodenum Carcinoma	1:									
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%		
fintestine Small: Duodenum Polyp Adenomatous										
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%		
fintestine Small: Ileum: Adenoma				•••••						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (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%)	1/50 (2%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	()	(-/		0/50 (0%)	` '	(/		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%		

Page: 13

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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: Jejunum: Adenoma									
		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%)	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%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)	
verall Incidence	Total	2/689 (0.29%)	Mean 0.31%	SD 0.75%	Total	0/690 (0%)	Mean 0%	SD 0%	
Intestine Small: Jejunum: Carcinoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	2/90 (2%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
verall Incidence	Total	8/689 (1.16%)	Mean 1.09%	SD 1.33%	Total	0/690 (0%)	Mean 0%	SD 0%	
Intestine Small: Jejunum: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)	
verall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	2/690 (0.29%)	Mean 0.31%	SD 0.75%	
Intestine Small: Jejunum: Mast Cell Tumor									
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%) 0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)	
	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%	

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

Page: 14

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 11/01/2019

Page: 15

Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Intestine Small: Site Unsp Adenoma	ecified:							
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)				1/50 (2%)		
verall Incidence	Total	9/689 (1.31%)	Mean 1.38%	SD 2.06%	Total	3/690 (0.43%)	Mean 0.46%	SD 0.88%
ntestine Small: Site Unsp Carcinoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/90 (3%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
verall Incidence	Total	9/689 (1.31%)	Mean 1.18%	SD 1.44%	Total	0/690 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Carcinoma or Adenoma								
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/49 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	3/90 (3%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		2/50 (4%)				1/50 (2%)		
verall Incidence	Total	18/689 (2.61%)	Mean 2.56%	SD 2.19%	Total	3/690 (0.43%)	Mean 0.46%	SD 0.88%
ntestine Small: Site Unsp Leiomyosarcoma								
-		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%)		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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	• •	, ,
	Total	0/689 (0%)						

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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						F	Female		
Intestine Small: Site Uns Mast Cell Tumor	pecified:													
		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/90	(1%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/689 (0.15	,	Mean 0		SD 0.319		Total	0/690 (,		n 0%	SD	
Intestine Small: Site Uns Polyp Adenomatous														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/689 (0.15	5%)	Mean 0	.15%	SD 0.559	%	Total	0/690 (0%)	Mea	n 0%	SD	0%
Islets, Pancreatic: Adenoma														
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)	1/47	(2%)	1/50	(2%)		1/50	(2%)	0/49	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/88	(0%)	1/47	(2%)		1/50	(2%)	0/87	(0%)	0/48	(0%)
		0/50	(0%)		` ,		` ,		0/50	(0%)		, ,		` ,
Overall Incidence	Total	8/679 (1.18	3%)	Mean 1	.25%	SD 1.319	%	Total	3/683 (0.	44%)	Mean	0.46%	SD 0.	.88%
Islets, Pancreatic:														
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)	0/47	(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%)	0/88	(0%)	0/47	(0%)		0/50	(0%)	1/87	(1%)	0/48	(0%)
		0/50	(0%)	3, 30	(-,-,	-, -,	(= / = /		0/50	(0%)		(· · · · ·)		(-,-)
Overall Incidence	Total	1/679 (0.15	` ,	Mean 0	150/	SD 0.559	1/	Total	1/683 (0.	` ,	Maan	0.09%	SD 0.	220/

Page: 16

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
Islets, Pancreatic: Carcinoma or Adenoma								
		0/49 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	1/47 (2%)	1/50 (2%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	0/88 (0%)	1/47 (2%)		1/50 (2%) 0/50 (0%)	1/87 (1%)	0/48 (0%)
Overall Incidence	Total	9/679 (1.33%)	Mean 1.4%	SD 1.51%	Total	4/683 (0.59%)	Mean 0.55%	SD 0.88%
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%)	0/48 (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%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	2/89 (2%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/687 (0.15%)	Mean 0.15%	SD 0.55%	Total	3/687 (0.44%)	Mean 0.33%	SD 0.8%
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%)	0/48 (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%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/687 (0.29%)	Mean 0.31%	SD 1.11%	Total	1/687 (0.15%)	Mean 0.15%	SD 0.55%
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%)	0/48 (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%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	2/89 (2%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	3/687 (0.44%)	Mean 0.46%	SD 1.66%	Total	4/687 (0.58%)	Mean 0.48%	SD 0.92%

.....

Page: 17

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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						F	emale		
Kidney: Renal Tubule: Hemangiosarcoma													
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	1/50	(2%)		0/50	(0%)	0/89	(0%)	0/50	(0%)
		0/50 (0%	,	= 0.				0/50	(0%)				
Overall Incidence	Total	1/687 (0.15%)	Mean (SD 0.55%		Total	0/687 (n 0%	SD	
Kidney: Renal Tubule: Mast Cell Tumor													
		0/50 (0%	6) 0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	,	(1%)	0/50	(0%)		0/50	(0%)	0/89	(0%)	0/50	(0%)
		0/50 (0%	%)					0/50	(0%)				
Overall Incidence	Total	1/687 (0.15%)	Mean (SD 0.31%		Total	0/687 (0%)	Mea	n 0%	SD	0%
Kidney: Renal Tubule: Renal Mesenchymal Tumo													
		0/50 (0%	6) 0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	6) 0/48	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	6) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	1/89	(1%)	0/50	(0%)
		0/50 (0%	%)					0/50	(0%)				
Overall Incidence	Total	0/687 (0%)	Mean		SD 0%		Total	1/687 (0.	,		0.09%	SD 0	.31%
Liver: Cholangiocarcinoma													
		1/50 (29	6) 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%)	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%)	1/50	(2%)		0/50	(0%)	0/89	(0%)	0/50	(0%)
		0/50 (0%	,	(-,-,	., 20	(-/-/		0/50	(0%)		(-,-)	0	(-,-,
Overall Incidence	Total	2/689 (0.29%)	Mean (31%	SD 0.75%	6	Total	0/689 (, ,	Mea	n 0%	SD	0%

Page: 18

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
*Liver: Hemangioma								
······································		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	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%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		2/50 (4%)	(****)	(,		0/50 (0%)	()	(111)
Overall Incidence	Total	5/689 (0.73%)	Mean 0.77%	SD 1.54%	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%
*Liver: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	0/49 (0%)	4/50 (8%)		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%)	1/90 (1%)	2/50 (4%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	13/689 (1.89%)	Mean 1.93%	SD 2.95%	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%
*Liver: Hepatoblastoma								
•		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	1/49 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	6/90 (7%)	4/50 (8%)		0/50 (0%)	1/89 (1%)	0/50 (0%)
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	23/689 (3.34%)	Mean 3.13%	SD 2.6%	Total	4/689 (0.58%)	Mean 0.55%	SD 0.88%
*Liver: Hepatocellular Adenoma								
-		30/50 (60%)	17/50 (34%)	18/50 (36%)		11/50 (22%)	6/50 (12%)	3/50 (6%)
		35/50 (70%)	21/49 (43%)	26/50 (52%)		12/50 (24%)	3/50 (6%)	7/50 (14%)
		24/50 (48%)	23/50 (46%)	25/50 (50%)		14/50 (28%)	9/50 (18%)	12/50 (24%)
		23/50 (46%)	52/90 (58%)	26/50 (52%)		5/50 (10%)	19/89 (21%)	11/50 (22%)
		32/50 (64%)	` ,	,		13/50 (26%)	,	,
Overall Incidence	Total	352/689 (51.09%)	Mean 50.66%	SD 10.4%	Total	125/689 (18.14%)	Mean 17.95%	SD 7.55%
		` '				` ,		

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

Page: 19

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
*Liver:								
Hepatocellular Carcino	ma							
		15/50 (30%)	17/50 (34%)	10/50 (20%)		6/50 (12%)	5/50 (10%)	1/50 (2%)
		15/50 (30%)	8/49 (16%)	12/50 (24%)		5/50 (10%)	1/50 (2%)	6/50 (12%)
		11/50 (22%)	21/50 (42%)	8/50 (16%)		10/50 (20%)	7/50 (14%)	7/50 (14%)
		18/50 (36%) 11/50 (22%)	28/90 (31%)	15/50 (30%)		4/50 (8%) 2/50 (4%)	8/89 (9%)	2/50 (4%)
Overall Incidence	Total	189/689 (27.43%)	Mean 27.19%	SD 7.86%	Total	64/689 (9.29%)	Mean 9.31%	SD 5.31%
Liver: Hepatocellular Carcino	ıma or Henatoh	lastoma						
patooonalai oaloillo	a or riopatob	16/50 (32%)	18/50 (36%)	10/50 (20%)		6/50 (12%)	6/50 (12%)	1/50 (2%)
		17/50 (34%)	8/49 (16%)	15/50 (30%)		5/50 (10%)	1/50 (2%)	6/50 (12%)
		11/50 (0470)	21/50 (42%)	9/50 (18%)		10/50 (20%)	7/50 (14%)	7/50 (14%)
		18/50 (36%)	32/90 (36%)	17/50 (34%)		4/50 (8%)	9/89 (10%)	2/50 (4%)
		12/50 (24%)	02/00 (00/0)	(0170)		2/50 (4%)	(1070)	_, 55 (1.75)
Overall Incidence	Total	204/689 (29.61%)	Mean 29.22%	SD 8.2%	Total	66/689 (9.58%)	Mean 9.55%	SD 5.36%
*Liver: Hepatocellular Carcino	ma or Hepatoc							
		39/50 (78%)	31/50 (62%)	24/50 (48%)		14/50 (28%)	11/50 (22%)	4/50 (8%)
		40/50 (80%)	26/49 (53%)	35/50 (70%)		14/50 (28%)	4/50 (8%)	12/50 (24%)
		32/50 (64%)	34/50 (68%)	30/50 (60%)		20/50 (40%)	15/50 (30%)	18/50 (36%)
		31/50 (62%)	67/90 (74%)	33/50 (66%)		8/50 (16%)	25/89 (28%)	13/50 (26%)
		39/50 (78%)				15/50 (30%)		
Overall Incidence	Total	461/689 (66.91%)	Mean 66.42%	SD 9.73%	Total	173/689 (25.11%)	Mean 24.93%	SD 9.55%
*Liver:								
Hepatocellular Carcino	ma, Hepatocell	lular Adenoma, or Hepat		0.4/50 (400%)		4.4/50 (0.00%)	10/50 (0.10/)	4/50 (001)
		39/50 (78%)	32/50 (64%)	24/50 (48%)		14/50 (28%)	12/50 (24%)	4/50 (8%)
		40/50 (80%)	26/49 (53%)	36/50 (72%)		14/50 (28%)	4/50 (8%)	12/50 (24%)
		32/50 (64%)	34/50 (68%)	31/50 (62%)		20/50 (40%)	15/50 (30%)	18/50 (36%)
		31/50 (62%)	68/90 (76%)	34/50 (68%)		8/50 (16%)	25/89 (28%)	13/50 (26%)
		39/50 (78%)				15/50 (30%)		
Overall Incidence	Total	466/689 (67.63%)	Mean 67.12%	SD 9.72%	Total	174/689 (25.25%)	Mean 25.08%	SD 9.51%

Page: 20

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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						F	emale		
*Liver:		,												
Hepatocholangiocarcin	noma													
		1/50	(2%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	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%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/90	(1%)	0/50	(0%)		0/50	(0%)	0/89	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	7/689 (1.02%	•	Mean 1		SD 1.73%		Total	1/689 (0.			0.15%	SD 0	
Liver: Mast Cell Tumor														
		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/90	(1%)	0/50	(0%)		0/50	(0%)	0/89	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/689 (0.15%	,	Mean 0		SD 0.31%		Total	0/689 (0%)	Mea	n 0%	SD	0%
*Lung: Alveolar/Bronchiolar A														
		10/50 (2	20%)	5/50	(10%)	9/50	(18%)		1/50	(2%)	3/50	(6%)	2/50	(4%)
		12/50 (2	24%)	7/49	(14%)	4/50	(8%)		5/50	(10%)	5/50	(10%)	1/50	(2%)
		5/50 (1	10%)	6/50	(12%)	11/50	(22%)		1/50	(2%)	4/50	(8%)	5/50	(10%)
		5/50 (1	10%)	13/90	(14%)	5/50	(10%)		1/50	(2%)	3/90	(3%)	2/50	(4%)
		6/50 (1	12%)						5/50	(10%)				
Overall Incidence	Total	98/689 (14.22%	•	Mean 14		SD 5.19%		Total	38/690 (5	,		5.64%	SD 3	.48%
*Lung: Alveolar/Bronchiolar C														
		4/50	(8%)	5/50	(10%)	3/50	(6%)		2/50	(4%)	3/50	(6%)	0/50	(0%)
		2/50	(4%)	5/49	(10%)	4/50	(8%)		1/50	(2%)	0/50	(0%)	2/50	(4%)
		8/50 (1	16%)	10/50	(20%)	6/50	(12%)		4/50	(8%)	5/50	(10%)	0/50	(0%)
		5/50 (1	10%)	13/90	(14%)	2/50	(4%)		0/50	(0%)	3/90	(3%)	2/50	(4%)
		4/50	(8%)		•		•		1/50	(2%)		•		
Overall Incidence	Total	71/689 (10.3%	6)	Mean 10	0.05%	SD 4.65%	6	Total	23/690 (3	.33%)	Mean	3.33%	SD 3	3.2%

Page: 21

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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	
Lung: Alveolar/Bronchiolar Ca	rcinoma or Al	veolar/Bronchiolar Aden	oma					
		13/50 (26%)	9/50 (18%)	11/50 (22%)		3/50 (6%)	6/50 (12%)	2/50 (4%)
		14/50 (28%)	11/49 (22%)	8/50 (16%)		6/50 (12%)	5/50 (10%)	3/50 (6%)
		13/50 (26%)	14/50 (28%)	17/50 (34%)		4/50 (8%)	9/50 (18%)	5/50 (10%)
		10/50 (20%)	23/90 (26%)	7/50 (14%)		1/50 (2%)	6/90 (7%)	4/50 (8%)
		10/50 (20%)	, ,	,		6/50 (12%)	,	,
verall Incidence	Total	160/689 (23.22%)	Mean 23.08%	SD 5.55%	Total	60/690 (8.7%)	Mean 8.82%	SD 4.17%
-ung: Hemangiosarcoma								
_		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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%
Lung: Mast Cell Tumor								
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	2/690 (0.29%)	Mean 0.31%	SD 0.75%

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

Page: 22

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
Lymph Node: Mast Cell Tumor								
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)
verall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor								
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%

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

Page: 23

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
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%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Mast Cell Tumor								
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: 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%)	0/49 (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%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)		. ,		0/50 (0%)		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	3/690 (0.43%)	Mean 0.46%	SD 0.88%

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

Page: 24

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/90 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/90 (0%)	1/50 (2%)
Overall Incidence	Total	2/689 (0.29%)	Mean 0.31%	SD 0.76%	Total	9/690 (1.3%)	Mean 1.38%	SD 1.89%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	4/50 (8%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/689 (0.29%)	Mean 0.31%	SD 0.76%	Total	12/690 (1.74%)	Mean 1.85%	SD 2.23%
#Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (0%)	4/50 (20/)	4/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/30 (0%)	1/50 (2%)	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%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88%
Overall Incidence #Mammary Gland: Fibroma, Fibroadenoma		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88%
Mammary Gland:		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88%
Mammary Gland:		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88%
Mammary Gland:		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%) r Adenoma 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88% 4/50 (8%) 1/50 (2%)
Mammary Gland:		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0% 0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 3/690 (0.43%) 1/50 (2%) 0/50 (0%) 2/50 (4%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46% 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88% 4/50 (8%) 1/50 (2%) 0/50 (0%)
Mammary Gland:		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/689 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%) Mean 0% 	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 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%) 3/690 (0.43%) 1/50 (2%) 0/50 (0%) 2/50 (4%)	1/50 (2%) 0/50 (0%) 0/90 (0%) Mean 0.46% 1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.88% 4/50 (8%) 1/50 (2%) 0/50 (0%)

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

Page: 25

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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	
#Mesentery: Hemangioma								,
_		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%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/90 (1%)	0/50 (0%)
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%
#Mesentery: Hemangiosarcoma								
·		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/90 (1%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/689 (0.29%)	Mean 0.24%	SD 0.61%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	. ,	. ,		0/50 (0%)	. ,	
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%

Page: 26

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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			
*Nose: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/48 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/89 (0%)	0/50 (0%)
Overall Incidence	Total	0/687 (0%)	Mean 0%	SD 0%	Total	1/687 (0.15%)	Mean 0.16%	SD 0.58%
Nose: Polyp								
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/687 (0.15%)	Mean 0.16%	SD 0.57%	Total	0/687 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous	sa, Tongue, Pha							
		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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	2/690 (0.29%)	Mean 0.31%	SD 0.75%
Oral Cavity (Oral Mucos	sa, Tongue, Pha							
•		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%

.....

Page: 27

^{*:} 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
Route: ALL ROUTES

Report Date: 11/01/2019

Page: 28

Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male						Female						
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma														
•	· •	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(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%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	1/50	(2%)
		0/50	(0%)						2/50	(4%)				
verall Incidence	Total	1/689 (0.15%	%)	Mean 0		SD 0.55%		Total	3/690 (0.	43%)	Mean	0.46%	SD 1	.2%
Oral Mucosa: Squamous Cell Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(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%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						1/50	(2%)				
verall Incidence	Total	0/689 (0%)		Mean		SD 0%		Total	1/690 (0.	,		0.15%	SD 0.	
Ovary: Cystadenocarcinoma														
									0/50	(0%)	0/49	(0%)	0/48	(0%)
									1/50	(2%)	0/48	(0%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/48	(0%)	0/75	(0%)	0/49	(0%)
									0/50	(0%)				
verall Incidence								Total	1/667 (0.	,		0.15%	SD 0.	55%
Ovary: Cystadenoma														
									1/50	(2%)	0/49	(0%)	3/48	(6%)
									3/50	(6%)	4/48	(8%)	1/50	(2%)
									2/50	(4%)	1/50	(2%)	2/50	(4%)
									2/48	(4%)	2/75	(3%)	3/49	(6%)
									2/50	(4%)		,		,

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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

Ma	ale	Female							
*Ovary: Granulosa Cell Tumor Benign									
		0/50 (0%)	0/49 (0%)	0/48 (0%)					
		0/50 (0%)	0/48 (0%)	0/50 (0%)					
		1/50 (2%)	1/50 (2%)	0/50 (0%)					
		1/48 (2%)	1/75 (1%)	0/49 (0%)					
		0/50 (0%)							
Overall Incidence	Total	4/667 (0.6%)	Mean 0.57%	SD 0.91%					
Ovary:									
Granulosa Cell Tumor Malignant		4/50 (00/)	0/40 (00/)	0/40 (00/)					
		1/50 (2%)	0/49 (0%)	0/48 (0%)					
		0/50 (0%)	0/48 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/48 (0%)	0/75 (0%)	0/49 (0%)					
Overall Institutes	Tatal	0/50 (0%)	Maar 0.450/	CD 0.550/					
Overall Incidence	Total	1/667 (0.15%)	Mean 0.15%	SD 0.55%					
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS									
33 -		1/50 (2%)	0/49 (0%)	0/48 (0%)					
		0/50 (0%)	0/48 (0%)	0/50 (0%)					
		1/50 (2%)	1/50 (2%)	0/50 (0%)					
		1/48 (2%)	1/75 (1%)	0/49 (0%)					
		0/50 (0%)							
Overall Incidence	Total	5/667 (0.75%)	Mean 0.72%	SD 0.97%					
*Ovary:									
Granulosa-Theca Tumor Malignant		0/50 /09/\	1/40 (20/)	0/49 (00/)					
		0/50 (0%) 0/50 (0%)	1/49 (2%) 0/48 (0%)	0/48 (0%) 0/50 (0%)					
		0/50 (0%)	0/48 (0%)	1/50 (2%)					
		0/50 (0%)	0/50 (0%)	0/49 (0%)					
		0/48 (0%)	0//3 (0/0)	0/43 (0/0)					
Overall Incidence	Total	` '	Mean 0.31%	SD 0.76%					
Overall illicidence	Total	2/667 (0.3%)	iviean 0.31%	JU 0.70%					

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

Page: 29

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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

N	N ale		Female					
*Ovary:								
Hemangioma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)				
		0/50 (0%)	1/48 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/48 (0%)	2/75 (3%)	0/49 (0%)				
		0/50 (0%)						
Overall Incidence	Total	3/667 (0.45%)	Mean 0.37%	SD 0.9%				
*Ovary:								
Hemangiosarcoma								
		1/50 (2%)	0/49 (0%)	2/48 (4%)				
		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/48 (0%)	0/75 (0%)	0/49 (0%)				
		0/50 (0%)						
Overall Incidence	Total	3/667 (0.45%)	Mean 0.47%	SD 1.24%				
*Ovary:								
Luteoma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)				
		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	2/50 (4%)				
		0/48 (0%)	0/75 (0%)	1/49 (2%)				
		0/50 (0%)						
Overall Incidence	Total	4/667 (0.6%)	Mean 0.62%	SD 1.26%				
*Ovary:								
Sarcoma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)				
		1/50 (2%)	0/48 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/48 (0%)	0/75 (0%)	0/49 (0%)				
		0/50 (0%)	- (/	()				
Overall Incidence	Total	1/667 (0.15%)	Mean 0.15%	SD 0.55%				

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

Page: 30

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Page: 31

Report Date: 11/01/2019

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

					Male						F	emale		
Ovary: Thecoma Malignant														
									0/50	(0%)	0/49	(0%)	0/48	(0%)
									0/50	(0%)	0/48	(0%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/48	(0%)	1/75	(1%)	0/49	(0%)
									0/50	(0%)				
Overall Incidence								Total	1/667 (0.	15%)	Mear	າ 0.1%	SD 0	.37%
Ovary: Tubulostromal Adenoma														
									0/50	(0%)	0/49	(0%)	0/48	(0%)
									0/50	(0%)	0/48	(0%)	1/50	(2%)
									0/50	(0%)	0/50	(0%)	0/50	(0%)
									0/48	(0%)	0/75	(0%)	0/49	(0%)
									0/50	(0%)		. ,		. ,
Overall Incidence								Total	1/667 (0.	15%)	Mean	0.15%	SD 0	.55%
Pancreas: Mast Cell Tumor														
		0/49	(0%)	0/48	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/87	(1%)	0/50	(0%)		0/50	(0%)	0/87	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/683 (0.15		Mean 0		SD 0.329		Total	0/686 (0			ın 0%	SD	
Parathyroid Gland: Adenoma														
		0/27	(0%)	0/40	(0%)	0/40	(0%)		0/27	(0%)	0/38	(0%)	0/43	(0%)
		0/41	(0%)	0/32	(0%)	0/48	(0%)		0/35	(0%)	0/21	(0%)	0/43	(0%)
		0/34	(0%)	0/28	(0%)	0/36	(0%)		0/26	(0%)	1/35	(3%)	0/36	(0%)
		0/48	(0%)	0/68	(0%)	0/44	(0%)		0/44	(0%)	0/60	(0%)	0/45	(0%)
		0/45	(0%)		` '		` '		0/34	(0%)		` '		` '
Overall Incidence	Total	0/531 (0%	` ,	Mean	Ω9/:	SD 0%		Total	1/487 (0.:	` '	Moon	0.22%	SD 0	700/

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Page: 32

Report Date: 11/01/2019

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 Dis	stalis or Unspeci	ified Site:				,				
Adenoma				- / / /						
		0/49 (0%)	0/50 (0%)	0/48 (0%)		9/49 (18%)	2/49 (4%)	1/49 (2%)		
		1/49 (2%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	3/49 (6%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		5/50 (10%)	8/48 (17%)	4/50 (8%)		
		0/47 (0%)	0/86 (0%)	0/48 (0%)		5/50 (10%)	6/80 (8%)	2/50 (4%)		
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	2/672 (0.3%)	Mean 0.31%	SD 0.76%	Total	46/671 (6.86%)	Mean 6.83%	SD 5.83%		
Pituitary Gland: Pars Dis Carcinoma										
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)		
		0/49 (0%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/48 (6%)	0/50 (0%)		
		0/47 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/50 (0%)		
		0/50 (0%)	, ,	,		0/50 (0%)	,	,		
Overall Incidence	Total	0/672 (0%)	Mean 0%	SD 0%	Total	3/671 (0.45%)	Mean 0.48%	SD 1.73%		
Pituitary Gland: Pars Dis Carcinoma or Adenom	•					-0				
		0/49 (0%)	0/50 (0%)	0/48 (0%)		9/49 (18%)	2/49 (4%)	1/49 (2%)		
		1/49 (2%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	3/49 (6%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		5/50 (10%)	11/48 (23%)	4/50 (8%)		
		0/47 (0%)	0/86 (0%)	0/48 (0%)		5/50 (10%)	6/80 (8%)	2/50 (4%)		
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	2/672 (0.3%)	Mean 0.31%	SD 0.76%	Total	49/671 (7.3%)	Mean 7.31%	SD 6.87%		
Pituitary Gland: Pars Int Adenoma	ermedia:									
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)		
		0/49 (0%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	1/47 (2%)	1/49 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)		
		0/47 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/672 (0%)	Mean 0%	SD 0%	Total	2/671 (0.3%)	Mean 0.32%	SD 0.78%		

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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					
Pituitary Gland: Pars Inter Carcinoma	media:											
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	1/49 (2%)	0/49 (0%)				
		0/49 (0%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		0/47 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
verall Incidence	Total	0/672 (0%)	Mean 0%	SD 0%	Total	1/671 (0.15%)	Mean 0.16%	SD 0.57%				
Pituitary Gland: Pars Inter Carcinoma or Adenoma												
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	1/49 (2%)	0/49 (0%)				
		0/49 (0%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	1/47 (2%)	1/49 (2%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		0/47 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/672 (0%)	Mean 0%	SD 0%	Total	3/671 (0.45%)	Mean 0.48%	SD 0.91%				
Pituitary Gland: Pars Inter Schwannoma Malignant												
		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)				
		0/49 (0%)	0/45 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		0/47 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	1/672 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/671 (0%)	Mean 0%	SD 0%				
Prostate: Mast Cell Tumor								•••••				
		0/49 (0%)	0/49 (0%)	0/50 (0%)								
		0/50 (0%)	0/49 (0%)	0/50 (0%)								
		0/50 (0%)	0/50 (0%)	0/50 (0%)								
		0/50 (0%)	1/90 (1%)	0/50 (0%)								
		` ,	` '	` '								
		0/50 (0%)										

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

Page: 33

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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:												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 1/688 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/50 (0%) 0/687 (0%)	Mean 0%	SD 0%				
		` ,				` '						
Salivary Glands: Carcinoma												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
verall Incidence	Total	0/688 (0%)	Mean 0%	SD 0%	Total	1/687 (0.15%)	Mean 0.15%	SD 0.55%				
Salivary Glands: Carcinoma or Adenoma												
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)				
		0/50 (0%)				0/50 (0%)						
verall Incidence	Total	1/688 (0.15%)	Mean 0.15%	SD 0.55%	Total	1/687 (0.15%)	Mean 0.15%	SD 0.55%				
Salivary Glands: Hemangiosarcoma												
3		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)				
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	• •				
verall Incidence	Total	1/688 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/687 (0%)	Mean 0%	SD 0%				

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

Page: 34

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Page: 35

Report Date: 11/01/2019

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Salivary Glands: **Mast Cell Tumor** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49(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%)1/90 (1%)0/50 (0%)0/50 (0%)0/89 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/688 (0.15%) Mean 0.09% SD 0.31% Total 0/687 (0%) Mean 0% SD 0% *Salivary Glands: Myxosarcoma 0/50 0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/49 (0%)(0%)0/50 (0%)0/49 (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 0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/89 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/688 (0%) Mean 0% SD 0% Total 1/687 (0.15%) Mean 0.15% SD 0.55% **#Seminal Vesicle:** Adenoma 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%)0/90 0/50 (0%)(0%)(0%) 0/50 **Overall Incidence** Total 1/689 (0.15%) Mean 0.15% SD 0.55% **#Seminal Vesicle: Fibroma**

0/50

0/50

0/50

0/50

(0%)

(0%)

(0%)

(0%)

Total

0/50

0/50

0/50

0/50

0/50

1/689 (0.15%)

(0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/49

0/50

1/90

Mean 0.09%

(0%)

(0%)

(0%)

(1%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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: Hemangiosarcoma										
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
verall Incidence	Total	0/50 (0%)	Mean 0.15%	SD 0.55%	Total	0/50 (0%) 1/690 (0.14%)	Mean 0.15%	SD 0.55%		
		1/689 (0.15%)				1/090 (0.14%)				
Skeletal Muscle: Osteosarcoma										
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)				
verall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%		
Skeletal Muscle: Rhabdomyosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	0/90 (0%)	0/50 (0%)		
	T-1-1	0/50 (0%)	M 0.450/	OD 0.550/	T-1-1	0/50 (0%)	M 4.000/	OD 4.550/		
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	7/690 (1.01%)	Mean 1.08%	SD 1.55%		
Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma	3								
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	. ,	. ,		0/50 (0%)				
verall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	7/690 (1.01%)	Mean 1.08%	SD 1.55%		

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

Page: 36

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC 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%)0/49(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%)1/90 (1%)0/50 (0%)0/50 (0%)0/90 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Total Overall Incidence Total 1/689 (0.15%) Mean 0.09% SD 0.31% 3/690 (0.43%) Mean 0.46% SD 0.88% #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%)0/49 (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%)0/90 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/689 (0%) Mean 0% SD 0% Total 2/690 (0.29%) Mean 0.31% SD 0.75% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (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%)0/50 0/90 (0%)0/50 (0%)0/50 0/90 (0%)(0%)0/50 (0%)1/50 (2%)Overall Incidence Total 0/689 (0%) Mean 0% SD 0% Total 2/690 (0.29%) Mean 0.31% SD 0.75% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)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%)0/90 (0%)(0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 0/50 (0%)(2%)1/50

SD 0%

2/690 (0.29%)

Total

Mean 0%

Total

Overall Incidence

Page: 37

Report Date: 11/01/2019

SD 0.75%

Mean 0.31%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Species: MICE Strain: B6C3F1/N

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 38

					Male						F	emale		
∮Skin:														
Basal or Sq. Cell Carc Adenoma, Papilloma,	inoma, Carcinom Sq Papilloma, Ke	na, Basosq. Tur eratoacanthoma	mor (M or l a, Trichoe	B), Basal Ce pithelioma	ell Adenon	na,								
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(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%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)						1/50	(2%)				
Overall Incidence	Total	1/689 (0.15		Mean 0		SD 0.55		Total	3/690 (0.	,		0.46%	SD 0	
#Skin:														
Fibroma		0/50	(00/)	0/50	(00/)	0/50	(00()		0/50	(00()	0/50	(00/)	0/50	(00/)
		0/50 0/50	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
		0/50 0/50	, ,		` '	0/50	` '			` '		` '		` '
		0/50 0/50	(0%) (0%)	0/50 0/90	(0%) (0%)	0/50	(0%) (0%)		0/50 0/50	(0%) (0%)	0/50 1/90	(0%) (1%)	0/50 0/50	(0%) (0%)
			` ,	0/90	(0%)	0/50	(0%)		0/50	(0%)	1/90	(1%)	0/50	(0%)
Normall Implication	Tatal	0/50	(0%)		00/	CD 00/		Tatal			14	0.000/	CD 0	040/
	Total	0/689 (0%	%) ` ′	Mean		SD 0%		Total	1/690 (0.	14%)		0.09%	SD 0	
		0/689 (0% coma, Myxosard 0/50	coma, Mal i	ignant Fibro	ous Histioo	cytoma, or	(0%)		1/690 (0. 2/50	(4%)	0/50	(0%)	2/50	(4%)
#Skin: Fibroma, Fibrosarcom		0/689 (0% coma, Myxosard 0/50 0/50	(0%) (0%)	ignant Fibro 0/50 0/49	(0%) (0%)	cytoma, or 0/50 1/50	(0%) (2%)		1/690 (0. 2/50 0/50	(4%) (0%)	0/50 0/50	(0%) (0%)	2/50 1/50	(4%) (2%)
#Skin: Fibroma, Fibrosarcom		0/689 (0% coma, Myxosard 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	ignant Fibro 0/50 0/49 1/50	(0%) (0%) (0%) (2%)	0/50 1/50 1/50	(0%) (2%) (2%)		2/50 0/50 0/50	(4%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)	2/50 1/50 1/50	(4%) (2%) (2%)
#Skin: Fibroma, Fibrosarcom		0/689 (0% xoma, Myxosaro 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%)	ignant Fibro 0/50 0/49	(0%) (0%)	cytoma, or 0/50 1/50	(0%) (2%)		2/50 0/50 0/50 1/50	(4%) (0%) (0%) (0%) (2%)	0/50 0/50	(0%) (0%)	2/50 1/50	(4%) (2%)
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma	a, Sarcoma, Мух	0/689 (0% xoma, Myxosard 0/50 0/50 0/50 0/50 1/50	(0%) (0%) (0%) (0%) (0%) (0%) (2%)	ignant Fibro 0/50 0/49 1/50 1/90	(0%) (0%) (0%) (2%) (1%)	0/50 1/50 1/50 0/50	(0%) (2%) (2%) (0%)		2/50 0/50 0/50 1/50 1/50	(4%) (0%) (0%) (0%) (2%) (2%)	0/50 0/50 0/50 6/90	(0%) (0%) (0%) (0%) (7%)	2/50 1/50 1/50 1/50	(4%) (2%) (2%) (2%)
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence		0/689 (0% coma, Myxosard 0/50 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (0%) (2%) 3%)	ignant Fibro 0/50 0/49 1/50 1/90	(0%) (0%) (0%) (2%) (1%)	0/50 1/50 1/50 0/50 SD 0.95	(0%) (2%) (2%) (2%) (0%)	Total	2/50 0/50 0/50 1/50	(4%) (0%) (0%) (0%) (2%) (2%)	0/50 0/50 0/50 6/90 Mean	(0%) (0%) (0%)	2/50 1/50 1/50	(4%) (2%) (2%) (2%)
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0% coma, Myxosard 0/50 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (0%) (2%) 3%)	ignant Fibro 0/50 0/49 1/50 1/90 Mean 0	(0%) (0%) (0%) (2%) (1%)	0/50 1/50 1/50 0/50 SD 0.95	(0%) (2%) (2%) (2%) (0%)	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (0%) (2%) (2%)	0/50 0/50 0/50 6/90 Mean	(0%) (0%) (0%) (0%) (7%)	2/50 1/50 1/50 1/50	(4%) (2%) (2%) (2%)
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0%) coma, Myxosard 0/50 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (0%) (2%) 3%)	ignant Fibro 0/50 0/49 1/50 1/90 Mean 0	(0%) (0%) (0%) (2%) (1%) 0.7%	0/50 1/50 1/50 0/50 SD 0.95	(0%) (2%) (2%) (0%)	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (0%) (2%) (2%) .17%)	0/50 0/50 0/50 6/90 Mean	(0%) (0%) (0%) (0%) (7%)	2/50 1/50 1/50 1/50 1/50 SD 2	(4%) (2%) (2%) (2%) (2%)
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0%) coma, Myxosard 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (2%) 3%) coma, or N	ignant Fibro 0/50 0/49 1/50 1/90 Mean 0 Malignant Fil 0/50	(0%) (0%) (0%) (2%) (1%) 0.7% 	0/50 1/50 1/50 0/50 SD 0.954 iocytoma 0/50	(0%) (2%) (2%) (0%) %	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (0%) (2%) (2%) .17%)	0/50 0/50 0/50 6/90 Mean	(0%) (0%) (0%) (7%) 1.9%	2/50 1/50 1/50 1/50 1/50 SD 2	(4%) (2%) (2%) (2%) (2%) .03%
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0%) coma, Myxosard 0/50 0/50 0/50 1/50 5/689 (0.73) coma, Myxosard 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (2%) 3%) coma, or N (0%) (0%)	0/50 0/49 1/50 1/90 Mean 0 Malignant Fil 0/50 0/49	(0%) (0%) (0%) (2%) (1%) 0.7% brous Hist (0%) (0%)	0/50 1/50 1/50 0/50 SD 0.954 iocytoma 0/50 1/50	(0%) (2%) (2%) (0%) %	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (2%) (2%) .17%) (4%) (0%)	0/50 0/50 0/50 6/90 Mean 0/50	(0%) (0%) (0%) (7%) 1.9%	2/50 1/50 1/50 1/50 1/50 SD 2 2/50 1/50	(4%) (2%) (2%) (2%) (2%) .03%
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0% coma, Myxosard 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (2%) 3%) 	0/50 0/49 1/50 1/90 Mean 0 Malignant Fil 0/50 0/49 1/50	(0%) (0%) (0%) (2%) (1%) 0.7% brous Hist (0%) (0%) (2%)	0/50 1/50 1/50 0/50 SD 0.95 iocytoma 0/50 1/50	(0%) (2%) (2%) (0%) % (0%) (2%) (2%)	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (2%) (2%) .17%) (4%) (0%) (0%)	0/50 0/50 0/50 6/90 Mean 0/50 0/50	(0%) (0%) (0%) (7%) 1.9% (0%) (0%) (0%)	2/50 1/50 1/50 1/50 1/50 SD 2 2/50 1/50 1/50	(4%) (2%) (2%) (2%) (2%) .03%
Hemangiopericytoma Overall Incidence #Skin:	na, Sarcoma, Myx	0/689 (0% coma, Myxosard 0/50 0/50 0/50 1/50 5/689 (0.73 coma, Myxosard 0/50 0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0%) (2%) 3%) coma, or N (0%) (0%) (0%) (0%)	0/50 0/49 1/50 1/90 Mean 0 Malignant Fil 0/50 0/49	(0%) (0%) (0%) (2%) (1%) 0.7% brous Hist (0%) (0%)	0/50 1/50 1/50 0/50 SD 0.954 iocytoma 0/50 1/50	(0%) (2%) (2%) (0%) %	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2 2/50 0/50 0/50 1/50	(4%) (0%) (0%) (2%) (2%) .17%) 	0/50 0/50 0/50 6/90 Mean 0/50	(0%) (0%) (0%) (7%) 1.9%	2/50 1/50 1/50 1/50 1/50 SD 2 2/50 1/50	(4%) (2%) (2%) (2%) (2%) .03%
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma Overall Incidence	na, Sarcoma, Myx	0/689 (0% coma, Myxosard 0/50 0/50 0/50 1/50 5/689 (0.73	(0%) (0%) (0%) (0%) (0%) (2%) 3%) coma, or N (0%) (0%) (0%) (0%) (0%)	0/50 0/49 1/50 1/90 Mean 0 Malignant Fil 0/50 0/49 1/50	(0%) (0%) (2%) (1%) 0.7% 	0/50 1/50 1/50 0/50 SD 0.95 iocytoma 0/50 1/50	(0%) (2%) (2%) (0%) % (0%) (2%) (2%) (0%)	Total	2/50 0/50 0/50 1/50 1/50 15/690 (2	(4%) (0%) (0%) (2%) (2%) .17%) 	0/50 0/50 0/50 6/90 Mean 0/50 0/50 0/50 6/90	(0%) (0%) (0%) (7%) 1.9% (0%) (0%) (0%)	2/50 1/50 1/50 1/50 1/50 SD 2 2/50 1/50 1/50	(4%) (2%) (2%) (2%) .03%

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	3/90 (3%)	0/50 (0%)		
Overall Incidence	Total	2/689 (0.29%)	Mean 0.31%	SD 0.75%	Total	6/690 (0.87%)	Mean 0.72%	SD 1.17%		
Skin:	•••••									
Fibrosarcoma, Sarcoma	, Myxosarcoma	a, or Malignant Fibrous H	istiocytoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)	0/49 (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%)		
		0/50 (0%)	1/90 (1%)	0/50 (0%)		1/50 (2%)	5/90 (6%)	1/50 (2%)		
		1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	5/689 (0.73%)	Mean 0.7%	SD 0.95%	Total	14/690 (2.03%)	Mean 1.81%	SD 1.83%		
Skin: Hemangioma										
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)				
verall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%		
Skin: Hemangiosarcoma										
<u> </u>		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	2/90 (2%)	0/50 (0%)		
		0/50 (0%)	. ,	. ,		1/50 (2%)				
Overall Incidence	Total	3/689 (0.44%)	Mean 0.39%	SD 1.13%	Total	6/690 (0.87%)	Mean 0.79%	SD 1.32%		

.....

Page: 39

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Page: 40

			Male			Female					
#Skin: Keratoacanthoma											
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%) 1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)			
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	0/690 (0%)	Mean 0%	SD 0%			
#Skin: Lipoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (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%)			
		2/50 (4%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	3/689 (0.44%)	Mean 0.39%	SD 1.13%	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%			
#Skin: Liposarcoma											
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)			
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%			
#Skin:											
Malignant Fibrous Hist	locytoma	0/50 (00/)	0/50 (00/)	0/50 (00/)		1/50 (20/)	0/50 (00/)	2/50 /40/\			
		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%)	2/50 (4%) 0/50 (0%)			
		` ,	` '	` '		(,	` '	` '			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/90 (1%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)			
Overall Incidence	Total	` '	Mean 0.24%	SD 0.61%	Total	` ,	Mean 0.62%	SD 1.26%			
	Total	2/689 (0.29%)			Total	4/690 (0.58%)		3D 1.20%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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						F	emale		
#Skin: Melanoma Benign									,					,
melanoma berngn		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%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)		` ,		, ,		0/50	(0%)		` ,		` ,
Overall Incidence	Total	1/689 (0.15	%)	Mean 0	15%	SD 0.55%	6	Total	0/690 (0	0%)	Mea	n 0%	SD	0%
Skin:														
Neurofibrosarcoma or	Schwannoma (n	nalignant or NO	S)											
		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)						1/50	(2%)				
Overall Incidence	Total	0/689 (0%	o)	Mean	0%	SD 0%		Total	1/690 (0.	14%)	Mean	0.15%	SD 0.	55%
tSkin: Neurofibrosarcoma, N	eurofibroma, or s	Schwannoma (b	(0%)	0/50	(0%) (0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
		0/50 0/50 0/50	(0%) (0%) (0%)	0/49 0/50 0/90	(0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)		0/50 0/50	(0%) (0%)	0/50 0/90	(0%) (0%)	0/50 0/50	(0%) (0%)
Overall Incidence	Total	0/50	(0%) (0%) (0%)	0/50	(0%) (0%)	0/50	(0%)	Total	0/50	(0%) (2%)	0/50 0/90	` '	0/50	(0%)
Overall Incidence #Skin: Osteosarcoma		0/50 0/50 0/50 0/689 (0%	(0%) (0%) (0%)	0/50 0/90 Mean	(0%) (0%) 0%	0/50 0/50 SD 0%	(0%) (0%)		0/50 0/50 1/50 1/690 (0.	(0%) (2%) 14%)	0/50 0/90 Mean	(0%)	0/50 0/50	(0%)
#Skin:		0/50 0/50 0/50 0/689 (0%	(0%) (0%) (0%)	0/50 0/90 Mean	(0%) (0%) 0%	0/50 0/50 SD 0%	(0%) (0%)		0/50 0/50 1/50 1/690 (0.	(0%) (2%) 14%)	0/50 0/90 Mean	(0%)	0/50 0/50	(0%)
#Skin:		0/50 0/50 0/50 0/50 0/689 (0%	(0%) (0%) (0%) (0%)	0/50 0/90 Mean	(0%) (0%) 0%	0/50 0/50 SD 0%	(0%) (0%)		0/50 0/50 1/50 1/690 (0.	(0%) (2%) 14%)	0/50 0/90 Mean	0.15%	0/50 0/50 SD 0.	(0%) 55%
#Skin:		0/50 0/50 0/50 0/689 (0%	(0%) (0%) (0%) (0%) 	0/50 0/90 Mean 0/50	(0%) (0%) 0% 	0/50 0/50 SD 0%	(0%) (0%) 		0/50 0/50 1/50 1/690 (0.	(0%) (2%) 14%) 	0/50 0/90 Mean 0/50	(0%)	0/50 0/50 SD 0.	(0%) 55% (0%)
#Skin:		0/50 0/50 0/50 0/689 (0% 0/50 0/50	(0%) (0%) (0%) (0%) (0) (0%)	0/50 0/90 Mean 0/50 0/49	(0%) (0%) 0% (0%) (0%)	0/50 0/50 SD 0% 	(0%) (0%) 		0/50 0/50 1/50 1/690 (0. 0/50	(0%) (2%) 14%) (0%) (0%)	0/50 0/90 Mean 0/50 0/50	(0%) 0.15% (0%) (0%) (0%)	0/50 0/50 SD 0. 0/50 0/50	(0%) 55%
#Skin:		0/50 0/50 0/50 0/689 (0% 0/50 0/50 0/50	(0%) (0%) (0%) (0%) (0) (0%) (0%) (0%)	0/50 0/90 Mean 0/50 0/49 0/50	(0%) (0%) 0% (0%) (0%) (0%) (0%)	0/50 0/50 SD 0% 	(0%) (0%) (0%) (0%) (0%) (0%)		0/50 0/50 1/50 1/690 (0. 0/50 0/50 0/50	(0%) (2%) 14%) 	0/50 0/90 Mean 0/50 0/50 0/50	(0%) 0.15% 	0/50 0/50 SD 0. 0/50 0/50 0/50	(0%) 55%

Page: 41

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Page: 42

Report Date: 11/01/2019

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
#Skin: Pilomatrixoma											
		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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%) 0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%)	0/50 (0%)			
Overall Incidence	Total	1/689 (0.15%)	Mean 0.09%	SD 0.31%	Total	0/690 (0%)	Mean 0%	SD 0%			
#Skin: Sarcoma											
		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%)	1/50 (2%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	2/90 (2%)	0/50 (0%)			
		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	4/690 (0.58%)	Mean 0.48%	SD 0.91%			
#Skin: Schwannoma Malignant											
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)			
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%			
¢Skin:											
Squamous Cell Carcino or Carcinoma	ma, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant	or NOS),							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)			
		0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	2/690 (0.29%)	Mean 0.31%	SD 0.75%			

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

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:								
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%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Skin:								
Squamous Cell Papilloma	a or Papilloma	l						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/689 (0%)	Mean 0%	SD 0%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Skin:						•••••		
Squamous Cell Papilloma	a, Papilloma, S	-						
		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%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Skin:								
Squamous Cell Papilloma	a, Papilloma, c	or Keratoacanthoma						
,		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%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	(****)	, ,		0/50 (0%)	(,	,

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

Page: 43

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

Page: 44

			Male	Female
#Spinal Cord: Schwannoma Malignant				
		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%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/90 (0%) 1/50 (2%)	0/50 (0%) 0/90 (0%) 0/50 (0%)
		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15% SD 0.55%	Total 0/690 (0%) Mean 0% SD 0%
*Spleen: Hemangiosarcoma				
		2/49 (4%)	0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		2/50 (4%)	1/48 (2%) 1/50 (2%)	0/50 (0%) 0/49 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%) 1/50 (2%)
		1/50 (2%)	0/87 (0%) 4/49 (8%)	0/50 (0%) 0/86 (0%) 0/50 (0%)
		1/50 (2%)		1/50 (2%)
Overall Incidence	Total	13/680 (1.91%)	Mean 2.03% SD 2.35%	Total 3/685 (0.44%) Mean 0.46% SD 0.88%
#Stomach, Forestomach: 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%)	0/49 (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%)	0/90 (0%) 1/50 (2%)	0/50 (0%) 0/90 (0%) 0/50 (0%)
		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15% SD 0.55%	Total 0/690 (0%) Mean 0% SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/49 (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%)	0/90 (0%) 0/50 (0%)	0/50 (0%) 0/90 (0%) 0/50 (0%)
		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15% SD 0.55%	Total 1/690 (0.14%) Mean 0.15% SD 0.55%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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 Carcinoma	or Papillom	na Squamous					
		1/50 (2%)	0/50 (0%) 1/50	(2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/49 (4%) 2/50	(4%)	2/50 (4%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/50 (2%) 1/50	(2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	0/90 (0%) 0/50	(0%)	0/50 (0%)	1/90 (1%)	1/50 (2%)
		5/50 (10%)			0/50 (0%)		
Overall Incidence	Total	15/689 (2.18%)	Mean 2.31% SD 2.81		otal 9/690 (1.3%)	Mean 1.32%	SD 1.25%
#Stomach, Forestomach: Squamous Cell Papilloma							
		1/50 (2%)	0/50 (0%) 1/50	(2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/49 (4%) 1/50	(2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	1/50 (2%) 1/50	(2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	0/90 (0%) 0/50	(0%)	0/50 (0%)	1/90 (1%)	1/50 (2%)
		5/50 (10%)	, ,	,	0/50 (0%)	, ,	` ,
Overall Incidence	Total	14/689 (2.03%)	Mean 2.16% SD 2.77		otal 8/690 (1.16%)	Mean 1.16%	SD 0.99%
#Stomach, Glandular: Adenoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	0/90 (0%) 0/50	(0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/689 (0%)	Mean 0% SD 0%		otal 1/690 (0.14%)	Mean 0.15%	SD 0.55%
#Stomach, Glandular: Carcinoma							
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	0/90 (0%) 0/50	(0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15% SD 0.55	5% T	otal 0/690 (0%)	Mean 0%	SD 0%

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

Page: 45

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: ALL ROUTES Strain: B6C3F1/N

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

Page: 46

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
	-	0/50 (0%)	NA 0.450/	00 0 550/	.	0/50 (0%)		00 0 550/
Overall Incidence	Total	1/689 (0.15%)	Mean 0.15%	SD 0.55%	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%
*Testis: Adenoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)				
		1/50 (2%)	0/49 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		2/50 (4%) 0/50 (0%)	2/90 (2%)	0/50 (0%)				
Overall Incidence	Total	` '	Mean 0.63%	SD 1.28%				
	Total	5/687 (0.73%)		1.20%				
*Testis: Hemangioma								
		0/49 (0%)	0/49 (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%)	0/90 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Maan 0.160/	SD 0.57%				
Overall incidence		1/687 (0.15%)	Mean 0.16%	0.5 <i>1</i> %				
*Thymus: Thymoma Benign								
-		0/41 (0%)	0/43 (0%)	0/45 (0%)		0/47 (0%)	0/47 (0%)	0/45 (0%)
		0/44 (0%)	0/45 (0%)	1/49 (2%)		0/47 (0%)	0/48 (0%)	0/49 (0%)
		0/41 (0%)	0/44 (0%)	0/48 (0%)		0/44 (0%)	0/48 (0%)	0/50 (0%)
		0/40 (0%)	0/75 (0%)	0/45 (0%)		0/48 (0%)	0/85 (0%)	0/49 (0%)
		0/47 (0%)				0/50 (0%)		
Overall Incidence	Total	1/607 (0.16%)	Mean 0.16%	SD 0.57%	Total	0/657 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

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					
Thymus: Thymoma NOS											
		0/41 (0%)	0/43 (0%)	0/45 (0%)		1/47 (2%)	0/47 (0%)	0/45 (0%)			
		0/44 (0%)	0/45 (0%)	0/49 (0%)		0/47 (0%)	0/48 (0%)	0/49 (0%)			
		0/41 (0%)	0/44 (0%)	0/48 (0%)		0/44 (0%)	0/48 (0%)	0/50 (0%)			
		0/40 (0%) 0/47 (0%)	0/75 (0%)	0/45 (0%)		0/48 (0%) 0/50 (0%)	0/85 (0%)	0/49 (0%)			
Overall Incidence	Total	0/607 (0%)	Mean 0%	SD 0%	Total	1/657 (0.15%)	Mean 0.16%	SD 0.59%			
Thymus:		•••••									
Thymoma: Benign, Mali	ignant, NOS										
		0/41 (0%)	0/43 (0%)	0/45 (0%)		1/47 (2%)	0/47 (0%)	0/45 (0%)			
		0/44 (0%)	0/45 (0%)	1/49 (2%)		0/47 (0%)	0/48 (0%)	0/49 (0%)			
		0/41 (0%)	0/44 (0%)	0/48 (0%)		0/44 (0%)	0/48 (0%)	0/50 (0%)			
		0/40 (0%)	0/75 (0%)	0/45 (0%)		0/48 (0%)	0/85 (0%)	0/49 (0%)			
		0/47 (0%)				0/50 (0%)					
verall Incidence	Total	1/607 (0.16%)	Mean 0.16%	SD 0.57%	Total	1/657 (0.15%)	Mean 0.16%	SD 0.59%			
Thyroid Gland: C-Cell: Adenoma											
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/89 (0%)	0/50 (0%)		1/50 (2%)	0/86 (0%)	0/49 (0%)			
		0/50 (0%)	, ,	,		0/50 (0%)	` ,	,			
verall Incidence	Total	0/687 (0%)	Mean 0%	SD 0%	Total	1/681 (0.15%)	Mean 0.15%	SD 0.55%			
Гhyroid Gland: C-Cell: Carcinoma	•••••			•••••			•••••				
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/48 (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%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	1/86 (1%)	0/49 (0%)			
		0/50 (0%)	0,00 (0,70)	0/00 (0/0)		0/50 (0%)	.,00 (1,0)	5, 10 (070)			
Iverall Incidence	Total	` '	Mean 0%	SD 0%	Total	,	Mean 0.55%	SD 0.80%			
Overall Incidence	Total	0/687 (0%)	Mean 0%	SD 0%	Total	4/681 (0.59%)	Mean 0.55%	SD 0.89%			

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

Page: 47

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

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					
Thyroid Gland: C-Cell: Carcinoma or Adenoma														
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/48	(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%)	0/89	(0%)	0/50	(0%)		1/50	(2%)	1/86	(1%)	0/49	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/687 (0%	,	Mean		SD 0%		Total	5/681 (0.			0.7%	SD 0	
Thyroid Gland: Follicular (Adenoma														
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	1/48	(2%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/89	(0%)	0/50	(0%)		1/50	(2%)	0/86	(0%)	1/49	(2%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/687 (0.29	,	Mean 0		SD 0.759		Total	5/681 (0.	,		0.78%	SD 1	.03%
Thyroid Gland: Follicular (Carcinoma or Adenoma														
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	1/48	(2%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/89	(0%)	0/50	(0%)		1/50	(2%)	0/86	(0%)	1/49	(2%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/687 (0.29	,	Mean 0		SD 0.759		Total	5/681 (0.			0.78%	SD 1	.03%
#Tongue: Squamous Cell Carcinon														
•	•	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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	1/50	(2%)
		0/50	(0%)		` '		` '		1/50	(2%)		` '		` ,
Overall Incidence	Total	1/689 (0.15		Mean 0	.15%	SD 0.559	%	Total	2/690 (0.	, ,	Mean	0.31%	SD 0	.75%

Page: 48

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 49

					Male				Female					
#Tongue:														
Squamous Cell Papilloma	а													
		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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	1/50	(2%)
	.	0/50	(0%)		450/	00 0 55	.,	T	1/50	(2%)		0.040/	00.0	750/
Overall Incidence	Total	1/689 (0.15)%)	Mean 0	.15%	SD 0.559	%	Total	2/690 (0	29%)	Mean	0.31%	SD 0	.75%
#Tooth:														
Odontoma														
		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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/90	(0%)	1/50	(2%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		2/50	(4%)		,		, ,		0/50	(0%)		` ,		,
Overall Incidence	Total	3/689 (0.44	·%)	Mean 0		SD 1.2%		Total	0/690 (0%)		n 0%	SD	
*Urinary Bladder: Hemangiosarcoma														
•		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/48	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/87	(0%)	0/50	(0%)		0/49	(0%)	0/86	(0%)	0/50	(0%)
		0/50	(0%)		()		()		0/50	(0%)		()		()
Overall Incidence	Total	1/685 (0.15	5%)	Mean 0		SD 0.559		Total	0/683 (0%)		n 0%	SD	
*Urinary Bladder: Mast Cell Tumor														
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/48	(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%)	1/87	(1%)	0/50	(0%)		0/49	(0%)	0/86	(0%)	0/50	(0%)
		0/50	(0%)	.,01	(170)	0,00	(0 /0)		0/50	(0%)	0,00	(0 /0)	0,00	(0 /0)
Overall Incidence	Total	1/685 (0.15	, ,	Mean 0	09%	SD 0.329	2/6	Total	0/683 (, ,	Mes	ın 0%	SD	0%
o . o. a moidono	iotai	1,000 (0.10	,,,,,	ivicaii 0	.0070	00 0.02	,,	iotai	0,000 (· /· /	IVICE	070	CD	J / U

^{*:} 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
Route: ALL ROUTES

Page: 50 Report Date: 11/01/2019

Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

	Male		Female					
EUterus: Adenoma								
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%)				
		1/50 (2%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)	(0,70)	(0,0)				
verall Incidence	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%				
Uterus:								
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%)	1/90 (1%)	0/50 (0%)				
		0/50 (0%)						
verall Incidence	Total	1/690 (0.14%)	Mean 0.09%	SD 0.31%				
Uterus:								
Granular 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%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)	0/00 (0/0)	0/00 (0/0)				
verall Incidence	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%				
Uterus:								
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%)				
		1/50 (2%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)						
Overall Incidence	Total	1/690 (0.14%)	Mean 0.15%	SD 0.55%				

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Page: 51

Report Date: 11/01/2019

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male		Female						
#Uterus: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	1/50 (2%)	1/50 (2%)				
		0/50 (0%)	0/90 (0%)	1/50 (2%)				
		0/50 (0%)						
Overall Incidence	Total	5/690 (0.72%)	Mean 0.77%	SD 1.01%				
#Uterus:								
Leiomyoma		2/52 (22/)	0.(50	. (=0 (00)				
		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%)	1/90 (1%)	0/50 (0%)				
	+	0/50 (0%)		00 0 700/				
Overall Incidence	Total	3/690 (0.43%)	Mean 0.39%	SD 0.78%				
#Uterus: Polyp Stromal								
•		4/50 (8%)	0/50 (0%)	0/50 (0%)				
		2/50 (4%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)	, ,	` ,				
Overall Incidence	Total	8/690 (1.16%)	Mean 1.23%	SD 2.39%				
#Uterus: Sarcoma Stromal								
ouround ouround		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)				
		()						
		2/50 (4%)						

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

Page: 52

Report Date: 11/01/2019

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male				Female							
#Uterus: Sarcoma Stromal or Polyp	Stromal					,							
								4/50	(8%)	0/50	(0%)	0/50	(0%)
								2/50	(4%)	1/50	(2%)	0/50	(0%)
								0/50	(0%)	1/50	(2%)	0/50	(0%)
								0/50	(0%)	0/90	(0%)	0/50	(0%)
								2/50	(4%)				
verall Incidence							Total	10/690 (1.4	45%)	Mean	1.54%	SD 2.	
Vagina:													
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%)	0/90	(0%)	0/50	(0%)
								0/50	(0%)	0/30	(070)	0/30	(070)
Overall Incidence							Total	1/690 (0.1	` ,	Mean	0.15%	SD 0.	55%
#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%)	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%)
		1/50 (2%	,	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50 (0%	,	()		()		0/50	(0%)		()		()
Overall Incidence	Total	1/689 (0.15%)	Mean 0	Mean 0.15%		SD 0.55%		0/690 (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%)	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%)
		1/50 (2%	,	(0%)	0/50	(0%)		0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50 (0%		(3,5)	0,00	(0,0)		0/50	(0%)	5, 5 5	(0,0)	0,00	(3,0)
Overall Incidence	Total	1/689 (0.15%)	Mean 0	15%	SD 0.559	2/6	Total	0/690 (0	` '	Мез	n 0%	SD (0%
veran incluence	i Ulai	1/009 (0.15%)	ivicali U	.13/0	30 0.33	/0	i Ulai	0/090 (0	70)	iviea	11 0/0	30 (0 /0

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

^{#:} Denominator is number of animals necropsied