

NTP Historical Controls Report

All Routes and Vehicles

MICE

July 2015

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: 06/29/2015

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

Length of Study: CHRONIC

Study Summary

					,		
Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	052060104	10/06/08	729	50(5)	38(708)	52.1	Antimony trioxide
Battelle Northwest	056031106	05/15/06	729	50(5)	39(715)	54.3	Cobalt
Battelle Columbus Laboratory	059903104	03/17/05	726	50(1)	34(687)	54.6	Ginkgo biloba extract
Battelle Columbus Laboratory	052020304	07/10/07	730	50(1)	33(694)	52.6	Green Tea Extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	729	50(5)	39(709)	52.6	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	729	50(5)	38(692)	52.4	Metal Working Fluids: Trim VX
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl Oxide (Technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
Battelle Northwest	052030306	06/20/05	729	50(5)	29(680)	53.1	Vinylidene Chloride
Battelle Columbus Laboratory	059601406	09/26/06	730	50(1)	25(660)	55.9	Water Disinfection Byproducts: Bromodichloroacetic Acid
					Female		
Battelle Northwest	052060104	10/06/08	731	50(5)	36(692)	54.1	Antimony trioxide
Battelle Northwest	056031106	05/15/06	731	50(5)	36(686)	66.7	Cobalt
Battelle Columbus Laboratory	059903104	03/18/05	727	50(5)	31(628)	64.5	Ginkgo biloba extract
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green Tea Extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	731	50(5)	39(696)	59.2	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	731	50(5)	35(692)	57.9	Metal Working Fluids: Trim VX
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl Oxide (Technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A
Battelle Northwest	052030306	06/20/05	731	50(5)	36(687)	66.0	Vinylidene Chloride
Battelle Columbus Laboratory	059601406	09/25/06	729	50(5)	30(680)	63.5	Water Disinfection Byproducts: Bromodichloroacetic Acid

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES Page: 4

			Male				Female					
All Organs: Benign Tumors												
		37/50 (74%)	35/50 (70%)	38/50 (76%)		25/50 (50%)	29/50 (58%)	25/50 (50%)				
		43/50 (86%)	33/50 (66%)	39/50 (78%)		20/50 (40%)	17/50 (34%)	26/50 (52%)				
		32/50 (64%)	30/50 (60%)	38/50 (76%)		23/50 (46%)	24/50 (48%)	22/50 (44%)				
		43/50 (86%)	43/50 (86%)			32/50 (64%)	36/50 (72%)					
verall Incidence	Total	411/550 (74.73%)	Mean 74.73%	SD 9.09%	Total	279/550 (50.73%)	Mean 50.73%	SD 10.74%				
All Organs: Malignant Tumors												
		25/50 (50%)	36/50 (72%)	35/50 (70%)		25/50 (50%)	31/50 (62%)	28/50 (56%)				
		28/50 (56%)	27/50 (54%)	26/50 (52%)		18/50 (36%)	19/50 (38%)	30/50 (60%)				
		32/50 (64%)	27/50 (54%)	21/50 (42%)		27/50 (54%)	16/50 (32%)	18/50 (36%)				
		37/50 (74%)	30/50 (60%)			33/50 (66%)	31/50 (62%)					
Overall Incidence	Total	324/550 (58.91%)	Mean 58.91%	SD 10.09%	Total	276/550 (50.18%)	Mean 50.18%	SD 12.47%				
All Organs: Malignant and Benign												
		45/50 (90%)	45/50 (90%)	44/50 (88%)		35/50 (70%)	40/50 (80%)	35/50 (70%)				
		49/50 (98%)	48/50 (96%)	46/50 (92%)		29/50 (58%)	30/50 (60%)	41/50 (82%)				
		42/50 (84%)	40/50 (80%)	47/50 (94%)		38/50 (76%)	34/50 (68%)	32/50 (64%)				
		49/50 (98%)	48/50 (96%)			45/50 (90%)	45/50 (90%)					
verall Incidence	Total	503/550 (91.45%)	Mean 91.45%	SD 5.8%	Total	404/550 (73.45%)	Mean 73.45%	SD 11.1%				
All Organs: Hemangioma	••••••											
ŭ		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		` ,	0/50 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	1/50 (2%)				
		0/50 (0%)	0/30 (0/0)	2/00 (4/0)								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	2/00 (4/0)		0/50 (0%)	0/50 (0%)	(=75)				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Page: 5

Mean 19.82%

SD 7.92%

Report Date: 06/29/2015

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
All Organs: Hemangiosarcoma								
		2/50 (4%)	7/50 (14%)	9/50 (18%)		4/50 (8%)	3/50 (6%)	2/50 (4%)
		5/50 (10%)	4/50 (8%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	3/50 (6%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	5/50 (10%)			4/50 (8%)	6/50 (12%)	
verall Incidence	Total	37/550 (6.73%)	Mean 6.73%	SD 5.75%	Total	27/550 (4.91%)	Mean 4.91%	SD 3.62%
All Organs: Hemangiosarcoma or I								
		2/50 (4%)	7/50 (14%)	9/50 (18%)		4/50 (8%)	3/50 (6%)	2/50 (4%)
		7/50 (14%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
		0/50 (0%)	1/50 (2%)	3/50 (6%)		3/50 (6%)	1/50 (2%)	2/50 (4%)
		3/50 (6%)	5/50 (10%)			4/50 (8%)	6/50 (12%)	
verall Incidence	Total	43/550 (7.82%)	Mean 7.82%	SD 5.62%	Total	31/550 (5.64%)	Mean 5.64%	SD 2.94%
All Organs: Histiocytic Sarcoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		4/50 (8%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	1/50 (2%)			2/50 (4%)	2/50 (4%)	
verall Incidence	Total	9/550 (1.64%)	Mean 1.64%	SD 1.5%	Total	18/550 (3.27%)	Mean 3.27%	SD 2.24%
All Organs:	Histocutic Lun	nphocytic, Mixed, NOS, o	r Undifferentiated Cal	LTuno				
mangham Lymphoma.	misuocytic, Lyn	4/50 (8%)	4/50 (8%)	1/50 (2%)		7/50 (14%)	14/50 (28%)	11/50 (22%)
		4/50 (8%)	3/50 (6%)	3/50 (6%)		7/50 (14%)	6/50 (12%)	18/50 (36%)
		6/50 (12%)	5/50 (10%)	3/50 (6%)		10/50 (14%)	7/50 (12%)	9/50 (18%)
		2/50 (4%)	0/50 (0%)	3/30 (0/0)		14/50 (28%)	6/50 (12%)	3/30 (10/0)
		2/30 (4%)	0/30 (0%)			14/30 (20%)	0/30 (12/0)	

SD 3.44%

Total

109/550 (19.82%)

Total

35/550 (6.36%)

Mean 6.36%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/29/2015

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female						
#All Organs: Mesothelioma: Benign, M	Malianant NOS										
wesomenoma. Benign, k	wangnant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	1/50 (2%)	0/30 (0/0)		0/50 (0%)	0/50 (0%)	0/30 (0/0)			
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%			
				• • • • • • • • • • • • • • • • • • • •							
#All Organs: Mesothelioma: Malignan	ıt										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%			
#All Organs: Osteoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%			
#All Organs:											
Osteosarcoma or Osteor	ma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	1/50 (2%)	` ,			
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%			
		2.222 (070)			. 5	(2.1.070)	0				

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

^{#:} Denominator is number of animals necropsied

SIOH. Jui2015

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
*Adrenal Cortex: Adenoma									,					
		4/49	(8%)	1/50	(2%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	0/50	(0%)	9/49	(18%)		0/49	(0%)	2/49	(4%)	0/49	(0%)
		3/50	(6%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	2/50	(4%)				1/50	(2%)	0/49	(0%)		
Overall Incidence	Total	23/547 (4.2		Mean 4		SD 5.289		Total	4/546 (0.	•		0.73%	SD 1.	
Adrenal Medulla: Pheochromocytoma B														
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/48	(2%)		0/49	(0%)	0/49	(0%)	1/49	(2%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		2/50	(4%)	0/49	(0%)	1/50	(2%)
		1/50	(2%)	0/50	(0%)				1/50	(2%)	0/50	(0%)		
Overall Incidence	Total	3/546 (0.55	,	Mean 0		SD 0.959		Total	6/546 (1	,		1.09%	SD 1.	
*Adrenal Medulla: Pheochromocytoma M														
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/48	(0%)		0/49	(0%)	0/49	(0%)	0/49	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)				1/50	(2%)	0/50	(0%)		
Overall Incidence	Total	1/546 (0.18	3%)	Mean 0	.18%	SD 0.6%	6	Total	1/546 (0.	18%)	Mean	0.18%	SD 0	0.6%
*Adrenal Medulla:						•••••		•••••						
Pheochromocytoma: B	Benian. Complex	. Malignant. NO	S											
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/48	(2%)		0/49	(0%)	0/49	(0%)	1/49	(2%)
			(0%)	1/50	(2%)	0/50	(0%)		2/50	(4%)	0/49	(0%)	1/50	(2%)
		0/50												
		0/50 2/50	(4%)	0/50	(0%)		()		2/50	(4%)	0/50	(0%)		, ,

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

^{#:} Denominator is number of animals necropsied

1011. Jui2013

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 8

					Male					Female					
#Blood Vessel: Hemangioma							,								
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/550 (0%	b)	Mean	0%	SD 0%		Total	1/550 (0.	.18%)	Mean	0.18%	SD 0	0.6%	
#Blood Vessel: Hemangiosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	0/550 (0%	•	Mean		SD 0%		Total	1/550 (0.	,		0.18%	SD 0		
*Bone Marrow: Hemangiosarcoma															
		0/49	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		1/50	(2%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)	
		1/50	(2%)	0/50	(0%)				0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	4/549 (0.73		Mean 0		SD 1.019		Total	1/548 (0.	,		0.18%	SD 0		
*Bone Marrow: Mast Cell Tumor Malignant															
_		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%)	
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)		. ,		0/50	(0%)	0/50	(0%)		, ,	
Overall Incidence	Total	1/549 (0.18	%)	Mean 0	100/	SD 0.6%	4	Total	1/548 (0.	18%)		0.18%	SD 0	6%	

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

^{#:} Denominator is number of animals necropsied

IOII. 3012013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Bone Marrow: Sarcoma 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%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 0/549 (0%) Mean 0% SD 0% 1/548 (0.18%) Mean 0.18% SD 0.6% Total Total #Bone: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) SD 0.6% Total Total Mean 0.18% #Bone: Osteoma 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)(2%)1/50 Overall Incidence 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Bone: Osteosarcoma or Osteoma (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)

SD 0%

0/50

1/550 (0.18%)

Total

(0%)

1/50

(2%)

SD 0.6%

Mean 0.18%

Total

0/50

0/550 (0%)

(0%)

0/50

Mean 0%

(0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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			Male				Female			
#Bone:										
Sarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%		
Brain:										
Granular Cell Tumor B	enign									
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%		
Brain: Meningioma Malignant										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%		
Brain:										
Meningioma: Benign, M	Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	(-,5)		0/50 (0%)	0/49 (0%)	(-,-)		
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%		
voi an incluence	i Ulai	1/330 (0.10/0)	WIGAII 0.1070	OD 0.070	i Ulai	0/343 (0/0)	IVICALI U/O	30 070		

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

^{#:} Denominator is number of animals necropsied

OII. Jui2015

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female #Coagulating Gland: Granular Cell Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total Total **#Coagulating Gland:** Sarcoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)(0%)(0%)1/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 **Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) SD 0% Total Total Mean 0% #Eye: **Melanoma Malignant** 0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 0/50 (0%)0/50 (0%)1/50 Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total Total #Harderian Gland: Adenoma (12%)(12%)4/50 3/50 (10%)6/50 6/50 (8%) 3/50 (6%)(6%)5/50 7/50 (14%)6/50 (12%)7/50 (14%)2/50 (4%)3/50 (6%)2/50 (4%)5/50 (10%)7/50 9/50 2/50 4/50 (8%)(14%)1/50 (2%)(18%)(4%)

SD 2.27%

1/50

36/550 (6.55%)

Total

(2%)

5/50

(10%)

SD 4.66%

Mean 6.55%

Total

7/50

65/550 (11.82%)

(14%)

6/50

Mean 11.82%

(12%)

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

^{#:} Denominator is number of animals necropsied

SIOH. Jui2015

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Harderian Gland: Carcinoma 1/50 (2%)2/50 (4%)3/50 (6%)4/50 (8%)0/50 (0%)1/50 (2%)(4%)1/50 (2%)1/50 (2%)5/50 (10%)2/50 0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)3/50 (6%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)Overall Incidence 17/550 (3.09%) Mean 3.09% SD 2.88% 15/550 (2.73%) Mean 2.73% SD 2.87% Total Total #Harderian Gland: Carcinoma or Adenoma 7/50 (14%)8/50 (16%)7/50 (14%)(14%)3/50 (6%)6/50 (12%)7/50 8/50 (16%)7/50 (14%)12/50 (24%)4/50 (8%)3/50 (6%)2/50 (4%)6/50 (12%)6/50 (12%)8/50 (16%)4/50 (8%)10/50 (20%)3/50 (6%)7/50 (14%)(8%) 6/50 (12%)4/50 5/50 (10%)**Overall Incidence** 82/550 (14.91%) Mean 14.91% SD 3.39% 51/550 (9.27%) Mean 9.27% SD 4.58% Total Total *Heart: Hemangiosarcoma 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)1/50 (2%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total Total #Intestine Large: Cecum: Carcinoma (0%) 0/50 0/50 (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%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)

SD 0.81%

......

1/50

1/550 (0.18%)

Total

(2%)

0/50

(0%)

SD 0.6%

Mean 0.18%

Total

1/50

2/550 (0.36%)

(2%)

1/50

Mean 0.36%

(2%)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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				Male						Female						
O/50 O/96 O/50 O/96 O/50 O/96 O/50 O/96 O/96 O/50 O/96	•							,		,						
O/50 O/% O/5			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence Total 2/550 (0.36%) Mean 0.36% SD 0.81% Total 1/550 (0.18%) Mean 0.18% SD 0.69% #Intestine Large: Cecum: Leiomyosarcoma Company of the property of t			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
#Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/5			1/50	(2%)	1/50	(2%)				1/50	(2%)	0/50	(0%)			
#Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/5			,	%)	Mean 0	.36%				,	18%)	Mean	0.18%	SD 0	0.6%	
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50	#Intestine Large: Cecum:							•••••								
O/50 (0%) O/50			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence Total O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Mean 0.18% SD 0.6% Total O/50 (0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)	
Overall Incidence Total 0/550 (0%) Mean 0% SD 0% Total 1/550 (0.18%) Mean 0.18% SD 0.6% #Intestine Small: Duodenum: Adenoma 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
#Intestine Small: Duodenum: Adenoma 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)			
#Intestine Small: Duodenum: Adenoma 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)																
O/50 (0%) 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) O/50 (0%) 0/50 (0%) 1/50 (2%)	#Intestine Small: Duodenum:															
2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			2/50	(4%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
Overall Incidence Total O/50 (0%) 1/50 (2%) Mean 1.64% SD 1.75% Total 2/550 (0.36%) Mean 0.36% SD 0.81% #Intestine Small: Duodenum: Carcinoma O/50 (0%)			0/50	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
Overall Incidence Total 9/550 (1.64%) Mean 1.64% SD 1.75% Total 2/550 (0.36%) Mean 0.36% SD 0.81% #Intestine Small: Duodenum: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/5			2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
Overall Incidence Total 9/550 (1.64%) Mean 1.64% SD 1.75% Total 2/550 (0.36%) Mean 0.36% SD 0.81% #Intestine Small: Duodenum: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/5			0/50	(0%)	1/50	(2%)		` ,		0/50	` '	0/50	(0%)		` ,	
#Intestine Small: Duodenum: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			,	,	Mean 1	.64%				,	,				.81%	
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	#Intestine Small: Duodenum:															
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)				` '		` ,		` ,			` ,		` ,		(0%)	
				` ,		` ,		` '			` '		` '		` ,	
(370)				` ,		` ,	5. 5 5	()			` ,		` ,	-,	()	
Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% Total 0/550 (0%) Mean 0% SD 0%	Overall Incidence	Total		, ,		` ,	SD 0.6%	6	Total		. ,		` ,	SD	0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)Overall Incidence 2/550 (0.36%) Mean 0.36% SD 0.81% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Intestine Small: Ileum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)(0%)1/50 0/50 **Overall Incidence** 0/550 (0%) Mean 0% SD 0% 2/550 (0.36%) Mean 0.36% SD 0.81% Total Total #Intestine Small: Jejunum: Adenoma 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 1/50 (2%)0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)Overall Incidence 2/550 (0.36%) Mean 0.36% SD 0.81% 0/550 (0%) Mean 0% SD 0% Total Total #Intestine Small: Jejunum: Carcinoma (2%) 0/50 0/50 1/50 (2%)0/50 (0%)1/50 0/50 (0%)(0%)(0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 0/50 0/50 (0%)0/50 (2%)0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)

SD 1.38%

Total

0/550 (0%)

Mean 0%

SD 0%

Total

6/550 (1.09%)

Mean 1.09%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Page: 15

Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/550 (0%) Mean 0% SD 0% 2/550 (0.36%) Mean 0.36% SD 0.81% Total #Intestine Small: Site Unspecified: Adenoma 0/50 2/50 (4%)2/50 (4%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(2%)0/50 3/50 (6%)1/50 0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)(2%)1/50 (2%)(2%)(0%)1/50 1/50 0/50 **Overall Incidence** 13/550 (2.36%) Mean 2.36% SD 1.96% 3/550 (0.55%) Mean 0.55% SD 0.93% Total Total #Intestine Small: Site Unspecified: Carcinoma (2%)0/50 1/50 (2%)(0%)(2%)0/50 (0%)1/50 (0%)0/50 1/50 2/50 (4%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)Mean 1.27% SD 1.62% Overall Incidence 7/550 (1.27%) 2/550 (0.36%) Mean 0.36% SD 0.81% Total Total #Intestine Small: Site Unspecified: Carcinoma or Adenoma (2%) 0/50 3/50 (6%)2/50 (4%)1/50 0/50 (0%)1/50 (2%)(0%)2/50 (4%)3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (0%)2/50 0/50 1/50 (4%)0/50 (4%)0/50 (0%)(0%)(2%)

SD 1.96%

.....

2/50

5/550 (0.91%)

Total

(4%)

0/50

(0%)

SD 1.38%

Mean 0.91%

Total

1/50

20/550 (3.64%)

(2%)

3/50

Mean 3.64%

(6%)

^{*:} 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: 06/29/2015

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Species: MICE Strain: B6C3F1

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male		Female						
#Intestine Small: Site Unspe Leiomyosarcoma	cified:										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%			
slets, Pancreatic: Adenoma											
		0/49 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
		2/50 (4%)	0/50 (0%)			1/50 (2%)	0/49 (0%)				
Overall Incidence	Total	8/548 (1.46%)	Mean 1.45%	SD 1.57%	Total	4/549 (0.73%)	Mean 0.73%	SD 1.01%			
Islets, Pancreatic: Carcinoma											
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)				
verall Incidence	Total	1/548 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%			
Islets, Pancreatic: Carcinoma or Adenoma											
		0/49 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
		2/50 (4%)	0/50 (0%)	, ,		1/50 (2%)	0/49 (0%)	. ,			
Overall Incidence	Total	9/548 (1.64%)	Mean 1.64%	SD 1.75%	Total	4/549 (0.73%)	Mean 0.73%	SD 1.01%			

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

^{#:} Denominator is number of animals necropsied

ii. Jui2015

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

		Male				Female								
Kidney: Pelvis and Transi	tional Enitheliu	ım·												
Carcinoma	tional Epitilent													
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	0/550 (0%	6)	Mean	0%	SD 0%		Total	1/549 (0.	18%)	Mean	0.18%	SD 0	.6%
								• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •		
(idney: Pelvis and Transi Carcinoma or Adenoma	tional Epitheliu	um:												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	0/550 (0%	,	Mean	0%	SD 0%		Total	1/549 (0.	18%)	Mean	0.18%	SD 0	.6%
Kidney: Renal Tubule: Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2/50	(4%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	3/550 (0.55	5%)	Mean 0	.55%	SD 1.299	6	Total	0/549 (0%)	Mea	n 0%	SD	0%
Kidney: Renal Tubule: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
					` '		. ,			. ,		. ,		` '
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)

SD 1.21%

Total

0/549 (0%)

Mean 0%

SD 0%

Total

2/550 (0.36%)

Mean 0.36%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/550 (0.91%) Mean 0.91% SD 2.07% 0/549 (0%) Mean 0% SD 0% Total *Kidney: Renal Tubule: Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) Mean 0% SD 0% Total Total *Liver: Cholangiocarcinoma (2%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)1/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/49 (0%)Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% 0/549 (0%) Mean 0% SD 0% Total *Liver: Hemangioma 0/50 0/50 (0%) 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

2/50

SD 1.62%

(4%)

0/50

0/50

0/549 (0%)

Total

(0%)

(0%)

0/50

0/49

(0%)

(0%)

Mean 0%

0/50

SD 0%

(0%)

(0%)

(0%)

0/50

0/50

Mean 0.73%

Total

0/50

0/50

4/550 (0.73%)

(0%)

(0%)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

					Male				Female						
Liver: Hemangiosarcoma							,								
		0/50	(0%)	4/50	(8%)	9/50	(18%)		0/50	(0%)	2/50	(4%)	0/50	(0%)	
		3/50	(6%)	4/50	(8%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		2/50	(4%)	1/50	(2%)				1/50	(2%)	2/49	(4%)			
verall Incidence	Total	23/550 (4.1	,	Mean 4		SD 5.62		Total	6/549 (1	,		n 1.1%	SD 1		
_iver: Hepatoblastoma															
-		2/50	(4%)	2/50	(4%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
		2/50	(4%)	3/50	(6%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
		0/50	(0%)	1/50	(2%)	2/50	(4%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		1/50	(2%)	4/50	(8%)				0/50	(0%)	0/49	(0%)			
verall Incidence	Total	20/550 (3.6		Mean 3	.64%	SD 2.59	%	Total	3/549 (0	.55%)	Mean	0.55%	SD 0	.93%	
_iver: Hepatocellular Adenoma															
		30/50	(60%)	28/50	(56%)	31/50	(62%)		11/50	(22%)	19/50	(38%)	17/50	(34%)	
		35/50	(70%)	26/50	(52%)	24/50	(48%)		12/50	(24%)	7/50	(14%)	14/50	(28%)	
		23/50	(46%)	23/50	(46%)	32/50	(64%)		9/50	(18%)	5/50	(10%)	13/50	(26%)	
		37/50	(74%)	39/50	(78%)				25/50	(50%)	33/49	(67%)			
verall Incidence	Total	328/550 (59.	.64%)	Mean 59	9.64%	SD 11.2	%	Total	165/549 (3	30.05%)	Mean	30.12%	SD 16	6.72%	
₋iver: Hepatocellular Carcinoma															
•		15/50	(30%)	25/50	(50%)	22/50	(44%)		6/50	(12%)	10/50	(20%)	9/50	(18%)	
		15/50	(30%)	12/50	(24%)	11/50	(22%)		5/50	(10%)	6/50	(12%)	10/50	(20%)	
		21/50	(42%)	18/50	(36%)	11/50	(22%)		7/50	(14%)	4/50	(8%)	2/50	(4%)	
		26/50	(52%)	12/50	(24%)		, ,		8/50	(16%)	9/49	(18%)		` '	
			` '	-	` ,					` '	_	` '			

SD 11.26%

Total

76/549 (13.84%)

Mean 13.85%

SD 5.2%

Total

188/550 (34.18%)

Mean 34.18%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Liver:								
Hepatocellular Carcino	oma or Hepatob	olastoma						
		16/50 (32%)	27/50 (54%)	24/50 (48%)		6/50 (12%)	10/50 (20%)	10/50 (20%)
		17/50 (34%)	15/50 (30%)	11/50 (22%)		5/50 (10%)	6/50 (12%)	10/50 (20%)
		21/50 (42%)	18/50 (36%)	12/50 (24%)		7/50 (14%)	4/50 (8%)	2/50 (4%)
		27/50 (54%)	15/50 (30%)			8/50 (16%)	9/49 (18%)	
verall Incidence	Total	203/550 (36.91%)	Mean 36.91%	SD 11.18%	Total	77/549 (14.03%)	Mean 14.03%	SD 5.4%
_iver:								
Hepatocellular Carcino	oma or Hepatoc	ellular Adenoma						
		39/50 (78%)	38/50 (76%)	39/50 (78%)		14/50 (28%)	25/50 (50%)	20/50 (40%)
		40/50 (80%)	35/50 (70%)	32/50 (64%)		14/50 (28%)	12/50 (24%)	20/50 (40%)
		34/50 (68%)	31/50 (62%)	39/50 (78%)		15/50 (30%)	8/50 (16%)	15/50 (30%)
		44/50 (88%)	42/50 (84%)			28/50 (56%)	36/49 (73%)	
verall Incidence	Total	413/550 (75.09%)	Mean 75.09%	SD 8.17%	Total	207/549 (37.7%)	Mean 37.77%	SD 16.56%
Liver:								
	oma, Hepatocel	Iular Adenoma, or Hepatol	blastoma					
•	•	39/50 (78%)	39/50 (78%)	39/50 (78%)		14/50 (28%)	25/50 (50%)	20/50 (40%)
		40/50 (80%)	36/50 (72%)	32/50 (64%)		14/50 (28%)	12/50 (24%)	20/50 (40%)
		34/50 (68%)	31/50 (62%)	39/50 (78%)		15/50 (30%)	8/50 (16%)	15/50 (30%)
		45/50 (90%)	42/50 (84%)	, ,		28/50 (56%)	36/49 (73%)	, ,
verall Incidence	Total	416/550 (75.64%)	Mean 75.64%	SD 8.43%	Total	207/549 (37.7%)	Mean 37.77%	SD 16.56%
Liver:								
Hepatocholangiocarcii	noma							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/00 (0/0)		0/50 (0%)	0/49 (0%)	0,00 (0,0)
verall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
verali iliciuelice	TOtal	2/330 (0.30%)	Weatt 0.30%	30 0.01%	i Olai	1/348 (0.16%)	IVICALI 0.10%	3D 0.0%

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

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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

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			Male				Female	
*Liver: Ito Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/49 (0%)	, ,
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/549 (0%)	Mean 0%	SD 0%
Liver:								
Mast Cell Tumor Malign	ant							
ŭ		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/49 (0%)	, ,
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/549 (0.18%)	Mean 0.18%	SD 0.6%
*Lung: Alveolar/Bronchiolar Ac								
		10/50 (20%)	7/50 (14%)	8/50 (16%)		1/50 (2%)	3/49 (6%)	0/50 (0%)
		12/50 (24%)	4/50 (8%)	5/50 (10%)		5/50 (10%)	1/50 (2%)	1/50 (2%)
		6/50 (12%)	5/50 (10%)	6/50 (12%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		7/50 (14%)	13/50 (26%)	` ,		3/50 (6%)	3/50 (6%)	` ,
Overall Incidence	Total	83/550 (15.09%)	Mean 15.09%	SD 5.89%	Total	27/549 (4.92%)	Mean 4.92%	SD 3.51%
*Lung:								
Alveolar/Bronchiolar Ca	arcinoma							
		4/50 (8%)	11/50 (22%)	11/50 (22%)		2/50 (4%)	5/49 (10%)	1/50 (2%)
		2/50 (4%)	4/50 (8%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	4/50 (8%)
				` '		` ,	` '	` '
		10/50 (20%)	5/50 (10%)	4/50 (8%)		5/50 (10%)	0/50 (0%)	1/50 (2%)
		10/50 (20%) 9/50 (18%)	5/50 (10%) 7/50 (14%)	4/50 (8%)		5/50 (10%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	1/50 (2%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
*Lung:								
Alveolar/Bronchiolar Carcin	oma or Al							
		13/50 (26%)	16/50 (32%)	17/50 (34%)		3/50 (6%)	8/49 (16%)	1/50 (2%)
		14/50 (28%)	8/50 (16%)	13/50 (26%)		6/50 (12%)	3/50 (6%)	4/50 (8%)
		14/50 (28%)	10/50 (20%)	10/50 (20%)		9/50 (18%)	1/50 (2%)	6/50 (12%)
		13/50 (26%)	19/50 (38%)			4/50 (8%)	5/50 (10%)	
Overall Incidence	Total	147/550 (26.73%)	Mean 26.73%	SD 6.47%	Total	50/549 (9.11%)	Mean 9.12%	SD 5.21%
'Lung: Hemangiosarcoma								
		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%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	0/549 (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%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(-,3)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Totali illoluciloc	iotai	0/330 (0/0)	Wican 070	3D 070	i Otai	1/000 (0.10/0)	WICAIT 0.1070	CD 0.070

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

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female #Lymph Node, Mediastinal: Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total #Lymph Node, Mesenteric: Hemangioma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Lymph Node, Mesenteric: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(2%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)1/50 0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 0/550 (0%) Mean 0% SD 0% Total Total **#Mammary Gland:** Carcinoma 0/50 0/50 (0%)0/50 (0%) 0/50 (0%)(0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 0/50 (0%)0/50 (2%)0/50

(0%)

SD 0%

0/50

1/50

8/550 (1.45%)

Total

(0%)

(2%)

1/50

1/50

(2%)

Mean 1.45%

(0%)

SD 1.29%

Total

(0%)

(0%)

0/50

Mean 0%

(0%)

0/50

0/550 (0%)

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

131011. Jul2013

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
#Mammary Gland: Carcinoma or Adenoma		,												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	2/50	(4%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				1/50	(2%)	1/50	(2%)		
Overall Incidence	Total	0/550 (0%	o)	Mean	0%	SD 0%		Total	8/550 (1.	45%)	Mean	1.45%	SD 1	.29%
#Mammary Gland:														
Fibroma, Fibroadenoma	, Carcinoma, o	r Adenoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	2/50	(4%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)		, ,		1/50	(2%)	1/50	(2%)		` ,
Overall Incidence	Total	0/550 (0%		Mean		SD 0%		Total	8/550 (1.			1.45%	SD 1	
#Mesentery: Hemangioma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		, ,
Overall Incidence	Total	1/550 (0.18	•	Mean 0		SD 0.6%		Total	0/550 (n 0%	SD	
#Mesentery: Hemangiosarcoma														
3		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	2.20	(- / - /		0/50	(0%)	1/50	(2%)	0	(-,-,

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: ALL ROUTES Strain: B6C3F1 Vehicle: ALL VEHICLES

Length of Study: CHRONIC

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			Male				Female	
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/48 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/540 (00/)	Mean 0%	CD 00/	T-4-1	1/E 10 (0 100/)	Mean 0.19%	SD 0.63%
		0/549 (0%)		SD 0%	Total	1/548 (0.18%)		
	sa, Tongue, Phar					, ,		
#Oral Cavity (Oral Muco	sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
#Oral Cavity (Oral Muco	sa, Tongue, Phar	ynx, Tooth, Gingiva):						
#Oral Cavity (Oral Muco	sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
#Oral Cavity (Oral Muco	sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
#Oral Cavity (Oral Mucos Papilloma Squamous Overall Incidence	sa, Tongue, Phar or Papilloma Total	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (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%) 1/550 (0.18%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%)
#Oral Cavity (Oral Mucos Papilloma Squamous Overall Incidence	sa, Tongue, Phar or Papilloma Total sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (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%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%) 1/50 (2%)
#Oral Cavity (Oral Muco Papilloma Squamous Overall Incidence	sa, Tongue, Phar or Papilloma Total sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (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%) 1/550 (0.18%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%) 1/50 (2%)
#Oral Cavity (Oral Muco Papilloma Squamous Overall Incidence	sa, Tongue, Phar or Papilloma Total sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%) ynx, Tooth, Gingiva):	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (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%) 1/550 (0.18%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%) 1/50 (2%) SD 0.6%
#Oral Cavity (Oral Muco: Papilloma Squamous of Overall Incidence #Oral Cavity (Oral Muco:	sa, Tongue, Phar or Papilloma Total sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%) ynx, Tooth, Gingiva): 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (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%) 1/550 (0.18%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%) 1/50 (2%) SD 0.6%
#Oral Cavity (Oral Muco Papilloma Squamous Overall Incidence	sa, Tongue, Phar or Papilloma Total sa, Tongue, Phar	ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/550 (0%) ynx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/550 (0.18%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.18% 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) SD 0.6% 1/50 (2%) 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
Oral Cavity (Oral Mucosa Squamous Cell Carcinor								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	3/550 (0.55%)	Mean 0.55%	SD 1.29%
#Oral Mucosa: Squamous Cell Carcinor	ma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%
Ovary: Choriocarcinoma								
						0/50 (0%)	0/48 (0%)	1/50 (2%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/48 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	1/546 (0.18%)	Mean 0.18%	SD 0.6%
*Ovary: Cystadenocarcinoma						•••••		
.,						0/50 (0%) 1/50 (2%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
O					T-1-1	0/50 (0%)	0/50 (0%)	OD 0.00/
Overall Incidence					Total	1/546 (0.18%)	Mean 0.18%	SD 0.6%

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

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^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Cystadenoma 1/50 (2%)1/48 (2%)2/50 (4%)3/50 (6%)1/50 (2%)2/50 (4%)1/50 (2%)2/48 (4%)2/50 (4%)1/50 (2%)(2%)1/50 **Overall Incidence** Total 17/546 (3.11%) Mean 3.11% SD 1.38% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)1/48 (2%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** 3/546 (0.55%) Mean 0.55% SD 0.95% Total *Ovary: **Granulosa Cell Tumor Malignant** (2%)0/48 0/50 (0%)1/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/546 (0.18%) Mean 0.18% SD 0.6% Total *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/48 0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)(2%)0/50 1/50 (2%)1/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 4/546 (0.73%) Mean 0.73% SD 1.02%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Hemangiosarcoma 1/50 (2%)0/48 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/546 (0.37%) Mean 0.36% SD 0.81% *Ovary: Luteoma 0/50 0/50 (0%)0/48 (0%)(0%)(0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)(2%)0/50 (0%)1/50 **Overall Incidence** 2/546 (0.37%) Mean 0.36% SD 0.81% Total *Ovary: Sarcoma 0/50 (0%)0/48 0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/546 (0.18%) Mean 0.18% SD 0.6% Total *Ovary: **Tubulostromal Adenoma** 0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)0/48 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/546 (0.18%) Mean 0.18% SD 0.6%

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

^{#:} Denominator is number of animals necropsied

JII. Jui2013

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Ovary: **Yolk Sac Carcinoma** 0/50 (0%)1/48 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/546 (0.18%) Mean 0.19% SD 0.63% Total *Pancreas: Carcinoma 0/50 0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/49 (0%)1/50 **Overall Incidence** 0/549 (0%) Mean 0% SD 0% 1/549 (0.18%) Mean 0.18% SD 0.6% Total Total *Pancreas: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 1/50 (2%)0/49 (0%)Overall Incidence 0/549 (0%) Mean 0% SD 0% 1/549 (0.18%) Mean 0.18% SD 0.6% Total Total *Parathyroid Gland: Adenoma (0%)(0%) 0/28 0/47 (0%)0/27 (0%)0/29 0/36 0/27 (0%)(0%)0/41 (0%)0/48 (0%)0/34 (0%)0/35 (0%)0/43 (0%)0/26 (0%)(0%)0/44 0/34 0/28 (0%)0/48 0/45 (0%)1/35 (3%)(0%)(0%)

SD 0%

0/24

1/388 (0.26%)

Total

(0%)

0/45

(0%)

SD 0.86%

Mean 0.26%

Total

0/26

0/406 (0%)

(0%)

0/44

Mean 0%

(0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management SystemTumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Page: 30

			Male				Female	
Pituitary Gland: Pars Di Adenoma	stalis or Unspec	ified Site:						
		0/49 (0%)	0/47 (0%)	0/49 (0%)		9/49 (18%)	3/47 (6%)	4/50 (8%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/49 (6%)	5/50 (10%)
		1/50 (2%)	0/47 (0%)	0/50 (0%)		8/48 (17%)	5/50 (10%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)			8/50 (16%)	2/49 (4%)	
verall Incidence	Total	2/540 (0.37%)	Mean 0.37%	SD 0.82%	Total	48/542 (8.86%)	Mean 8.87%	SD 6.06%
Pituitary Gland: Pars Di Carcinoma		rified Site:						
		0/49 (0%)	0/47 (0%)	0/49 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/47 (0%)	0/50 (0%)		3/48 (6%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Verall Incidence	Total	0/540 (0%)	Mean 0%	SD 0%	Total	3/542 (0.55%)	Mean 0.57%	SD 1.88%
Pituitary Gland: Pars Di		itial Cita.						
Carcinoma or Adenom	•	inted Site:						
•	•	0/49 (0%)	0/47 (0%)	0/49 (0%)		9/49 (18%)	3/47 (6%)	4/50 (8%)
•	•		0/47 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		9/49 (18%) 0/50 (0%)	3/47 (6%) 3/49 (6%)	4/50 (8%) 5/50 (10%)
•	•	0/49 (0%)	` ,	` ,		(,	` ,	` ,
•	•	0/49 (0%) 1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	3/49 (6%)	5/50 (10%)
Carcinoma or Adenom	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%) 2/540 (0.37%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44%	5/50 (10%) 1/50 (2%) SD 7.08%
Carcinoma or Adenom Overall Incidence	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37%	0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44%	5/50 (10%) 1/50 (2%) SD 7.08%
Carcinoma or Adenom Overall Incidence Pituitary Gland: Pars Inf	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%) 2/540 (0.37%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37%	0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44%	5/50 (10%) 1/50 (2%) SD 7.08%
Carcinoma or Adenom Overall Incidence Pituitary Gland: Pars Inf	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%) 2/540 (0.37%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37%	0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44%	5/50 (10%) 1/50 (2%) SD 7.08%
Carcinoma or Adenom Overall Incidence Pituitary Gland: Pars Inc	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%) 2/540 (0.37%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37%	0/50 (0%) 0/50 (0%) SD 0.82%		0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%) 0/49 (0%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44%	5/50 (10%) 1/50 (2%) SD 7.08%
Carcinoma or Adenom Overall Incidence Pituitary Gland: Pars Inc	Total	0/49 (0%) 1/49 (2%) 1/50 (2%) 0/49 (0%) 2/540 (0.37%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/47 (0%) 0/50 (0%) Mean 0.37% 0/47 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0.82% 		0/50 (0%) 11/48 (23%) 8/50 (16%) 51/542 (9.41%) 0/49 (0%) 0/50 (0%)	3/49 (6%) 5/50 (10%) 2/49 (4%) Mean 9.44% 0/47 (0%) 1/49 (2%)	5/50 (10%) 1/50 (2%) SD 7.08%

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

^{#:} Denominator is number of animals necropsied

m: Juizu 15

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/49 (0%)0/47 (0%)0/49 (0%)0/49 (0%)0/47 (0%)1/50 (2%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/47 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 1/540 (0.19%) Mean 0.19% SD 0.62% 2/542 (0.37%) Mean 0.37% SD 0.82% Total *Salivary Glands: Adenoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(2%)(0%)(0%)0/50 (0%)0/50 1/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 0/548 (0%) Mean 0% SD 0% Total Total *Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)(2%)(0%)(0%)0/50 (0%)0/50 (0%)1/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/48 (0%)**Overall Incidence** Total 1/550 (0.18%) Mean 0.18% SD 0.6% 0/548 (0%) Mean 0% SD 0% Total *Salivary Glands: Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%) (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)

SD 0.6%

0/50

0/548 (0%)

Total

(0%)

0/48

(0%)

SD 0%

Mean 0%

Total

0/50

1/550 (0.18%)

(0%)

0/50

Mean 0.18%

(0%)

Overall Incidence

Page: 31

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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0/50

1/50

(0%)

(2%)

Mean 0.36%

0/50

0/50

2/550 (0.36%)

Total

(0%)

(0%)

0/50

SD 0.81%

(0%)

Report Date: 06/29/2015

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Salivary Glands: Myxoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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%)0/48 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% 1/548 (0.18%) Mean 0.18% SD 0.6% Total *Salivary Glands: Myxosarcoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/48 **Overall Incidence** 0/550 (0%) Mean 0% SD 0% 1/548 (0.18%) Mean 0.18% SD 0.6% Total Total **#Seminal Vesicle:** Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% Total **#Skeletal Muscle:** Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%) 0/50 (2%)(0%)0/50 (0%)(0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0.6%

......

(0%)

Total

0/50

1/50

1/550 (0.18%)

(0%)

(2%)

(0%)

(0%)

0/50

0/50

Mean 0.18%

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

^{#:} Denominator is number of animals necropsied

131011. Jul2013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female #Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/550 (0%) Mean 0% SD 0% 3/550 (0.55%) Mean 0.55% SD 1.29% Total **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(4%)0/50 0/50 0/50 2/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 3/550 (0.55%) Mean 0.55% SD 1.29% Total Total **#Skeletal Muscle:** Sarcoma 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 1/50 (2%)(0%)0/50 Overall Incidence 0/550 (0%) Mean 0% SD 0% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Skin: **Basal Cell Carcinoma** (0%) 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(2%)

SD 0%

0/50

2/550 (0.36%)

Total

(0%)

0/50

(0%)

SD 0.81%

Mean 0.36%

Total

0/50

0/550 (0%)

(0%)

0/50

Mean 0%

(0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 2/550 (0.36%) Mean 0.36% SD 0.81% Total Total #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/550 (0%) Mean 0% SD 0% 2/550 (0.36%) Mean 0.36% SD 0.81% Total Total #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (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%) (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 2/550 (0.36%) Mean 0.36% SD 0.81% 3/550 (0.55%) Mean 0.55% SD 0.93% Total Total #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)2/50 (4%)3/50 (6%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)(2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)2/50 (4%)4/50 (8%)**Overall Incidence** Total 5/550 (0.91%) Mean 0.91% SD 1.04% Total 16/550 (2.91%) Mean 2.91% SD 2.59%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

					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%)	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%)	1/50	(2%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)				1/50	(2%)	0/50	(0%)		
verall Incidence	Total	2/550 (0.36		Mean 0		SD 0.81		Total	4/550 (0.	,		0.73%	SD 1.	01%
Skin: Fibrosarcoma, Sarcoma														
,	, ,	0/50	(0%)	0/50	(0%)	0/50	(0%)		2/50	(4%)	2/50	(4%)	3/50	(6%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	1/50	(2%)
		1/50	(2%)	1/50	(2%)	.,	(= / -/		2/50	(4%)	4/50	(8%)	.,	(-,-,
verall Incidence	Total	5/550 (0.91	I%)	Mean 0	.91%	SD 1.04		Total	16/550 (2	91%)	Mean	2.91%	SD 2.	
Skin: Fibrous Histiocytoma	••••••								•••••					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)				0/50	(0%)	3/50	(6%)		
verall Incidence	Total	2/550 (0.36	6%)	Mean 0	.36%	SD 0.81	%	Total	4/550 (0.	73%)	Mean	0.73%	SD 1.	85%
Skin: Hemangioma														
-		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		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%)		. ,
			` '		` '					` '		` '		

SD 0%

Total

1/550 (0.18%)

Mean 0.18%

SD 0.6%

Total

0/550 (0%)

Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 5/550 (0.91%) Mean 0.91% SD 1.38% Total Total #Skin: Keratoacanthoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%)0/50 0/50 **Overall Incidence** 2/550 (0.36%) Mean 0.36% SD 0.81% 0/550 (0%) SD 0% Total Total Mean 0% #Skin: Lipoma 0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)(2%) 0/50 (0%)0/50 (0%)1/50 Overall Incidence 3/550 (0.55%) Mean 0.55% SD 1.29% 0/550 (0%) Mean 0% SD 0% Total Total #Skin: Liposarcoma 0/50 0/50 (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)

SD 0.6%

......

0/50

0/550 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

1/50

1/550 (0.18%)

(2%)

0/50

Mean 0.18%

(0%)

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

ion: Juizu 15

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
#Skin: Melanoma Benign							,							
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/550 (0.18	•	Mean 0		SD 0.6%		Total	0/550 (ın 0%	SD	
#Skin: Melanoma Malignant														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/550 (0.18	,	Mean 0		SD 0.6%		Total	1/550 (0.	,		0.18%	SD 0	
#Skin: Neural Crest Tumor														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/550 (0.18	3%)	Mean 0	.18%	SD 0.6%	6	Total	1/550 (0.	18%)	Mean	0.18%	SD 0	0.6%
#Skin:														
Neurofibrosarcoma or So	chwannoma (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%)	0/50	(0%)	0/50	(0%)		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%)
		2. 30	` ,		` '	0	(-,-)			` '		` '		(/
		0/50	(0%)	0/50	(0%)				0/50	(0%)	3/50	(6%)		

^{*:} 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: 06/29/2015

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Species: MICE Strain: B6C3F1

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Skin:				,				
Neurofibrosarcoma, Neu	ırofibroma, or S	Schwannoma (benign, r	nalignant or NOS)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	4/550 (0.73%)	Mean 0.73%	SD 1.85%
∕Skin: Sarcoma								
Carooma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(=75)		1/50 (2%)	1/50 (2%)	(171)
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	8/550 (1.45%)	Mean 1.45%	SD 2.02%
#Skin: Schwannoma Malignant	:							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	4/550 (0.73%)	Mean 0.73%	SD 1.85%
Skin:								
Squamous Cell Carcinon or Carcinoma	ma, Basal Cell (Carcinoma, Basosquan	nous Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES **Page:** 39

			Male				Female	
#Skin: Squamous Cell Papillo	oma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Skin:								
Squamous Cell Papillo	oma or Papilloma	a 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/30 (0 /0)		0/50 (0%)	0/50 (0%)	0/30 (0/8)
Overall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Skin:								
Squamous Cell Papillo	oma, Papilloma, S	Squamous Cell Carcinon						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Skin: Squamous Cell Papillo	oma Panilloma (or Karatoacanthoma						
oquanious oen rapino	oma, i apinoma, c	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1700 (270)		0/50 (0%)	0/50 (0%)	3,30 (0,70)
Overall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 0.81%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
veran incluence	illai	2/000 (0.00%)	IVICALI 0.30%	JD 0.0170	i Ulai	1/000 (0.16%)	WEAT 0.10%	3D 0.0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female** *Spleen: Hemangiosarcoma 2/49 (4%)3/50 (6%)0/50 (0%)0/50 (0%)2/49 (4%)1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/49 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)2/50 (4%)3/50 (6%)0/49 (0%)Overall Incidence 14/548 (2.55%) Mean 2.55% SD 2.02% 8/548 (1.46%) Mean 1.46% SD 2.03% Total Total *Spleen: **Mast Cell Tumor Malignant** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)1/49 (0%)(0%)(0%)0/50 0/50 0/50 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%)(0%)0/50 0/49 **Overall Incidence** 0/548 (0%) Mean 0% SD 0% 1/548 (0.18%) Mean 0.19% SD 0.62% Total Total **#Stomach**, Forestomach: **Squamous Cell Carcinoma** 0/50 0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)(2%)0/50 0/50 1/50 (2%)0/50 1/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)(0%)0/50 0/50 Overall Incidence Total 1/550 (0.18%) Mean 0.18% SD 0.6% 1/550 (0.18%) Mean 0.18% SD 0.6% Total **#Stomach**, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%) 2/50 1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)(4%)0/50 (0%)2/50 (4%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 5/50 0/50 (2%)2/50 (4%)(10%)1/50 (2%)0/50 (0%)(0%)

SD 3.03%

......

0/50

9/550 (1.64%)

Total

(0%)

1/50

(2%)

SD 1.5%

Mean 1.64%

Total

1/50

12/550 (2.18%)

(2%)

0/50

Mean 2.18%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Male **Female #Stomach, Forestomach: Squamous Cell Papilloma** 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)5/50 (10%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence 11/550 (2%) Mean 2% SD 2.97% 8/550 (1.45%) Mean 1.45% SD 1.29% Total Total #Stomach, Glandular: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(2%)0/50 0/50 1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)1/50 0/50 (0%)**Overall Incidence** 1/550 (0.18%) Mean 0.18% SD 0.6% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total #Stomach, Glandular: Carcinoma or Adenoma (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(2%)(0%)0/50 0/50 0/50 1/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) (2%)(0%)1/50 0/50 Overall Incidence 1/550 (0.18%) Mean 0.18% SD 0.6% 1/550 (0.18%) Mean 0.18% SD 0.6% Total Total *Testes: Adenoma 0/49 (2%) (0%)1/50 (2%)1/50 1/50 (2%)0/50 (0%)0/50 (0%)(0%) 0/50 0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)

SD 1.35%

Total

7/549 (1.28%)

Mean 1.27%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 06

					Male						F	emale		
*Testes: Hemangioma														
		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%)									
Overall Incidence	Total	1/549 (0.18	,	Mean 0		SD 0.6%								
*Thymus: Neoplasm NOS														
		0/41	(0%)	0/42	(0%)	0/50	(0%)		0/47	(0%)	1/46	(2%)	0/50	(0%)
		0/44	(0%)	0/49	(0%)	0/41	(0%)		0/47	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/40	(0%)	0/47	(0%)		0/48	(0%)	0/48	(0%)	0/50	(0%)
		0/39	(0%)	0/45	(0%)				0/47	(0%)	0/50	(0%)		
Overall Incidence	Total	0/482 (0%	(a)	Mean	0%	SD 0%		Total	1/526 (0	.19%)	Mear	າ 0.2%	SD 0	.66%
*Thymus: Thymoma Benign				•••••										
		0/41	(0%)	0/42	(0%)	0/50	(0%)		0/47	(0%)	0/46	(0%)	0/50	(0%)
		0/44	(0%)	1/49	(2%)	0/41	(0%)		0/47	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/40	(0%)	0/47	(0%)		0/48	(0%)	0/48	(0%)	0/50	(0%)
		0/39	(0%)	0/45	(0%)				0/47	(0%)	0/50	(0%)		
Overall Incidence	Total	1/482 (0.21	•	Mean 0		SD 0.62		Total	0/526 (,		ın 0%	SD	
*Thymus: Thymoma NOS														
•		0/41	(0%)	0/42	(0%)	0/50	(0%)		1/47	(2%)	0/46	(0%)	0/50	(0%)
		0/44	(0%)	0/49	(0%)	0/41	(0%)		0/47	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/40	(0%)	0/47	(0%)		0/48	(0%)	0/48	(0%)	0/50	(0%)
		0/39	(0%)	0/45	(0%)		` '		0/47	(0%)	0/50	(0%)		` '
Overall Incidence	Total	0/482 (0%		Mean	` ,	SD 0%		Total	1/526 (0	` '		0.19%	SD 0	6.49/

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

^{#:} Denominator is number of animals necropsied

11. Jui2015

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Thymus: Thymoma: Benign, Malignant, NOS 0/41 (0%)0/42 (0%)0/50 (0%)1/47 (2%)0/46 (0%)0/50 (0%)0/44(0%)1/49 (2%)0/41 (0%)0/47 (0%)0/49 (0%)0/44 (0%)0/44 (0%)0/40 (0%)0/47 (0%)0/48 (0%)0/48 (0%)0/50 (0%)0/39 (0%)0/45 (0%)0/47 (0%)0/50 (0%)Overall Incidence Total 1/482 (0.21%) Mean 0.19% SD 0.62% 1/526 (0.19%) Mean 0.19% SD 0.64% Total *Thyroid Gland: C-Cell: Adenoma (0%)0/49 (0%)0/49 (0%)0/49 0/48 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** 0/547 (0%) Mean 0% SD 0% 1/546 (0.18%) Mean 0.18% SD 0.6% Total Total *Thyroid Gland: C-Cell: Carcinoma 0/49 (0%)0/49 (0%)0/49 (0%)(0%)0/50 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(2%)0/50 0/50 0/50 1/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/49 (0%)Overall Incidence Total 0/547 (0%) Mean 0% SD 0% 2/546 (0.37%) Mean 0.36% SD 0.81% Total *Thyroid Gland: C-Cell: Carcinoma or Adenoma 0/49 0/49 (0%)0/49 (0%) 0/50 0/49 (0%)(0%)0/48 (0%)(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 0/50 (0%)1/50 (2%)1/50 (2%)(0%)

SD 0%

0/50

3/546 (0.55%)

Total

(0%)

0/49

(0%)

SD 0.93%

Mean 0.55%

Total

0/50

0/547 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Thyroid Gland: Follicular Adenoma	Cell:							
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	1/50 (2%)	0/49 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	3/547 (0.55%)	Mean 0.55%	SD 0.93%	Total	3/546 (0.55%)	Mean 0.55%	SD 0.93%
Thyroid Gland: Follicular Carcinoma or Adenoma								
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	1/50 (2%)	0/49 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	3/547 (0.55%)	Mean 0.55%	SD 0.93%	Total	3/546 (0.55%)	Mean 0.55%	SD 0.93%
#Tongue: Squamous Cell Carcino								
·	·	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/550 (0%)	Mean 0%	SD 0%	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
		, ,						
Tongue:								
		, ,	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Tongue:								` '
Tongue:		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	` ,
Tongue:		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)

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

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^{#:} Denominator is number of animals necropsied

II. Jui2013

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
‡Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N	T-1-1	0/50 (0%)	0/50 (0%)	OD 4 040/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
verall Incidence	Total	2/550 (0.36%)	Mean 0.36%	SD 1.21%	Total	0/550 (0%)	Mean 0%	SD 0%
Urethra: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	1/50 (2%)	OD 0.00/	T	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/48 (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%)	0/49 (0%)	0/50 (0%)
Normall Implications	Tatal	0/50 (0%)	0/50 (0%)	CD 0.00/	Tatal	0/49 (0%)	0/50 (0%)	CD 00/
verall Incidence	Total	1/548 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/547 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	
verall Incidence					Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
#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%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Uterus:				
Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0/0)
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%
#Uterus: Hemangiosarcoma				
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	5/550 (0.91%)	Mean 0.91%	SD 1.04%
#Uterus: Leiomyoma				
•		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%

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

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^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/29/2015

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus:								
Polyp Stromal						(50)	0/50 (404)	. (== (==()
						4/50 (8%)	2/50 (4%)	1/50 (2%)
						2/50 (4%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	0/50 (0%)
						2/50 (4%)	4/50 (8%)	
Overall Incidence					Total	16/550 (2.91%)	Mean 2.91%	SD 3.02%
#Uterus:								
Sarcoma Stromal								
						0/50 (0%)	0/50 (0%)	1/50 (2%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	2/50 (4%)
						0/50 (0%)	0/50 (0%)	` ,
Overall Incidence					Total	3/550 (0.55%)	Mean 0.55%	SD 1.29%
#Uterus:								
Sarcoma Stromal or P	olyn Stromal							
Sursoma Stromar or 1	oryp otromar					4/50 (8%)	2/50 (4%)	2/50 (4%)
						2/50 (4%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	2/50 (4%)
						2/50 (4%)	4/50 (8%)	2/30 (470)
Overall Incidence					Total	` ,	Mean 3.45%	SD 2.84%
						19/550 (3.45%)		SD 2.04%
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/00 (0/0)		0/50 (0%)	0/50 (0%)	0,00 (0,0)
Overell Incidence	Total	` '	` ,	CD 0.60/	Total	` '	` '	SD 09/
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ALL VEHICLES

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			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/550 (0.18%)	Mean 0.18%	SD 0.6%	Total	0/550 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied