NTP Historical Controls Report

All Routes and Vehicles

MICE

August 2017

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
M3
M4
M5
Female
F1
F2
F3
F4
F5

the data would be shown as:

	Male			**Female**	
M1	M2	M3	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.

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 3
Report Date: 01/20/2018

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Northwest	052060104	10/06/08	729	50(5)	38(708)	52.1	Antimony trioxide
Battelle Northwest	052072504	08/31/09	729	50(5)	35(697)	51.1	2,3-Butanedione
Battelle Columbus Laboratory	052020304	07/10/07	730	50(1)	33(694)	52.6	Green Tea Extract
Battelle Columbus Laboratory	051026002	07/16/10	727	49(1)	34(691)	47.6	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	729	50(5)	39(709)	52.6	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	729	50(5)	38(692)	52.4	Metal Working Fluids: TRIM VX
Battelle Northwest	051047204	01/31/11	729	50(5)	40(705)	52.7	p-Chloro-a,a,a-trifluorotoluene
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
I. I. T. Research Institute	052010578	06/18/12	729	90(1)	66(687)	51.5	Radiofrequency Radiation
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
Female							
Battelle Northwest	052060104	10/06/08	731	50(5)	36(692)	54.1	Antimony trioxide
Battelle Northwest	052072504	08/31/09	731	50(5)	36(697)	51.0	2,3-Butanedione
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green Tea Extract
Battelle Columbus Laboratory	051026002	07/15/10	726	50(4)	42(716)	54.7	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Northwest	052051504	05/05/08	731	50(5)	39(696)	59.2	Metal Working Fluids: CIMSTAR 3800
Battelle Northwest	052052304	08/03/09	731	50(5)	35(692)	57.9	Metal Working Fluids: TRIM VX
Battelle Northwest	051047204	01/31/11	731	50(5)	38(700)	55.9	p-Chloro-a,a,a-trifluorotoluene
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl Ether Mixture [DE-71 (Technical Grade)]
I. I. T. Research Institute	052010578	06/18/12	739	90(1)	67(704)	62.6	Radiofrequency Radiation
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

Species: MICE

Strain: B6C3F1/N   **Route:** ALL ROUTES

Length of Study: CHRONIC   **Vehicle:** ALL VEHICLES

		Male					Female				
#All Organs:											
Benign Tumors											
		37/50	(74%)	22/50	(44%)	43/50	(86%)	25/50	(50%)	15/50	(30%)	20/50	(40%)
		28/49	(57%)	33/50	(66%)	39/50	(78%)	17/50	(34%)	17/50	(34%)	26/50	(52%)
		32/50	(64%)	32/50	(64%)	30/50	(60%)	23/50	(46%)	24/50	(48%)	24/50	(48%)
		61/90	(68%)	38/50	(76%)			36/90	(40%)	22/50	(44%)		
Overall Incidence	Total	395/589 (67.06%)		Mean 66.99%		SD 11.43%	Total	249/590 (42.2%)		Mean 42.36%		SD 7.31%

		Male					Female				
#All Organs:											
Malignant Tumors											
		25/50	(50%)	27/50	(54%)	28/50	(56%)	25/50	(50%)	24/50	(48%)	18/50	(36%)
		19/49	(39%)	27/50	(54%)	26/50	(52%)	11/50	(22%)	19/50	(38%)	30/50	(60%)
		32/50	(64%)	25/50	(50%)	27/50	(54%)	27/50	(54%)	24/50	(48%)	16/50	(32%)
		49/90	(54%)	21/50	(42%)			33/90	(37%)	18/50	(36%)		
Overall Incidence	Total	306/589 (51.95%)		Mean 51.75%		SD 6.78%	Total	245/590 (41.53%)		Mean 41.88%		SD 11.05%

		Male					Female				
#All Organs:											
Malignant and Benign Tumors											
		45/50	(90%)	37/50	(74%)	49/50	(98%)	35/50	(70%)	34/50	(68%)	29/50	(58%)
		37/49	(76%)	48/50	(96%)	46/50	(92%)	25/50	(50%)	30/50	(60%)	41/50	(82%)
		42/50	(84%)	44/50	(88%)	40/50	(80%)	38/50	(76%)	38/50	(76%)	34/50	(68%)
		79/90	(88%)	47/50	(94%)			59/90	(66%)	32/50	(64%)		
Overall Incidence	Total	514/589 (87.27%)		Mean 87.21%		SD 8.03%	Total	395/590 (66.95%)		Mean 67.05%		SD 9.1%

		Male					Female				
#All Organs:											
Hemangioma											
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
		1/90	(1%)	2/50	(4%)			4/90	(4%)	1/50	(2%)		
Overall Incidence	Total	7/589 (1.19%)		Mean 1.2%		SD 1.6%	Total	10/590 (1.69%)		Mean 1.49%		SD 1.65%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

	Male				**Female**		

#All Organs:
Hemangiosarcoma

	Male				Female		
	2/50 (4%)	1/50 (2%)	5/50 (10%)		4/50 (8%)	0/50 (0%)	2/50 (4%)
	1/49 (2%)	4/50 (8%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
	0/50 (0%)	2/50 (4%)	1/50 (2%)		2/50 (4%)	3/50 (6%)	0/50 (0%)
	2/90 (2%)	1/50 (2%)			2/90 (2%)	1/50 (2%)	

Overall Incidence   Total   20/589 (3.4%)   Mean 3.48%   SD 2.97%   Total   17/590 (2.88%)   Mean 2.93%   SD 2.87%

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#All Organs:
Hemangiosarcoma or Hemangioma

	Male				Female		
	2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	0/50 (0%)	2/50 (4%)
	2/49 (4%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
	0/50 (0%)	2/50 (4%)	1/50 (2%)		3/50 (6%)	3/50 (6%)	1/50 (2%)
	3/90 (3%)	3/50 (6%)			6/90 (7%)	2/50 (4%)	

Overall Incidence   Total   27/589 (4.58%)   Mean 4.67%   SD 3.73%   Total   27/590 (4.58%)   Mean 4.42%   SD 2.39%

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#All Organs:
Histiocytic Sarcoma

	Male				Female		
	1/50 (2%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
	0/49 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
	0/50 (0%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	2/50 (4%)	1/50 (2%)
	0/90 (0%)	0/50 (0%)			8/90 (9%)	1/50 (2%)	

Overall Incidence   Total   5/589 (0.85%)   Mean 0.91%   SD 1.38%   Total   24/590 (4.07%)   Mean 3.72%   SD 2.81%

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#All Organs:
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type

	Male				Female		
	4/50 (8%)	6/50 (12%)	4/50 (8%)		7/50 (14%)	9/50 (18%)	7/50 (14%)
	3/49 (6%)	3/50 (6%)	3/50 (6%)		5/50 (10%)	6/50 (12%)	18/50 (36%)
	6/50 (12%)	6/50 (12%)	5/50 (10%)		10/50 (20%)	9/50 (18%)	7/50 (14%)
	6/90 (7%)	3/50 (6%)			2/90 (2%)	9/50 (18%)	

Overall Incidence   Total   49/589 (8.32%)   Mean 8.44%   SD 2.59%   Total   89/590 (15.08%)   Mean 16.02%   SD 8.26%

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*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017   **Toxicology Data Management System**   **Page:** 6
Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018
Species: MICE   **Route:** ALL ROUTES
Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

		Male				Female		

#All Organs:
  Malignant Schwannoma

		Male				Female		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)			0/90 (0%)	1/50 (2%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%

#All Organs:
  Osteosarcoma

		Male				Female		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)			3/90 (3%)	0/50 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	3/590 (0.51%)	Mean 0.3%	SD 1.01%

#All Organs:
  Osteosarcoma or Osteoma

		Male				Female		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)			3/90 (3%)	0/50 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	3/590 (0.51%)	Mean 0.3%	SD 1.01%

*Adrenal Cortex:
  Adenoma

		Male				Female		
		4/49 (8%)	2/50 (4%)	1/49 (2%)		1/50 (2%)	1/50 (2%)	0/49 (0%)
		1/48 (2%)	0/50 (0%)	9/49 (18%)		0/50 (0%)	2/49 (4%)	0/49 (0%)
		3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	1/50 (2%)			1/84 (1%)	0/50 (0%)	
Overall Incidence	Total	21/585 (3.59%)	Mean 3.88%	SD 5.51%	Total	5/581 (0.86%)	Mean 0.84%	SD 1.35%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 7
Report Date: 01/20/2018

		Male						Female				

*Adrenal Medulla:
  Pheochromocytoma Benign

		Male							Female			
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	1/50	(2%)	0/49	(0%)
		1/48	(2%)	0/50	(0%)	1/48	(2%)	0/50	(0%)	0/49	(0%)	1/49	(2%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	1/50	(2%)	0/49	(0%)
		0/90	(0%)	0/50	(0%)			0/83	(0%)	1/50	(2%)		

Overall Incidence   Total 3/584 (0.51%)   Mean 0.56%   SD 0.96%   Total 6/579 (1.04%)   Mean 1.09%   SD 1.38%

*Adrenal Medulla:
  Pheochromocytoma Malignant

		Male							Female			
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)
		0/48	(0%)	0/50	(0%)	0/48	(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%)	0/49	(0%)
		0/90	(0%)	0/50	(0%)			2/83	(2%)	0/50	(0%)		

Overall Incidence   Total 0/584 (0%)   Mean 0%   SD 0%   Total 2/579 (0.35%)   Mean 0.22%   SD 0.73%

*Adrenal Medulla:
  Pheochromocytoma: Benign, Complex, Malignant, NOS

		Male							Female			
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	1/50	(2%)	0/49	(0%)
		1/48	(2%)	0/50	(0%)	1/48	(2%)	0/50	(0%)	0/49	(0%)	1/49	(2%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	1/50	(2%)	0/49	(0%)
		0/90	(0%)	0/50	(0%)			2/83	(2%)	1/50	(2%)		

Overall Incidence   Total 3/584 (0.51%)   Mean 0.56%   SD 0.96%   Total 8/579 (1.38%)   Mean 1.31%   SD 1.38%

#Blood Vessel:
  Hemangioma

		Male							Female			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		

Overall Incidence   Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/590 (0.17%)   Mean 0.18%   SD 0.6%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

	Male					**Female**			

#Blood Vessel:
Hemangiosarcoma

		Male					Female		
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)	
	0/90 (0%)	0/50 (0%)				0/90 (0%)	0/50 (0%)		
Overall Incidence	Total 0/589 (0%)	Mean 0%	SD 0%		Total 1/590 (0.17%)	Mean 0.18%	SD 0.6%		

*Bone Marrow:
Hemangiosarcoma

		Male					Female		
	0/49 (0%)	0/48 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	1/50 (2%)	
	0/47 (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%)			0/49 (0%)	0/50 (0%)	0/49 (0%)	
	0/90 (0%)	0/50 (0%)				0/90 (0%)	0/50 (0%)		
Overall Incidence	Total 2/584 (0.34%)	Mean 0.36%	SD 0.81%		Total 1/587 (0.17%)	Mean 0.18%	SD 0.6%		

*Bone Marrow:
Mast Cell Tumor Malignant

		Male					Female		
	0/49 (0%)	1/48 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	1/47 (2%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
	1/50 (2%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/49 (0%)	
	0/90 (0%)	0/50 (0%)				0/90 (0%)	0/50 (0%)		
Overall Incidence	Total 3/584 (0.51%)	Mean 0.56%	SD 0.97%		Total 0/587 (0%)	Mean 0%	SD 0%		

*Bone Marrow:
Sarcoma

		Male					Female		
	0/49 (0%)	0/48 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/47 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	1/50 (2%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/49 (0%)	
	0/90 (0%)	0/50 (0%)				0/90 (0%)	0/50 (0%)		
Overall Incidence	Total 0/584 (0%)	Mean 0%	SD 0%		Total 1/587 (0.17%)	Mean 0.18%	SD 0.6%		

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Species: MICE   **Route:** ALL ROUTES
Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

	Male					Female				

#Bone:
Fibroma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				0/90 (0%)	1/50 (2%)	

Overall Incidence   Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/590 (0.17%)   Mean 0.18%   SD 0.6%

#Bone:
Hemangioma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				1/90 (1%)	0/50 (0%)	

Overall Incidence   Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/590 (0.17%)   Mean 0.1%   SD 0.34%

#Bone:
Osteosarcoma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				1/90 (1%)	0/50 (0%)	

Overall Incidence   Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/590 (0.17%)   Mean 0.1%   SD 0.34%

#Bone:
Osteosarcoma or Osteoma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				1/90 (1%)	0/50 (0%)	

Overall Incidence   Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/590 (0.17%)   Mean 0.1%   SD 0.34%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 10
Report Date: 01/20/2018

		Male						Female					

#Bone:
  Sarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%

*Clitoral/Preputial Gland:
  Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)	0/47	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	0/44	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/46	(0%)	0/48	(0%)	0/49	(0%)
		1/89	(1%)	0/50	(0%)			0/82	(0%)	0/50	(0%)		
Overall Incidence	Total	1/587 (0.17%)		Mean 0.1%		SD 0.34%		Total	0/562 (0%)		Mean 0%		SD 0%

#Coagulating Gland:
  Granular Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)		Mean 0%		SD 0%

#Coagulating Gland:
  Sarcoma

		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)		Mean 0%		SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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		

*Epididymis:
  Mast Cell Tumor

		Male					Female		
		0/50 (0%)	0/49 (0%)	0/50 (0%)					
		0/49 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		1/90 (1%)	0/50 (0%)						
Overall Incidence	Total	1/588 (0.17%)	Mean 0.1%	SD 0.34%					

#Harderian Gland:
  Adenoma

		6/50 (12%)	3/50 (6%)	7/50 (14%)		3/50 (6%)	3/50 (6%)	2/50 (4%)
		6/49 (12%)	6/50 (12%)	7/50 (14%)		1/50 (2%)	3/50 (6%)	2/50 (4%)
		4/50 (8%)	5/50 (10%)	5/50 (10%)		1/50 (2%)	2/50 (4%)	9/50 (18%)
		6/90 (7%)	7/50 (14%)			4/90 (4%)	2/50 (4%)	
Overall Incidence	Total 62/589 (10.53%)	Mean 10.81%	SD 2.91%		Total 32/590 (5.42%)	Mean 5.49%	SD 4.38%	

#Harderian Gland:
  Carcinoma

		1/50 (2%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	2/50 (4%)
		1/49 (2%)	1/50 (2%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	1/50 (2%)
		3/90 (3%)	1/50 (2%)			0/90 (0%)	1/50 (2%)	
Overall Incidence	Total 17/589 (2.89%)	Mean 2.85%	SD 2.56%		Total 13/590 (2.2%)	Mean 2.36%	SD 2.66%	

#Harderian Gland:
  Carcinoma or Adenoma

		7/50 (14%)	3/50 (6%)	8/50 (16%)		7/50 (14%)	4/50 (8%)	4/50 (8%)
		7/49 (14%)	7/50 (14%)	12/50 (24%)		2/50 (4%)	3/50 (6%)	2/50 (4%)
		6/50 (12%)	6/50 (12%)	6/50 (12%)		4/50 (8%)	2/50 (4%)	10/50 (20%)
		9/90 (10%)	8/50 (16%)			4/90 (4%)	3/50 (6%)	
Overall Incidence	Total 79/589 (13.41%)	Mean 13.66%	SD 4.46%		Total 45/590 (7.63%)	Mean 7.86%	SD 4.98%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male						Female				

#Harderian Gland:
  Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	0/590 (0%)		Mean 0%		SD 0%	

*Heart:
  Hemangiosarcoma

		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)		Mean 0%		SD 0%	

#Intestine Large: Cecum:
  Leiomyosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

#Intestine Small: Duodenum:
  Adenoma

		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	2/50	(4%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	7/589 (1.19%)		Mean 1.27%		SD 1.85%		Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male							Female					

#Intestine Small: Duodenum:
   Carcinoma

0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
1/90	(1%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   1/589 (0.17%)   Mean 0.1%   SD 0.34%   Total   0/590 (0%)   Mean 0%   SD 0%

#Intestine Small: Duodenum:
   Polyp Adenomatous

0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total   0/590 (0%)   Mean 0%   SD 0%

#Intestine Small: Ileum:
   Adenoma

0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   0/589 (0%)   Mean 0%   SD 0%   Total   1/590 (0.17%)   Mean 0.18%   SD 0.6%

#Intestine Small: Jejunum:
   Adenoma

0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/49	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
0/90	(0%)	1/50	(2%)				0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   2/589 (0.34%)   Mean 0.36%   SD 0.81%   Total   0/590 (0%)   Mean 0%   SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male					Female			
#Intestine Small: Jejunum: Carcinoma										
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/90 (2%)	1/50 (2%)			0/90 (0%)	0/50 (0%)	
Overall Incidence	Total	7/589 (1.19%)	Mean 1.11%	SD 1.39%	Total	0/590 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)			0/90 (0%)	0/50 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%
#Intestine Small: Jejunum: Mast Cell Tumor										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/90 (1%)	0/50 (0%)			0/90 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%	Total	0/590 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecified: Adenoma										
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/90 (0%)	1/50 (2%)			0/90 (0%)	1/50 (2%)	
Overall Incidence	Total	9/589 (1.53%)	Mean 1.64%	SD 2.16%	Total	3/590 (0.51%)	Mean 0.55%	SD 0.93%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

	Male				Female		

#Intestine Small: Site Unspecified:
Carcinoma

Male			Female		
1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
3/90 (3%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	

Overall Incidence — Total 8/589 (1.36%) — Mean 1.21% — SD 1.51% — Total 0/590 (0%) — Mean 0% — SD 0%

#Intestine Small: Site Unspecified:
Carcinoma or Adenoma

Male			Female		
3/50 (6%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
3/90 (3%)	2/50 (4%)		0/90 (0%)	1/50 (2%)	

Overall Incidence — Total 17/589 (2.89%) — Mean 2.85% — SD 2.23% — Total 3/590 (0.51%) — Mean 0.55% — SD 0.93%

#Intestine Small: Site Unspecified:
Leiomyosarcoma

Male			Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/90 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	

Overall Incidence — Total 0/589 (0%) — Mean 0% — SD 0% — Total 2/590 (0.34%) — Mean 0.36% — SD 0.81%

#Intestine Small: Site Unspecified:
Mast Cell Tumor

Male			Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
1/90 (1%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	

Overall Incidence — Total 1/589 (0.17%) — Mean 0.1% — SD 0.34% — Total 0/590 (0%) — Mean 0% — SD 0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Species: MICE Tumor Incidence for Selected Control Animal Groups
Strain: B6C3F1/N **Route:** ALL ROUTES
Length of Study: CHRONIC **Vehicle:** ALL VEHICLES

		Male					Female				

#Intestine Small: Site Unspecified:
Polyp Adenomatous

		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/90 (0%)	0/50 (0%)			0/90 (0%)	0/50 (0%)				
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%			

*Islets, Pancreatic:
Adenoma

		0/49 (0%)	0/48 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	1/50 (2%)			
		1/47 (2%)	1/50 (2%)	2/50 (4%)		0/49 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0/88 (0%)	0/50 (0%)			0/87 (0%)	0/50 (0%)				
Overall Incidence	Total	7/582 (1.2%)	Mean 1.28%	SD 1.36%	Total	3/585 (0.51%)	Mean 0.55%	SD 0.93%			

*Islets, Pancreatic:
Carcinoma

		0/49 (0%)	0/48 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)			
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/88 (0%)	0/50 (0%)			1/87 (1%)	0/50 (0%)				
Overall Incidence	Total	1/582 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/585 (0.17%)	Mean 0.1%	SD 0.35%			

*Islets, Pancreatic:
Carcinoma or Adenoma

		0/49 (0%)	0/48 (0%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	1/50 (2%)			
		1/47 (2%)	1/50 (2%)	2/50 (4%)		0/49 (0%)	0/50 (0%)	1/50 (2%)			
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
		0/88 (0%)	0/50 (0%)			1/87 (1%)	0/50 (0%)				
Overall Incidence	Total	8/582 (1.37%)	Mean 1.47%	SD 1.58%	Total	4/585 (0.68%)	Mean 0.65%	SD 0.93%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male					Female		

*Kidney: Renal Tubule:
  Adenoma

		Male						Female			
	0/50 (0%)	0/49 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/48 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				2/89 (2%)	0/50 (0%)	
Overall Incidence	Total	1/587 (0.17%)	Mean 0.18%	SD 0.6%	Total	3/587 (0.51%)	Mean 0.39%	SD 0.86%

*Kidney: Renal Tubule:
  Carcinoma

		Male						Female			
	0/50 (0%)	0/49 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
	0/48 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				0/89 (0%)	0/50 (0%)	
Overall Incidence	Total	2/587 (0.34%)	Mean 0.36%	SD 1.21%	Total	1/587 (0.17%)	Mean 0.18%	SD 0.6%

*Kidney: Renal Tubule:
  Carcinoma or Adenoma

		Male						Female			
	0/50 (0%)	0/49 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
	0/48 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)				2/89 (2%)	0/50 (0%)	
Overall Incidence	Total	3/587 (0.51%)	Mean 0.55%	SD 1.81%	Total	4/587 (0.68%)	Mean 0.57%	SD 0.97%

*Kidney: Renal Tubule:
  Mast Cell Tumor

		Male						Female			
	0/50 (0%)	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/48 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	1/90 (1%)	0/50 (0%)				0/89 (0%)	0/50 (0%)	
Overall Incidence	Total	1/587 (0.17%)	Mean 0.1%	SD 0.34%	Total	0/587 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male					Female			

*Kidney: Renal Tubule:
  Renal Mesenchymal Tumor

		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)			1/89 (1%)	0/50 (0%)			
Overall Incidence	Total	0/587 (0%)	Mean 0%	SD 0%	Total	1/587 (0.17%)	Mean 0.1%	SD 0.34%		

*Liver:
  Cholangiocarcinoma

		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)			0/89 (0%)	0/50 (0%)			
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/589 (0%)	Mean 0%	SD 0%		

*Liver:
  Hemangioma

		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	2/50 (4%)			0/89 (0%)	0/50 (0%)			
Overall Incidence	Total	4/589 (0.68%)	Mean 0.73%	SD 1.62%	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%		

*Liver:
  Hemangiosarcoma

		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/49 (0%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)	0/50 (0%)			0/89 (0%)	0/50 (0%)			
Overall Incidence	Total	8/589 (1.36%)	Mean 1.37%	SD 2.84%	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%		

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Species: MICE　　　　　　　　　　　　　　　　　　　　**Route:** ALL ROUTES
Strain: B6C3F1/N　　　　　　　　　　　　　　　　　**Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

		Male				**Female**		
*Liver:								
Hepatoblastoma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/49 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		6/90 (7%)	2/50 (4%)			1/89 (1%)	0/50 (0%)	
Overall Incidence	Total	19/589 (3.23%)	Mean 2.97%	SD 2.18%	Total	4/589 (0.68%)	Mean 0.65%	SD 0.93%
*Liver:								
Hepatocellular Adenoma								
		30/50 (60%)	17/50 (34%)	35/50 (70%)		11/50 (22%)	6/50 (12%)	12/50 (24%)
		21/49 (43%)	26/50 (52%)	24/50 (48%)		3/50 (6%)	7/50 (14%)	14/50 (28%)
		23/50 (46%)	25/50 (50%)	23/50 (46%)		9/50 (18%)	12/50 (24%)	5/50 (10%)
		52/90 (58%)	32/50 (64%)			19/89 (21%)	13/50 (26%)	
Overall Incidence	Total	308/589 (52.29%)	Mean 51.88%	SD 10.32%	Total	111/589 (18.85%)	Mean 18.67%	SD 7.2%
*Liver:								
Hepatocellular Carcinoma								
		15/50 (30%)	17/50 (34%)	15/50 (30%)		6/50 (12%)	5/50 (10%)	5/50 (10%)
		8/49 (16%)	12/50 (24%)	11/50 (22%)		1/50 (2%)	6/50 (12%)	10/50 (20%)
		21/50 (42%)	8/50 (16%)	18/50 (36%)		7/50 (14%)	7/50 (14%)	4/50 (8%)
		28/90 (31%)	11/50 (22%)			8/89 (9%)	2/50 (4%)	
Overall Incidence	Total	164/589 (27.84%)	Mean 27.59%	SD 8.25%	Total	61/589 (10.36%)	Mean 10.45%	SD 4.93%
*Liver:								
Hepatocellular Carcinoma or Hepatoblastoma								
		16/50 (32%)	18/50 (36%)	17/50 (34%)		6/50 (12%)	6/50 (12%)	5/50 (10%)
		8/49 (16%)	15/50 (30%)	11/50 (22%)		1/50 (2%)	6/50 (12%)	10/50 (20%)
		21/50 (42%)	9/50 (18%)	18/50 (36%)		7/50 (14%)	7/50 (14%)	4/50 (8%)
		32/90 (36%)	12/50 (24%)			9/89 (10%)	2/50 (4%)	
Overall Incidence	Total	177/589 (30.05%)	Mean 29.63%	SD 8.34%	Total	63/589 (10.7%)	Mean 10.74%	SD 4.92%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male						Female				

*Liver:

Hepatocellular Carcinoma or Hepatocellular Adenoma

		39/50	(78%)	31/50	(62%)	40/50	(80%)	14/50	(28%)	11/50	(22%)	14/50 (28%)
		26/49	(53%)	35/50	(70%)	32/50	(64%)	4/50	(8%)	12/50	(24%)	20/50 (40%)
		34/50	(68%)	30/50	(60%)	31/50	(62%)	15/50	(30%)	18/50	(36%)	8/50 (16%)
		67/90	(74%)	39/50	(78%)			25/89	(28%)	15/50	(30%)	
Overall Incidence	Total	404/589 (68.59%)		Mean 68.14%		SD 8.74%	Total	156/589 (26.49%)		Mean 26.37%		SD 8.85%

*Liver:

Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma

		39/50	(78%)	32/50	(64%)	40/50	(80%)	14/50	(28%)	12/50	(24%)	14/50 (28%)
		26/49	(53%)	36/50	(72%)	32/50	(64%)	4/50	(8%)	12/50	(24%)	20/50 (40%)
		34/50	(68%)	31/50	(62%)	31/50	(62%)	15/50	(30%)	18/50	(36%)	8/50 (16%)
		68/90	(76%)	39/50	(78%)			25/89	(28%)	15/50	(30%)	
Overall Incidence	Total	408/589 (69.27%)		Mean 68.78%		SD 8.59%	Total	157/589 (26.66%)		Mean 26.55%		SD 8.77%

*Liver:

Hepatocholangiocarcinoma

		1/50	(2%)	1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50 (0%)
		1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	3/50	(6%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/89	(0%)	0/50	(0%)	
Overall Incidence	Total	7/589 (1.19%)		Mean 1.2%		SD 1.84%	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%

*Liver:

Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/89	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%	Total	0/589 (0%)		Mean 0%		SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male				Female		

*Lung:
Alveolar/Bronchiolar Adenoma

		Male				Female		
		10/50 (20%)	5/50 (10%)	12/50 (24%)		1/50 (2%)	3/50 (6%)	5/50 (10%)
		7/49 (14%)	4/50 (8%)	5/50 (10%)		5/50 (10%)	1/50 (2%)	1/50 (2%)
		6/50 (12%)	11/50 (22%)	5/50 (10%)		4/50 (8%)	5/50 (10%)	1/50 (2%)
		13/90 (14%)	6/50 (12%)			3/90 (3%)	5/50 (10%)	
Overall Incidence	Total	84/589 (14.26%)	Mean 14.25%	SD 5.4%	Total	34/590 (5.76%)	Mean 5.94%	SD 3.73%

*Lung:
Alveolar/Bronchiolar Carcinoma

		Male				Female		
		4/50 (8%)	5/50 (10%)	2/50 (4%)		2/50 (4%)	3/50 (6%)	1/50 (2%)
		5/49 (10%)	4/50 (8%)	8/50 (16%)		0/50 (0%)	2/50 (4%)	4/50 (8%)
		10/50 (20%)	6/50 (12%)	5/50 (10%)		5/50 (10%)	0/50 (0%)	0/50 (0%)
		13/90 (14%)	4/50 (8%)			3/90 (3%)	1/50 (2%)	
Overall Incidence	Total	66/589 (11.21%)	Mean 10.97%	SD 4.44%	Total	21/590 (3.56%)	Mean 3.58%	SD 3.32%

*Lung:
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma

		Male				Female		
		13/50 (26%)	9/50 (18%)	14/50 (28%)		3/50 (6%)	6/50 (12%)	6/50 (12%)
		11/49 (22%)	8/50 (16%)	13/50 (26%)		5/50 (10%)	3/50 (6%)	4/50 (8%)
		14/50 (28%)	17/50 (34%)	10/50 (20%)		9/50 (18%)	5/50 (10%)	1/50 (2%)
		23/90 (26%)	10/50 (20%)			6/90 (7%)	6/50 (12%)	
Overall Incidence	Total	142/589 (24.11%)	Mean 24%	SD 5.26%	Total	54/590 (9.15%)	Mean 9.33%	SD 4.27%

*Lung:
Hemangiosarcoma

		Male				Female		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)			0/90 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male						Female				

*Lung:
Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%	Total	0/590 (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%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50 (0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%	Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%

#Lymph Node:
Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%	Total	0/590 (0%)		Mean 0%		SD 0%

#Lymph Node, Mandibular:
Mast Cell Tumor

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%	Total	0/590 (0%)		Mean 0%		SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male						Female				
#Lymph Node, Mesenteric:												
Hemangioma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	1/590 (0.17%)	Mean 0.18%		SD 0.6%
#Lymph Node, Mesenteric:												
Hemangiosarcoma												
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)	Mean 0%		SD 0%
#Lymph Node, Mesenteric:												
Mast Cell Tumor												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	0/590 (0%)	Mean 0%		SD 0%
#Mammary Gland:												
Adenoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	2/590 (0.34%)	Mean 0.36%		SD 0.81%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Species: MICE

Route: ALL ROUTES

Strain: B6C3F1/N

Vehicle: ALL VEHICLES

Length of Study: CHRONIC

		Male						Female			

#Mammary Gland:
Carcinoma

0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)
0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		

Overall Incidence Total 2/589 (0.34%) Mean 0.37% SD 0.82% Total 5/590 (0.85%) Mean 0.91% SD 1.38%

#Mammary Gland:
Carcinoma or Adenoma

0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
1/49	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	2/50	(4%)
0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		

Overall Incidence Total 2/589 (0.34%) Mean 0.37% SD 0.82% Total 7/590 (1.19%) Mean 1.27% SD 1.35%

#Mammary Gland:
Fibroma, Fibroadenoma or Adenoma

0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		

Overall Incidence Total 0/589 (0%) Mean 0% SD 0% Total 2/590 (0.34%) Mean 0.36% SD 0.81%

#Mammary Gland:
Fibroma, Fibroadenoma, Carcinoma, or Adenoma

0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
1/49	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)	2/50	(4%)
0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		

Overall Incidence Total 2/589 (0.34%) Mean 0.37% SD 0.82% Total 7/590 (1.19%) Mean 1.27% SD 1.35%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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					

#Mesentery:
  Hemangioma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			1/90	(1%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)	Mean 0.1%		SD 0.34%	

#Mesentery:
  Hemangiosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	1/590 (0.17%)	Mean 0.18%		SD 0.6%	

#Mesentery:
  Lipoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	1/590 (0.17%)	Mean 0.18%		SD 0.6%	

#Mesentery:
  Sarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)	Mean 0.18%		SD 0.6%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male						Female					

*Nose:
  Adenoma

		Male						Female			
		0/50 (0%)	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/48 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)				0/89 (0%)	0/50 (0%)	
Overall Incidence	Total	0/587 (0%)	Mean 0%	SD 0%	Total		1/587 (0.17%)	Mean 0.19%	SD 0.63%

*Nose:
  Polyp

		Male						Female			
		0/50 (0%)	1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)				0/89 (0%)	0/50 (0%)	
Overall Incidence	Total	1/587 (0.17%)	Mean 0.19%	SD 0.62%	Total		0/587 (0%)	Mean 0%	SD 0%

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):
  Papilloma Squamous or Papilloma

		Male						Female			
		0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)				0/90 (0%)	1/50 (2%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total		1/590 (0.17%)	Mean 0.18%	SD 0.6%

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):
  Squamous Cell Carcinoma

		Male						Female			
		0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)				0/90 (0%)	1/50 (2%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total		1/590 (0.17%)	Mean 0.18%	SD 0.6%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male					Female		

#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):
  Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma

		Male						Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	2/50	(4%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%	Total	2/590 (0.34%)		Mean 0.36%		SD 1.21%

#Oral Mucosa:
  Squamous Cell Carcinoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%

*Ovary:
  Cystadenocarcinoma

									0/50	(0%)	0/49	(0%)	1/50	(2%)
									0/48	(0%)	0/50	(0%)	0/50	(0%)
									0/50	(0%)	0/50	(0%)	0/48	(0%)
									0/75	(0%)	0/50	(0%)		
Overall Incidence							Total	1/570 (0.18%)		Mean 0.18%		SD 0.6%

*Ovary:
  Cystadenoma

									1/50	(2%)	0/49	(0%)	3/50	(6%)
									4/48	(8%)	1/50	(2%)	2/50	(4%)
									1/50	(2%)	2/50	(4%)	2/48	(4%)
									2/75	(3%)	2/50	(4%)		
Overall Incidence							Total	20/570 (3.51%)		Mean 3.56%		SD 2.25%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

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: 01/20/2018

	Male			Female					

*Ovary:
  Granulosa Cell Tumor Benign

			0/50	(0%)	0/49	(0%)	0/50	(0%)	
			0/48	(0%)	0/50	(0%)	1/50	(2%)	
			1/50	(2%)	0/50	(0%)	1/48	(2%)	
			1/75	(1%)	0/50	(0%)			
Overall Incidence	Total	4/570 (0.7%)		Mean 0.67%		SD 0.95%			

*Ovary:
  Granulosa Cell Tumor Malignant

			1/50	(2%)	0/49	(0%)	0/50	(0%)	
			0/48	(0%)	0/50	(0%)	0/50	(0%)	
			0/50	(0%)	0/50	(0%)	0/48	(0%)	
			0/75	(0%)	0/50	(0%)			
Overall Incidence	Total	1/570 (0.18%)		Mean 0.18%		SD 0.6%			

*Ovary:
  Granulosa Cell Tumor: Benign, Malignant, NOS

			1/50	(2%)	0/49	(0%)	0/50	(0%)	
			0/48	(0%)	0/50	(0%)	1/50	(2%)	
			1/50	(2%)	0/50	(0%)	1/48	(2%)	
			1/75	(1%)	0/50	(0%)			
Overall Incidence	Total	5/570 (0.88%)		Mean 0.86%		SD 1%			

*Ovary:
  Granulosa-Theca Tumor Malignant

			0/50	(0%)	1/49	(2%)	0/50	(0%)	
			0/48	(0%)	0/50	(0%)	0/50	(0%)	
			0/50	(0%)	1/50	(2%)	0/48	(0%)	
			0/75	(0%)	0/50	(0%)			
Overall Incidence	Total	2/570 (0.35%)		Mean 0.37%		SD 0.82%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

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: 01/20/2018

	Male			Female				

*Ovary:

Hemangioma

				0/50	(0%)	0/49	(0%)	0/50	(0%)
				1/48	(2%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/48	(0%)
				2/75	(3%)	0/50	(0%)		
Overall Incidence	Total			3/570	(0.53%)	Mean 0.43%		SD 0.97%	

*Ovary:

Hemangiosarcoma

				1/50	(2%)	0/49	(0%)	0/50	(0%)
				0/48	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/48	(0%)
				0/75	(0%)	0/50	(0%)		
Overall Incidence	Total			1/570	(0.18%)	Mean 0.18%		SD 0.6%	

*Ovary:

Luteoma

				0/50	(0%)	0/49	(0%)	0/50	(0%)
				0/48	(0%)	0/50	(0%)	1/50	(2%)
				0/50	(0%)	2/50	(4%)	0/48	(0%)
				0/75	(0%)	0/50	(0%)		
Overall Incidence	Total			3/570	(0.53%)	Mean 0.55%		SD 1.29%	

*Ovary:

Sarcoma

				0/50	(0%)	0/49	(0%)	1/50	(2%)
				0/48	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/48	(0%)
				0/75	(0%)	0/50	(0%)		
Overall Incidence	Total			1/570	(0.18%)	Mean 0.18%		SD 0.6%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

	Male						Female					

*Ovary:
  Thecoma Malignant

							0/50	(0%)	0/49	(0%)	0/50	(0%)
							0/48	(0%)	0/50	(0%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	0/48	(0%)
							1/75	(1%)	0/50	(0%)		

Overall Incidence — Total 1/570 (0.18%) — Mean 0.12% — SD 0.4%

*Ovary:
  Tubulostromal Adenoma

							0/50	(0%)	0/49	(0%)	0/50	(0%)
							0/48	(0%)	1/50	(2%)	0/50	(0%)
							0/50	(0%)	0/50	(0%)	0/48	(0%)
							0/75	(0%)	0/50	(0%)		

Overall Incidence — Total 1/570 (0.18%) — Mean 0.18% — SD 0.6%

*Pancreas:
  Mast Cell Tumor

0/49	(0%)	0/48	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
0/49	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
1/87	(1%)	0/50	(0%)			0/87	(0%)	0/50	(0%)		

Overall Incidence — Total 1/583 (0.17%) — Mean 0.1% — SD 0.35% — Total 0/586 (0%) — Mean 0% — SD 0%

*Parathyroid Gland:
  Adenoma

0/27	(0%)	0/40	(0%)	0/41	(0%)	0/27	(0%)	0/38	(0%)	0/35	(0%)
0/32	(0%)	0/48	(0%)	0/34	(0%)	0/21	(0%)	0/43	(0%)	0/26	(0%)
0/28	(0%)	0/36	(0%)	0/48	(0%)	1/35	(3%)	0/36	(0%)	0/44	(0%)
0/68	(0%)	0/45	(0%)			0/60	(0%)	0/34	(0%)		

Overall Incidence — Total 0/447 (0%) — Mean 0% — SD 0% — Total 1/399 (0.25%) — Mean 0.26% — SD 0.86%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Aug2017   **Toxicology Data Management System**   **Page:** 31
Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018
Species: MICE   **Route:** ALL ROUTES
Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

		Male						Female				

*Pituitary Gland: Pars Distalis or Unspecified Site:
  Adenoma

		Male							Female				
		0/49	(0%)	0/50	(0%)	1/49	(2%)		9/49	(18%)	2/49	(4%)	0/50	(0%)
		0/45	(0%)	0/50	(0%)	0/50	(0%)		0/47	(0%)	3/49	(6%)	5/50	(10%)
		1/50	(2%)	0/50	(0%)	0/47	(0%)		8/48	(17%)	4/50	(8%)	5/50	(10%)
		0/86	(0%)	0/50	(0%)				6/80	(8%)	1/50	(2%)		
Overall Incidence	Total	2/576 (0.35%)		Mean 0.37%		SD 0.82%		Total	43/572 (7.52%)		Mean 7.52%		SD 6.09%	

*Pituitary Gland: Pars Distalis or Unspecified Site:
  Carcinoma

		0/49	(0%)	0/50	(0%)	0/49	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)
		0/45	(0%)	0/50	(0%)	0/50	(0%)		0/47	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/47	(0%)		3/48	(6%)	0/50	(0%)	0/50	(0%)
		0/86	(0%)	0/50	(0%)				0/80	(0%)	0/50	(0%)		
Overall Incidence	Total	0/576 (0%)		Mean 0%		SD 0%		Total	3/572 (0.52%)		Mean 0.57%		SD 1.88%	

*Pituitary Gland: Pars Distalis or Unspecified Site:
  Carcinoma or Adenoma

		0/49	(0%)	0/50	(0%)	1/49	(2%)		9/49	(18%)	2/49	(4%)	0/50	(0%)
		0/45	(0%)	0/50	(0%)	0/50	(0%)		0/47	(0%)	3/49	(6%)	5/50	(10%)
		1/50	(2%)	0/50	(0%)	0/47	(0%)		11/48	(23%)	4/50	(8%)	5/50	(10%)
		0/86	(0%)	0/50	(0%)				6/80	(8%)	1/50	(2%)		
Overall Incidence	Total	2/576 (0.35%)		Mean 0.37%		SD 0.82%		Total	46/572 (8.04%)		Mean 8.09%		SD 7.22%	

*Pituitary Gland: Pars Intermedia:
  Adenoma

		0/49	(0%)	0/50	(0%)	0/49	(0%)		0/49	(0%)	0/49	(0%)	0/50	(0%)
		0/45	(0%)	0/50	(0%)	0/50	(0%)		1/47	(2%)	1/49	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/47	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/86	(0%)	0/50	(0%)				0/80	(0%)	0/50	(0%)		
Overall Incidence	Total	0/576 (0%)		Mean 0%		SD 0%		Total	2/572 (0.35%)		Mean 0.38%		SD 0.84%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

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: 01/20/2018

		Male					Female				

*Pituitary Gland: Pars Intermedia:
  Carcinoma

		Male				Female		
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/49 (2%)	0/50 (0%)
		0/45 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/47 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/86 (0%)	0/50 (0%)			0/80 (0%)	0/50 (0%)	
Overall Incidence	Total	0/576 (0%)	Mean 0%	SD 0%	Total	1/572 (0.17%)	Mean 0.19%	SD 0.62%

*Pituitary Gland: Pars Intermedia:
  Carcinoma or Adenoma

		Male				Female		
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/49 (2%)	0/50 (0%)
		0/45 (0%)	0/50 (0%)	0/50 (0%)		1/47 (2%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/47 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/86 (0%)	0/50 (0%)			0/80 (0%)	0/50 (0%)	
Overall Incidence	Total	0/576 (0%)	Mean 0%	SD 0%	Total	3/572 (0.52%)	Mean 0.56%	SD 0.97%

*Pituitary Gland: Pars Intermedia:
  Schwannoma Malignant

		Male				Female		
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/45 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/47 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/86 (0%)	0/50 (0%)			0/80 (0%)	0/50 (0%)	
Overall Incidence	Total	1/576 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/572 (0%)	Mean 0%	SD 0%

*Prostate:
  Mast Cell Tumor

		Male			
		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)		
Overall Incidence	Total	1/587 (0.17%)	Mean 0.1%	SD 0.34%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

	Male							Female					

*Salivary Glands:
  Adenoma

	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
	0/49	(0%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/90	(0%)	0/50	(0%)				0/89	(0%)	0/50	(0%)		

Overall Incidence Total 1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total 0/587 (0%)   Mean 0%   SD 0%

*Salivary Glands:
  Carcinoma

	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
	0/49	(0%)	0/50	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
	0/90	(0%)	0/50	(0%)				0/89	(0%)	0/50	(0%)		

Overall Incidence Total 0/589 (0%)   Mean 0%   SD 0%   Total 1/587 (0.17%)   Mean 0.18%   SD 0.6%

*Salivary Glands:
  Carcinoma or Adenoma

	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
	0/49	(0%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
	0/90	(0%)	0/50	(0%)				0/89	(0%)	0/50	(0%)		

Overall Incidence Total 1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total 1/587 (0.17%)   Mean 0.18%   SD 0.6%

*Salivary Glands:
  Hemangiosarcoma

	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
	0/49	(0%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/90	(0%)	0/50	(0%)				0/89	(0%)	0/50	(0%)		

Overall Incidence Total 1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total 0/587 (0%)   Mean 0%   SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male					Female			

*Salivary Glands:
Mast Cell Tumor

	Male						Female			
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	1/90 (1%)	0/50 (0%)				0/89 (0%)	0/50 (0%)		

Overall Incidence   Total   1/589 (0.17%)   Mean 0.1%   SD 0.34%   Total   0/587 (0%)   Mean 0%   SD 0%

*Salivary Glands:
Myxosarcoma

	Male						Female			
	0/50 (0%)	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/49 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/90 (0%)	0/50 (0%)				0/89 (0%)	0/50 (0%)		

Overall Incidence   Total   0/589 (0%)   Mean 0%   SD 0%   Total   1/587 (0.17%)   Mean 0.18%   SD 0.6%

#Seminal Vesicle:
Adenoma

	Male		
	1/50 (2%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/90 (0%)	0/50 (0%)	

Overall Incidence   Total   1/589 (0.17%)   Mean 0.18%   SD 0.6%

#Seminal Vesicle:
Fibroma

	Male		
	0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/49 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)
	1/90 (1%)	0/50 (0%)	

Overall Incidence   Total   1/589 (0.17%)   Mean 0.1%   SD 0.34%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Species: MICE

Strain: B6C3F1/N

Length of Study: CHRONIC

Route: ALL ROUTES

Vehicle: ALL VEHICLES

		Male						Female					

#Skeletal Muscle:
Osteosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			1/90	(1%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.1%		SD 0.34%

#Skeletal Muscle:
Rhabdomyosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	1/50	(2%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	6/590 (1.02%)		Mean 1.09%		SD 1.64%

#Skeletal Muscle:
Rhabdomyosarcoma or Rhabdomyoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	1/50	(2%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	6/590 (1.02%)		Mean 1.09%		SD 1.64%

#Skeletal Muscle:
Sarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)			0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	2/590 (0.34%)		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 Tumor Incidence for Selected Control Animal Groups

Species: MICE **Route:** ALL ROUTES
Strain: B6C3F1/N **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

		Male							Female					

#Skin:

Basal Cell Carcinoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%	

#Skin:

Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%	

#Skin:

Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%	

#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%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	3/590 (0.51%)		Mean 0.55%		SD 0.93%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018
Species: MICE   **Route:** ALL ROUTES
Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

		Male						Female				

#Skin:
  Fibroma

		Male							Female			
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			1/90	(1%)	0/50	(0%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%	Total	1/590 (0.17%)		Mean 0.1%		SD 0.34%

#Skin:
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or
Hemangiopericytoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
		1/90	(1%)	1/50	(2%)			6/90	(7%)	1/50	(2%)	
Overall Incidence	Total	5/589 (0.85%)		Mean 0.83%		SD 0.98%	Total	12/590 (2.03%)		Mean 1.7%		SD 2.12%

#Skin:
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
		1/90	(1%)	1/50	(2%)			6/90	(7%)	1/50	(2%)	
Overall Incidence	Total	5/589 (0.85%)		Mean 0.83%		SD 0.98%	Total	12/590 (2.03%)		Mean 1.7%		SD 2.12%

#Skin:
  Fibrosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)	0/50	(0%)			3/90	(3%)	1/50	(2%)	
Overall Incidence	Total	2/589 (0.34%)		Mean 0.36%		SD 0.81%	Total	6/590 (1.02%)		Mean 0.85%		SD 1.23%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male						Female				

#Skin:

Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma

		Male							Female				
		0/50	(0%)	0/50	(0%)	0/50	(0%)		2/50	(4%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	1/50	(2%)
		1/90	(1%)	1/50	(2%)				5/90	(6%)	1/50	(2%)	
Overall Incidence	Total	5/589 (0.85%)		Mean 0.83%		SD 0.98%		Total	11/590 (1.86%)		Mean 1.6%		SD 1.87%

#Skin:

Hemangioma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%

#Skin:

Hemangiosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
		0/50	(0%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)				2/90	(2%)	1/50	(2%)	
Overall Incidence	Total	3/589 (0.51%)		Mean 0.46%		SD 1.22%		Total	6/590 (1.02%)		Mean 0.93%		SD 1.39%

#Skin:

Keratoacanthoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)				0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)		Mean 0%		SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male						Female			

#Skin:
  Lipoma

		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/90 (1%)	0/50 (0%)			1/90 (1%)	0/50 (0%)				
Overall Incidence	Total	3/589 (0.51%)	Mean 0.46%	SD 1.22%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%			

#Skin:
  Malignant Fibrous Histiocytoma

		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/90 (1%)	0/50 (0%)			0/90 (0%)	0/50 (0%)				
Overall Incidence	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%			

#Skin:
  Melanoma Benign

		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/90 (0%)	0/50 (0%)			0/90 (0%)	0/50 (0%)				
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%			

#Skin:
  Neurofibrosarcoma or Schwannoma (malignant or NOS)

		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/90 (0%)	0/50 (0%)			0/90 (0%)	1/50 (2%)				
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 40
Report Date: 01/20/2018

		Male						Female					

#Skin:
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%

#Skin:
Osteosarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/90	(0%)	0/50	(0%)				1/90	(1%)	0/50	(0%)	
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.1%		SD 0.34%

#Skin:
Pilomatrixoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		1/90	(1%)	0/50	(0%)				0/90	(0%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.1%		SD 0.34%		Total	0/590 (0%)		Mean 0%		SD 0%

#Skin:
Sarcoma

		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50 (0%)
		0/90	(0%)	1/50	(2%)				2/90	(2%)	0/50	(0%)	
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	4/590 (0.68%)		Mean 0.57%		SD 0.97%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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				

#Skin:

Schwannoma Malignant

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

#Skin:

Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	2/590 (0.34%)		Mean 0.36%		SD 0.81%	

#Skin:

Squamous Cell Papilloma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

#Skin:

Squamous Cell Papilloma or Papilloma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	0/589 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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					

#Skin:
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

#Skin:
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

*Spleen:
Hemangiosarcoma

		Male							Female					
		2/49	(4%)	0/48	(0%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/48	(2%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/87	(0%)	1/50	(2%)				0/86	(0%)	1/50	(2%)		
Overall Incidence	Total	9/581 (1.55%)		Mean 1.65%		SD 1.52%		Total	3/585 (0.51%)		Mean 0.55%		SD 0.93%	

#Stomach, Forestomach:
Squamous Cell Carcinoma

		Male							Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/49	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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		

#Stomach, Forestomach:
Squamous Cell Carcinoma or Papilloma Squamous

Male			Female		
1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
2/49 (4%)	2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
0/90 (0%)	5/50 (10%)		1/90 (1%)	0/50 (0%)	

Overall Incidence — Total 14/589 (2.38%) — Mean 2.55% — SD 2.98% — Total 8/590 (1.36%) — Mean 1.37% — SD 1.28%

#Stomach, Forestomach:
Squamous Cell Papilloma

Male			Female		
1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
2/49 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
1/50 (2%)	1/50 (2%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
0/90 (0%)	5/50 (10%)		1/90 (1%)	0/50 (0%)	

Overall Incidence — Total 13/589 (2.21%) — Mean 2.37% — SD 2.95% — Total 7/590 (1.19%) — Mean 1.19% — SD 0.98%

#Stomach, Glandular:
Adenoma

Male			Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/90 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	

Overall Incidence — Total 0/589 (0%) — Mean 0% — SD 0% — Total 1/590 (0.17%) — Mean 0.18% — SD 0.6%

#Stomach, Glandular:
Carcinoma

Male			Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
0/90 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	

Overall Incidence — Total 1/589 (0.17%) — Mean 0.18% — SD 0.6% — Total 0/590 (0%) — Mean 0% — SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male							Female					

#Stomach, Glandular:
  Carcinoma or Adenoma

		Male								Female					
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)				0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%	

*Testis:
  Adenoma

		0/49	(0%)	0/49	(0%)	1/50	(2%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	2/50	(4%)
		2/90	(2%)	0/50	(0%)		
Overall Incidence	Total	5/587 (0.85%)		Mean 0.75%		SD 1.37%	

*Testis:
  Hemangioma

		0/49	(0%)	0/49	(0%)	0/50	(0%)
		1/49	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)		
Overall Incidence	Total	1/587 (0.17%)		Mean 0.19%		SD 0.62%	

*Thymus:
  Thymoma Benign

		Male								Female					
		0/41	(0%)	0/43	(0%)	0/44	(0%)		0/47	(0%)	0/47	(0%)	0/47	(0%)
		0/45	(0%)	1/49	(2%)	0/41	(0%)		0/48	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/48	(0%)	0/40	(0%)		0/48	(0%)	0/50	(0%)	0/48	(0%)
		0/75	(0%)	0/47	(0%)				0/85	(0%)	0/50	(0%)		
Overall Incidence	Total	1/517 (0.19%)		Mean 0.19%		SD 0.62%		Total	0/563 (0%)		Mean 0%		SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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					

*Thymus:
  Thymoma NOS

		0/41	(0%)	0/43	(0%)	0/44	(0%)		1/47	(2%)	0/47	(0%)	0/47	(0%)
		0/45	(0%)	0/49	(0%)	0/41	(0%)		0/48	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/48	(0%)	0/40	(0%)		0/48	(0%)	0/50	(0%)	0/48	(0%)
		0/75	(0%)	0/47	(0%)				0/85	(0%)	0/50	(0%)		
Overall Incidence	Total	0/517 (0%)		Mean 0%		SD 0%		Total	1/563 (0.18%)		Mean 0.19%		SD 0.64%	

*Thymus:
  Thymoma: Benign, Malignant, NOS

		0/41	(0%)	0/43	(0%)	0/44	(0%)		1/47	(2%)	0/47	(0%)	0/47	(0%)
		0/45	(0%)	1/49	(2%)	0/41	(0%)		0/48	(0%)	0/49	(0%)	0/44	(0%)
		0/44	(0%)	0/48	(0%)	0/40	(0%)		0/48	(0%)	0/50	(0%)	0/48	(0%)
		0/75	(0%)	0/47	(0%)				0/85	(0%)	0/50	(0%)		
Overall Incidence	Total	1/517 (0.19%)		Mean 0.19%		SD 0.62%		Total	1/563 (0.18%)		Mean 0.19%		SD 0.64%	

*Thyroid Gland: C-Cell:
  Adenoma

		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(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%)
		0/89	(0%)	0/50	(0%)				0/86	(0%)	0/50	(0%)		
Overall Incidence	Total	0/587 (0%)		Mean 0%		SD 0%		Total	1/582 (0.17%)		Mean 0.18%		SD 0.6%	

*Thyroid Gland: C-Cell:
  Carcinoma

		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/89	(0%)	0/50	(0%)				1/86	(1%)	0/50	(0%)		
Overall Incidence	Total	0/587 (0%)		Mean 0%		SD 0%		Total	3/582 (0.52%)		Mean 0.47%		SD 0.83%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male						Female			
*Thyroid Gland: C-Cell:											
Carcinoma or Adenoma											
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/48	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	1/50	(2%)
		0/89	(0%)	0/50	(0%)			1/86	(1%)	0/50	(0%)		
Overall Incidence	Total	0/587 (0%)		Mean 0%		SD 0%		Total	4/582 (0.69%)	Mean 0.65%		SD 0.93%	
*Thyroid Gland: Follicular Cell:											
Adenoma											
		0/49	(0%)	0/50	(0%)	1/50	(2%)	0/48	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/48	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/89	(0%)	0/50	(0%)			0/86	(0%)	0/50	(0%)		
Overall Incidence	Total	2/587 (0.34%)		Mean 0.36%		SD 0.81%		Total	4/582 (0.69%)	Mean 0.73%		SD 1.02%	
*Thyroid Gland: Follicular Cell:											
Carcinoma or Adenoma											
		0/49	(0%)	0/50	(0%)	1/50	(2%)	0/48	(0%)	1/50	(2%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/48	(2%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/89	(0%)	0/50	(0%)			0/86	(0%)	0/50	(0%)		
Overall Incidence	Total	2/587 (0.34%)		Mean 0.36%		SD 0.81%		Total	4/582 (0.69%)	Mean 0.73%		SD 1.02%	
#Tongue:											
Squamous Cell Carcinoma or Papilloma Squamous											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)			0/90	(0%)	1/50	(2%)		
Overall Incidence	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%		Total	1/590 (0.17%)	Mean 0.18%		SD 0.6%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

Species: MICE   **Route:** ALL ROUTES

Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES

Length of Study: CHRONIC

		Male					Female			

#Tongue:
Squamous Cell Papilloma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/90 (0%)	0/50 (0%)				0/90 (0%)	1/50 (2%)		

Overall Incidence   Total   1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total   1/590 (0.17%)   Mean 0.18%   SD 0.6%

#Tooth:
Odontoma

	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/90 (0%)	2/50 (4%)				0/90 (0%)	0/50 (0%)		

Overall Incidence   Total   2/589 (0.34%)   Mean 0.36%   SD 1.21%   Total   0/590 (0%)   Mean 0%   SD 0%

*Urinary Bladder:
Hemangiosarcoma

	0/50 (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%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/49 (0%)	
	0/87 (0%)	0/50 (0%)				0/86 (0%)	0/50 (0%)		

Overall Incidence   Total   1/585 (0.17%)   Mean 0.18%   SD 0.6%   Total   0/585 (0%)   Mean 0%   SD 0%

*Urinary Bladder:
Mast Cell Tumor

	0/50 (0%)	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/49 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/49 (0%)	
	1/87 (1%)	0/50 (0%)				0/86 (0%)	0/50 (0%)		

Overall Incidence   Total   1/585 (0.17%)   Mean 0.1%   SD 0.35%   Total   0/585 (0%)   Mean 0%   SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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				

#Uterus:
  Adenoma

				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	1/50	(2%)
				0/90	(0%)	0/50	(0%)		

Overall Incidence — Total — 1/590 (0.17%) — Mean 0.18% — SD 0.6%

#Uterus:
  Fibroma

				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				1/90	(1%)	0/50	(0%)		

Overall Incidence — Total — 1/590 (0.17%) — Mean 0.1% — SD 0.34%

#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%)
				0/90	(0%)	0/50	(0%)		

Overall Incidence — Total — 1/590 (0.17%) — Mean 0.18% — SD 0.6%

#Uterus:
  Hemangioma

				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)	1/50	(2%)
				0/90	(0%)	0/50	(0%)		

Overall Incidence — Total — 1/590 (0.17%) — Mean 0.18% — SD 0.6%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Aug2017
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1/N
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: 01/20/2018

		Male				Female		

#Uterus:
  Hemangiosarcoma

					1/50	(2%)	0/50	(0%)	0/50	(0%)
					0/50	(0%)	0/50	(0%)	1/50	(2%)
					1/50	(2%)	1/50	(2%)	0/50	(0%)
					0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   4/590 (0.68%)   Mean 0.73%   SD 1.01%

#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%)
					1/90	(1%)	0/50	(0%)		

Overall Incidence   Total   2/590 (0.34%)   Mean 0.28%   SD 0.66%

#Uterus:
  Polyp Stromal

					4/50	(8%)	0/50	(0%)	2/50	(4%)
					1/50	(2%)	0/50	(0%)	0/50	(0%)
					1/50	(2%)	0/50	(0%)	0/50	(0%)
					0/90	(0%)	0/50	(0%)		

Overall Incidence   Total   8/590 (1.36%)   Mean 1.45%   SD 2.54%

#Uterus:
  Sarcoma Stromal

					0/50	(0%)	0/50	(0%)	0/50	(0%)
					0/50	(0%)	0/50	(0%)	0/50	(0%)
					0/50	(0%)	0/50	(0%)	0/50	(0%)
					0/90	(0%)	2/50	(4%)		

Overall Incidence   Total   2/590 (0.34%)   Mean 0.36%   SD 1.21%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories   Tumor Incidence for Selected Control Animal Groups   **Report Date:** 01/20/2018
Species: MICE   **Route:** ALL ROUTES
Strain: B6C3F1/N   **Vehicle:** ALL VEHICLES
Length of Study: CHRONIC

	Male							Female				

#Uterus:
  Sarcoma Stromal or Polyp Stromal

Male							Female		
							4/50 (8%)	0/50 (0%)	2/50 (4%)
							1/50 (2%)	0/50 (0%)	0/50 (0%)
							1/50 (2%)	0/50 (0%)	0/50 (0%)
							0/90 (0%)	2/50 (4%)	

Overall Incidence   Total 10/590 (1.69%)   Mean 1.82%   SD 2.6%

#Zymbal's Gland:
  Carcinoma

Male							Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	0/50 (0%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	1/50 (2%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/90 (0%)	0/50 (0%)						0/90 (0%)	0/50 (0%)	

Overall Incidence   Total 1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total 0/590 (0%)   Mean 0%   SD 0%

#Zymbal's Gland:
  Carcinoma or Adenoma

Male							Female		
0/50 (0%)	0/50 (0%)	0/50 (0%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/49 (0%)	0/50 (0%)	0/50 (0%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/50 (0%)	0/50 (0%)	1/50 (2%)					0/50 (0%)	0/50 (0%)	0/50 (0%)
0/90 (0%)	0/50 (0%)						0/90 (0%)	0/50 (0%)	

Overall Incidence   Total 1/589 (0.17%)   Mean 0.18%   SD 0.6%   Total 0/590 (0%)   Mean 0%   SD 0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied