

NTP Historical Controls Report

All Routes and Vehicles

MICE

October 2022

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

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Report Date: 11/18/2022

Species: MICE Strain: B6C3F1/N 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 Columbus Laboratory	050005804	N/A	N/A	0(0)	0(0)	N/A	Black Cohosh
Battelle Columbus Laboratory	051098702	08/17/10	730	50(1)	44(722)	48.9	Dibutyl Phthalate
Battelle Columbus Laboratory	051026002	07/16/10	727	49(1)	34(691)	47.6	2-Hydroxy-4-methoxybenzophenone
Battelle Northwest	051047204	01/31/11	729	50(5)	40(705)	52.7	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010578	06/18/12	729	90(1)	66(687)	51.5	Radiofrequency Radiation
Battelle Columbus Laboratory	052032306	05/22/12	730	50(1)	35(698)	52.5	Resveratrol
Battelle Columbus Laboratory	050303804	01/17/12	730	50(1)	26(683)	54.6	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071204	10/25/11	731	50(1)	39(701)	50.0	Tris(Chloropropyl)phosphate
Battelle Columbus Laboratory	051105402	05/19/15	730	50(1)	34(701)	56.1	Sulfolane
					Female		
Battelle Columbus Laboratory	050005804	04/09/12	729	50(4)	40(703)	58.8	Black Cohosh
Battelle Columbus Laboratory	051098702	08/16/10	729	50(4)	42(713)	51.5	Dibutyl Phthalate
Battelle Columbus Laboratory	051026002	07/15/10	726	50(4)	42(716)	54.7	2-Hydroxy-4-methoxybenzophenone
Battelle Northwest	051047204	01/31/11	731	50(5)	38(700)	55.9	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010578	06/18/12	739	90(1)	67(704)	62.6	Radiofrequency Radiation
Battelle Columbus Laboratory	052032306	05/21/12	729	50(4)	44(716)	58.8	Resveratrol
Battelle Columbus Laboratory	050303804	01/16/12	729	50(4)	38(700)	61.6	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071204	10/24/11	729	50(4)	46(726)	51.9	Tris(Chloropropyl)phosphate
Battelle Columbus Laboratory	051105402	05/18/15	728	50(4)	35(702)	61.8	Sulfolane

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

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Report Date: 11/18/2022

Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

			Male				Female	
#All Organs: Benign Tumors								
			26/50 (52%)	28/49 (57%)		15/50 (30%)	13/50 (26%)	17/50 (34%)
		32/50 (64%)	61/90 (68%)	33/50 (66%)		24/50 (48%)	36/90 (40%)	17/50 (34%)
	-	31/50 (62%)	25/50 (50%)	32/50 (64%)	-	20/50 (40%)	21/50 (42%)	25/50 (50%)
Overall Incidence	Total	268/439 (61.05%)	Mean 60.37%	SD 6.59%	Total	188/490 (38.37%)	Mean 38.22%	SD 7.97%
#All Organs: Malignant Tumors								
			19/50 (38%)	19/49 (39%)		22/50 (44%)	19/50 (38%)	11/50 (22%)
		25/50 (50%)	49/90 (54%)	24/50 (48%)		24/50 (48%)	33/90 (37%)	18/50 (36%)
		30/50 (60%)	20/50 (40%)	22/50 (44%)		15/50 (30%)	12/50 (24%)	18/50 (36%)
Overall Incidence	Total	208/439 (47.38%)	Mean 46.65%	SD 7.93%	Total	172/490 (35.1%)	Mean 34.96%	SD 8.51%
All Organs: Malignant and Benign 1								
			33/50 (66%)	37/49 (76%)		31/50 (62%)	28/50 (56%)	25/50 (50%)
		44/50 (88%)	79/90 (88%)	41/50 (82%)		38/50 (76%)	59/90 (66%)	27/50 (54%)
		42/50 (84%)	34/50 (68%)	41/50 (82%)		32/50 (64%)	27/50 (54%)	34/50 (68%)
Overall Incidence	Total	351/439 (79.95%)	Mean 79.16%	SD 8.48%	Total	301/490 (61.43%)	Mean 61.06%	SD 8.28%
#All Organs: Hemangioma								
J			0/50 (0%)	1/49 (2%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	4/90 (4%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	6/439 (1.37%)	Mean 1.39%	SD 1.41%	Total	11/490 (2.24%)	Mean 2.05%	SD 2.29%

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

^{#:} Denominator is number of animals necropsied

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

### Hemangiosarcoma Hemangiosarcoma				Male				Female	
2/50 (4%) 2/90 (2%) 3/50 (6%) 3/50 (6%) 2/90 (2%) 1/50 (
1/50 1/50				` ,	` ,		` '	` ,	(,
Verall Incidence Total 21/439 (4.78%) Mean 5.03% SD 2.58% Total 13/490 (2.65%) Mean 2.69% SD 1.99%			` '	` ,	` '		` ,	` ,	` '
Hemangiosarcoma or Hemangioma			` '	` ,	` '		` '	` ,	` ,
Hemangiosarcoma or Hemangioma 3/50 (6%) 2/49 (4%) 2/50 (4%) 4/50 (8%) 2/50 (4%) 2/50 (4%) 3/90 (3%) 3/50 (6%) 3/50 (6%) 6/50 (12%) 3/50 (6%) 4/50 (8%) Verall Incidence Total 26/439 (5.92%) Mean 6.18% SD 2.79% Total 24/490 (4.9%) 4/50 (2%) Mean 4.74% SD 2.5% All Organs: Histiocytic Sarcoma 2/50 (4%) 0/69 (0%) 1/50 (2%) 1/50 (0%) 1/5	rerall incidence	l otal	` ,		SD 2.58%	l otal	13/490 (2.65%)	Mean 2.69%	SD 1.99%
2/50 (4%) 3/90 (3%) 3/50 (6%) 3/50 (6%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50 (2%) 4/50 (8%) 1/50 (2%) 1/50	•	Hemangioma							
Company Comp				3/50 (6%)	2/49 (4%)		2/50 (4%)	4/50 (8%)	2/50 (4%)
Verall Incidence Total 26/439 (5.92%) Mean 6.18% SD 2.79% Total 24/490 (4.9%) Mean 4.74% SD 2.5%			2/50 (4%)	3/90 (3%)	3/50 (6%)		` '	6/90 (7%)	1/50 (2%)
Compansi			6/50 (12%)	3/50 (6%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	4/50 (8%)
Histiocytic Sarcoma 2/50 (4%) 0/49 (0%) 2/50 (4%) 1/50 (2%) 1/			, ,				,		SD 2.5%
0/50 (0%) 0/90 (0%) 1/50 (2%) 2/50 (4%) 8/90 (9%) 2/50 (4%)	All Organs:								
1/50 (2%) 0/50 (0%) 0/50 (0%) 2/50 (4%) 0/50 (0%) 2/50 (4%) verall Incidence Total 4/439 (0.91%) Mean 1% SD 1.51% Total 20/490 (4.08%) Mean 3.65% SD 2.42% All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 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%)	0/49 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
All Organs: Leukemia: Lymphocytic, Monocytic, Mo			()	0/90 (0%)	1/50 (2%)		2/50 (4%)	8/90 (9%)	2/50 (4%)
All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 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%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			,				` ,		SD 2.42%
0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	All Organs:								
0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Leukemia: Lympnocyti	ic, Monocytic, M	iononuclear, or Undifferer		0/40 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50 (0%)	` '	` ,		` '	` ,	` ,
			` ,	` ,	` '		` '	` ,	` '
	verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

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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/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

			Male				Female	
#All Organs: Malignant Lymphoma: Hist	iocytic. I vn	nnhocytic Mixed NOS or	Undifferentiated Cell	Type				
manghant Lymphoma. Thos	looytio, Lyii	inpridoytio, imixeu, 1100, or	4/50 (8%)	3/49 (6%)		10/50 (20%)	11/50 (22%)	5/50 (10%)
		6/50 (12%)	6/90 (7%)	7/50 (14%)		9/50 (18%)	2/90 (2%)	9/50 (18%)
		5/50 (10%)	5/50 (10%)	2/50 (4%)		4/50 (8%)	8/50 (16%)	5/50 (10%)
Overall Incidence	Total	38/439 (8.66%)	Mean 8.85%	SD 3.29%	Total	63/490 (12.86%)	Mean 13.8%	SD 6.54%
#All Organs: Malignant Schwannoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.5%	SD 0.93%	Total	0/490 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
			0/50 (0%)	0/49 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	3/90 (3%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	6/490 (1.22%)	Mean 1.04%	SD 1.64%
#All Organs: Osteosarcoma or Osteoma								
			0/50 (0%)	0/49 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	3/90 (3%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	6/490 (1.22%)	Mean 1.04%	SD 1.64%

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

^{#:} Denominator is number of animals necropsied

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

			Male				Female	
*Adrenal Cortex: Adenoma								
			0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/84 (1%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	3/435 (0.69%)	Mean 0.76%	SD 1.05%	Total	1/482 (0.21%)	Mean 0.13%	SD 0.4%
Adrenal Medulla: Pheochromocytoma B								
			0/50 (0%)	1/48 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	0/83 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence	Total	1/434 (0.23%)	Mean 0.26%	SD 0.74%	Total	2/480 (0.42%)	Mean 0.44%	SD 0.88%
*Adrenal Medulla: Pheochromocytoma M								
			0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	2/83 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	1/434 (0.23%)	Mean 0.25%	SD 0.71%	Total	2/480 (0.42%)	Mean 0.27%	SD 0.8%
*Adrenal Medulla: Pheochromocytoma: E		t, Malignant, NOS						
-		•	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		1/50 (2%)	2/83 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence	Total	2/434 (0.46%)	Mean 0.51%	SD 0.95%	Total	4/480 (0.83%)	Mean 0.71%	SD 1.07%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/18/2022

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Bone Marrow: Hemangiosarcoma								
			0/50 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
O	T-1-1	2/50 (4%)	0/50 (0%)	0/50 (0%)	T-1-1	0/48 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/437 (0.46%)	Mean 0.5%	SD 1.41%	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%
Bone Marrow: Mast Cell Tumor Malignar	nt							
_			0/50 (0%)	1/47 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/437 (0.46%)	Mean 0.52%	SD 0.96%	Total	0/487 (0%)	Mean 0%	SD 0%
#Bone: Hemangioma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
#Bone: Hemangiosarcoma								
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/18/2022

Route: ALL ROUTES
Vehicle: ALL VEHICLES

			Male				Female	
#Bone: Osteosarcoma								
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
	T	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	3/490 (0.61%)	Mean 0.57%	SD 0.89%
#Bone: Osteosarcoma or Osteo	oma							
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	3/490 (0.61%)	Mean 0.57%	SD 0.89%
Brain: Meningioma Malignant								
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/87 (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	0/439 (0%)	Mean 0%	SD 0%	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%
*Brain: Meningioma: Benign, N	Malignant. NOS							
gg,	J		0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/87 (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	0/439 (0%)	Mean 0%	SD 0%	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/18/2022

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

			Male			Female			
*Clitoral/Preputial Gland: Mast Cell Tumor									
		0/50 (00/)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%) 0/49 (0%)	1/89 (1%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/48 (0%) 0/49 (0%)	0/82 (0%) 0/50 (0%)	0/49 (0%) 0/43 (0%)	
Overall Incidence	Total	1/437 (0.23%)	Mean 0.14%	SD 0.4%	Total	0/471 (0%)	Mean 0%	SD 0%	
*Epididymis: Mast Cell Tumor				•••••					
			0/50 (0%)	0/49 (0%)					
		0/50 (0%)	1/90 (1%)	0/50 (0%)					
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%					
#Harderian Gland: Adenoma									
			3/50 (6%)	6/49 (12%)		2/50 (4%)	3/50 (6%)	1/50 (2%)	
		5/50 (10%)	6/90 (7%)	6/50 (12%)		2/50 (4%)	4/90 (4%)	3/50 (6%)	
Occasional descriptions of	T-1-1	2/50 (4%)	0/50 (0%)	5/50 (10%)	T-1-1	1/50 (2%)	4/50 (8%)	1/50 (2%)	
Overall Incidence	Total	33/439 (7.52%)	Mean 7.61%	SD 4.25%	Total	21/490 (4.29%)	Mean 4.27%	SD 2.11%	
#Harderian Gland: Adenocarcinoma									
			1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)	3/90 (3%)	2/50 (4%)		0/50 (0%)	0/90 (0%)	1/50 (2%)	
		1/50 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	12/439 (2.73%)	Mean 2.67%	SD 0.94%	Total	4/490 (0.82%)	Mean 0.89%	SD 1.45%	

^{*:} 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 Strain: B6C3F1/N

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Adenoma or Adenocarcinor	na							
		0/20 (4.004)	4/50 (8%)	7/49 (14%)		2/50 (4%)	3/50 (6%)	2/50 (4%)
		6/50 (12%)	9/90 (10%)	8/50 (16%)		2/50 (4%)	4/90 (4%)	4/50 (8%)
Overall Incidence	Total	3/50 (6%) 45/439 (10.25%)	2/50 (4%) Mean 10.29%	6/50 (12%) SD 4.1%	Total	1/50 (2%) 25/490 (5.1%)	6/50 (12%) Mean 5.16%	1/50 (2%) SD 3.16%
#Harderian Gland: Mast Cell Tumor								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/490 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Intestine Small: Duodenum: Adenocarcinoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/490 (0%)	Mean 0%	SD 0%

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

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^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Route: ALL ROUTES

Vehicle: ALL VEHICLES

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Length of Study: CHRONIC

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			Male				Female	
#Intestine Small: Ileum: Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	0/90 (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	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Intestine Small: Jejunum: Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/439 (0.68%)	Mean 0.75%	SD 1.49%	Total	0/490 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenocarcinoma								
			1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/90 (2%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	6/439 (1.37%)	Mean 1.28%	SD 1.51%	Total	2/490 (0.41%)	Mean 0.44%	SD 1.33%
#Intestine Small: Jejunum: Mast Cell Tumor								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/490 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

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Report Date: 11/18/2022

		Male				Female	
		0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	(,	` '		` ,	0/90 (0%)	1/50 (2%)
		` '	` '			` ,	0/50 (0%)
Total	4/439 (0.91%)	Mean 1%	SD 2.14%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
		1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	1/50 (2%)	3/90 (3%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
	0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Total	7/439 (1.59%)	Mean 1.42%	SD 1.65%	Total	2/490 (0.41%)	Mean 0.44%	SD 1.33%
noma							
		1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	1/50 (2%)	3/90 (3%)	1/50 (2%)		1/50 (2%)	0/90 (0%)	1/50 (2%)
	0/50 (0%)	2/50 (4%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Total	11/439 (2.51%)	Mean 2.42%	SD 2.01%	Total	4/490 (0.82%)	Mean 0.89%	SD 1.45%
		0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/490 (0%)	Mean 0%	SD 0%
	oma Total	0/50 (0%) Total 4/439 (0.91%) 1/50 (2%) 0/50 (0%) Total 7/439 (1.59%) noma 1/50 (2%) 0/50 (0%) Total 11/439 (2.51%) 0/50 (0%) 0/50 (0%)	O/50 (0%) Total 4/439 (0.91%) Mean 1% 1/50 (2%) 3/90 (3%) O/50 (0%) 2/50 (4%) Total 7/439 (1.59%) Mean 1.42% 1/50 (2%) 3/90 (3%) O/50 (0%) 2/50 (4%) Total 11/439 (2.51%) Mean 2.42% O/50 (0%)	0/50 (0%) 0/90 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 3/50 (6%) Total 4/439 (0.91%) Mean 1% SD 2.14% 1/50 (2%) 3/90 (3%) 0/50 (0%) 0/50 (0%) 2/50 (4%) 0/50 (0%) Total 7/439 (1.59%) Mean 1.42% SD 1.65% 1/50 (2%) 3/90 (3%) 1/50 (2%) 0/50 (0%) 2/50 (4%) 3/50 (6%) Total 1/50 (2%) 3/90 (3%) 1/50 (2%) 0/50 (0%) 2/50 (4%) 3/50 (6%) Total 11/439 (2.51%) Mean 2.42% SD 2.01%	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/90 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 3/50 (6%) Total 4/439 (0.91%) Mean 1% SD 2.14% Total 1/50 (2%) 0/49 (0%) 0/50 (0%) 2/50 (4%) 0/50 (0%) Total 7/439 (1.59%) Mean 1.42% SD 1.65% Total 1/50 (2%) 3/90 (3%) 1/50 (2%) 0/50 (0%) 2/50 (4%) 3/50 (6%) Total 1/50 (2%) 3/90 (3%) 1/50 (2%) 0/50 (0%) 2/50 (4%) 3/50 (6%) Total 11/439 (2.51%) Mean 2.42% SD 2.01% Total	O/50 (0%) O/50 (0%) O/49 (0%) O/50	1/50 (2%) 0/50 (0%) 0/49 (0%) 0/50

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 11/18/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

			Male				Female	
*Islets, Pancreatic: Adenoma								
			0/50 (0%)	1/47 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	0/88 (0%)	0/50 (0%)		0/50 (0%)	0/87 (0%)	0/49 (0%)
		1/47 (2%)	1/50 (2%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/432 (0.93%)	Mean 1.03%	SD 1.1%	Total	0/483 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Carcinoma								
			0/50 (0%)	0/47 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/88 (0%)	0/50 (0%)		0/50 (0%)	1/87 (1%)	0/49 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/432 (0%)	Mean 0%	SD 0%	Total	1/483 (0.21%)	Mean 0.13%	SD 0.38%
Islets, Pancreatic: Carcinoma or Adenoma								
			0/50 (0%)	1/47 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	0/88 (0%)	0/50 (0%)		0/50 (0%)	1/87 (1%)	0/49 (0%)
		1/47 (2%)	1/50 (2%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/432 (0.93%)	Mean 1.03%	SD 1.1%	Total	1/483 (0.21%)	Mean 0.13%	SD 0.38%
Kidney: Renal Tubule:								
			0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		1/50 (2%)	2/89 (2%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/437 (0.23%)	Mean 0.26%	SD 0.72%	Total	3/488 (0.61%)	Mean 0.47%	SD 0.94%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		2/22 (22/)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%) 0/50 (0%)	0/90 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	2/89 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/437 (0.23%)	Mean 0.26%	SD 0.72%	Total	3/488 (0.61%)	Mean 0.47%	SD 0.94%
*Kidney: Renal Tubule: Hemangiosarcoma								
•			0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/437 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/488 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mast Cell Tumor								
			0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/437 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/488 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Renal Mesenchymal Tumor								
•			0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/89 (1%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/437 (0%)	Mean 0%	SD 0%	Total	1/488 (0.2%)	Mean 0.12%	SD 0.37%

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

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^{#:} Denominator is number of animals necropsied

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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	
*Liver: Cholangiocarcinoma								
_			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%
*Liver: Hemangioma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/439 (0.91%)	Mean 1%	SD 1.51%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%
*Liver: Hemangiosarcoma								
_			3/50 (6%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	1/50 (2%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	10/439 (2.28%)	Mean 2.39%	SD 2.61%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%
*Liver: Hepatoblastoma								
-			0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	6/90 (7%)	1/50 (2%)		0/50 (0%)	1/89 (1%)	0/50 (0%)
		4/50 (8%)	1/50 (2%)	7/50 (14%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	21/439 (4.78%)	Mean 4.59%	SD 4.66%	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/18/2022

SD 9.23%

Mean 20.68%

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Liver: Hepatocellular Adenoma 18/50 (36%)21/49 (43%)6/50 (12%)3/50 (6%)3/50 (6%)25/50 (50%)52/90 (58%)25/50 (50%)12/50 (24%)19/89 (21%)(16%)26/50 (52%)21/50 (42%)22/50 (44%)11/50 (22%)11/50 (22%)10/50 (20%)210/439 (47.84%) 83/489 (16.97%) **Overall Incidence** Total Mean 46.83% SD 6.88% Total Mean 16.59% SD 7.01% *Liver: **Hepatocellular Carcinoma** 10/50 (20%)8/49 (16%)3/50 (2%)1/50 (6%)1/50 (2%)8/50 28/90 (31%)7/50 (14%)7/50 (14%)8/89 (9%)3/50 (6%)(16%)15/50 (30%)5/50 (10%)11/50 (22%)2/50 (4%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 92/439 (20.96%) Mean 19.93% SD 7.49% Total 28/489 (5.73%) Mean 5.44% SD 3.97% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 10/50 (20%)8/49 (16%)3/50 (6%)1/50 (2%)1/50 (2%)9/50 (18%)32/90 (36%)8/50 (16%)7/50 (14%)9/89 (10%)3/50 (6%)17/50 (34%)6/50 (12%)18/50 (36%)2/50 (4%)1/50 (2%)2/50 (4%)108/439 (24.6%) Mean 23.49% SD 9.96% SD 4.11% **Overall Incidence** Total Total 29/489 (5.93%) Mean 5.57% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 24/50 (48%)(53%)26/49 8/50 (16%)4/50 (8%)4/50 (8%)(60%)67/90 (74%)29/50 (58%)18/50 (36%)25/89 (28%)(18%)30/50 33/50 (66%)23/50 (46%)30/50 (60%)13/50 (26%)12/50 (24%)11/50 (22%)

SD 9.34%

104/489 (21.27%)

Total

Total

262/439 (59.68%)

Mean 58.19%

.....

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/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

			Male				Female	
*Liver: Hepatocellular Carcino	oma, Hepatocel	lular Adenoma, or Hepatol	blastoma					
•	•	, .	24/50 (48%)	26/49 (53%)		8/50 (16%)	4/50 (8%)	4/50 (8%)
		31/50 (62%)	68/90 (76%)	30/50 (60%)		18/50 (36%)	25/89 (28%)	9/50 (18%)
		34/50 (68%)	24/50 (48%)	36/50 (72%)		13/50 (26%)	12/50 (24%)	11/50 (22%)
Overall Incidence	Total	273/439 (62.19%)	Mean 60.83%	SD 10.59%	Total	104/489 (21.27%)	Mean 20.68%	SD 9.23%
*Liver: Hepatocholangiocarcir								
			0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	1/90 (1%)	2/50 (4%)		0/50 (0%)	0/89 (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	8/439 (1.82%)	Mean 1.89%	SD 2.16%	Total	0/489 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/489 (0%)	Mean 0%	SD 0%
*Liver: Mast Cell Tumor								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/489 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

*Lung:

Hemangiosarcoma

Overall Incidence

Toxicology Data Management System

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Report Date: 11/18/2022

0/50

0/50

0/50

SD 0%

(0%)

(0%)

(0%)

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Lung: Alveolar/Bronchiolar Adenoma (4%) 9/50 (18%)7/49 (14%)2/50 (4%)2/50 5/50 (10%)11/50 (22%)13/90 (14%)8/50 (16%)5/50 (10%)3/90 (3%)1/50 (2%)5/50 (10%)8/50 (16%)9/50 (18%)2/50 (4%)3/50 (6%)0/50 (0%)70/439 (15.95%) Mean 16.09% Mean 4.81% SD 3.36% **Overall Incidence** Total SD 3.49% Total 23/490 (4.69%) *Lung: Alveolar/Bronchiolar Carcinoma 3/50 (6%)5/49 (10%)0/50 (0%)0/50 0/50 (0%)(0%)3/50 6/50 (12%)13/90 (14%)4/50 (8%) 0/50 (0%)3/90 (3%)(6%)2/50 (4%)1/50 (2%)1/50 (2%)2/50 (4%)1/50 (2%)2/50 (4%)Mean 7.33% SD 2.28% **Overall Incidence** Total 35/439 (7.97%) SD 4.64% Total 11/490 (2.24%) Mean 2.15% *Luna: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 11/50 (22%)11/49 (22%)2/50 (4%)2/50 (4%)5/50 (10%)17/50 (34%)23/90 (26%)11/50 (22%)5/50 (10%)6/90 (7%)4/50 (8%)7/50 (14%)9/50 (18%)10/50 (20%)4/50 (8%)4/50 (8%)2/50 (4%)**Overall Incidence** 99/439 (22.55%) Mean 22.25% SD 5.86% SD 2.45% Total Total 34/490 (6.94%) Mean 6.96%

0/49

0/50

0/50

SD 0.71%

(0%)

(0%)

(0%)

Total

0/50

0/50

0/50

0/490 (0%)

(0%)

(0%)

(0%)

0/50

0/90

0/50

(0%)

(0%)

(0%)

Mean 0%

0/50

0/90

0/50

Mean 0.25%

1/50

0/50

1/439 (0.23%)

(2%)

(0%)

.....

(0%)

(0%)

(0%)

Total

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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Report Date: 11/18/2022

			Male				Female	
*Lung: Mast Cell Tumor								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	0/50 (0%) Mean 0.14%	0/50 (0%) SD 0.39%	Total	0/50 (0%) 0/490 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangiosarcoma					•••••			
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Lymph Node: Mast Cell Tumor								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	0/490 (0%)	Mean 0%	SD 0%
#Lymph Node, Axillary: Hemangioma								
-			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/18/2022

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female
#Lymph Node, Mandibular: Mast Cell Tumor						
			0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14% S	SD 0.39%	Total 0/490 (0%)	Mean 0% SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant						
_			0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25% S	SD 0.71%	Total 0/490 (0%)	Mean 0% SD 0%
#Lymph Node, Mesenteric: Hemangioma						
_			0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14% S	SD 0.39%	Total 0/490 (0%)	Mean 0% SD 0%
#Lymph Node, Mesenteric: Mast Cell Tumor						
			0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/90 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14% S	SD 0.39%	Total 0/490 (0%)	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/18/2022

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

			Male				Female	
#Lymph Node, Mesenteric: Mast Cell Tumor Malignant								
		2/22 (22/)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/439 (0.23%)	0/50 (0%) Mean 0.25%	0/50 (0%) SD 0.71%	Total	0/50 (0%) 0/490 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		••••••				·····		
#Mammary Gland: Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	5/490 (1.02%)	Mean 1.11%	SD 1.45%
#Mammary Gland: Adenocarcinoma								
			0/50 (0%)	1/49 (2%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (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	2/439 (0.46%)	Mean 0.51%	SD 0.94%	Total	4/490 (0.82%)	Mean 0.89%	SD 2.03%
#Mammary Gland: Adenoma or Adenocarcinor	ma							
			0/50 (0%)	1/49 (2%)		0/50 (0%)	4/50 (8%)	1/50 (2%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.51%	SD 0.94%	Total	9/490 (1.84%)	Mean 2%	SD 2.65%

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

^{#:} Denominator is number of animals necropsied

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	
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
			0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	5/490 (1.02%)	Mean 1.11%	SD 1.45%
#Mammary Gland: Fibroma, Fibroadenoma								
			0/50 (0%)	1/49 (2%)		0/50 (0%)	4/50 (8%)	1/50 (2%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.51%	SD 0.94%	Total	9/490 (1.84%)	Mean 2%	SD 2.65%
#Mesentery: Hemangioma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
#Mesentery: Hemangiosarcoma								
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		1/50 (2%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.39%	SD 0.76%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Mesentery: Lipoma								
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Mesentery: Sarcoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
Nose: Carcinoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%
Nose: Polyp								
••			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/89 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/489 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES

Report Date: 11/18/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: ALL VEHICLES

			Male				Female	
#Oral Cavity (Oral Mucos Papilloma Squamous o	. •	rynx, Tooth, Gingiva):						
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (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	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Oral Cavity (Oral Mucos	. •	rynx, Tooth, Gingiva):						
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	. •	rynx, Tooth, Gingiva): Squamous, or Papilloma						
•	•		0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
#Oral Mucosa: Squamous Cell Carcine	oma			•••••				
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	(,	Mean 0%	SD 0%	Total	` ,	Mean 0.22%	SD 0.67%
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: ALL ROUTES

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Report Date: 11/18/2022

Vehicle: ALL VEHICLES

Ma	ile		Female	
Ovary: Cystadenoma				
		2/49 (4%)	3/48 (6%)	4/48 (8%)
		2/50 (4%)	2/75 (3%)	3/49 (6%)
Occupation of the second	Tatal	3/49 (6%)	0/49 (0%)	3/48 (6%)
Overall Incidence	Total	22/465 (4.73%)	Mean 4.87%	SD 2.47%
Ovary: Granulosa Cell Tumor Benign				
•		0/49 (0%)	0/48 (0%)	0/48 (0%)
		0/50 (0%)	1/75 (1%)	0/49 (0%)
		0/49 (0%)	1/49 (2%)	0/48 (0%)
Overall Incidence	Total	2/465 (0.43%)	Mean 0.37%	SD 0.76%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/49 (0%)	0/48 (0%)	0/48 (0%)
		0/50 (0%)	1/75 (1%)	0/49 (0%)
		0/49 (0%)	1/49 (2%)	0/48 (0%)
Overall Incidence	Total	2/465 (0.43%)	Mean 0.37%	SD 0.76%
'Ovary: Granulosa-Theca Tumor Malignant				
		0/49 (0%)	0/48 (0%)	0/48 (0%)
		1/50 (2%)	0/75 (0%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/465 (0.22%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/18/2022

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

	Male		Female	
Ovary: Hemangioma				
_		0/49 (0%)	0/48 (0%)	1/48 (2%)
		0/50 (0%)	2/75 (3%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	2/48 (4%)
Overall Incidence	Total	5/465 (1.08%)	Mean 0.99%	SD 1.58%
Ovary: Hemangiosarcoma				
-		0/49 (0%)	2/48 (4%)	0/48 (0%)
		0/50 (0%)	0/75 (0%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	2/465 (0.43%)	Mean 0.46%	SD 1.39%
Ovary: Luteoma				
		0/49 (0%)	0/48 (0%)	0/48 (0%)
		2/50 (4%)	0/75 (0%)	0/49 (0%)
		1/49 (2%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	3/465 (0.65%)	Mean 0.67%	SD 1.42%
Ovary: Thecoma Benign				
U		0/49 (0%)	0/48 (0%)	0/48 (0%)
		0/50 (0%)	0/75 (0%)	0/49 (0%)
		0/49 (0%)	0/49 (0%)	1/48 (2%)
Overall Incidence	Total	1/465 (0.22%)	Mean 0.23%	SD 0.69%

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/18/2022

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female	
					0/49 (0%)	0/48 (0%)	0/48 (0%)
					` '	1/75 (1%)	0/49 (0%)
					0/49 (0%)	0/49 (0%)	0/48 (0%)
				Total	1/465 (0.22%)	Mean 0.15%	SD 0.44%
a							
					0/49 (0%)	0/48 (0%)	0/48 (0%)
					0/50 (0%)	0/75 (0%)	1/49 (2%)
					0/49 (0%)	0/49 (0%)	0/48 (0%)
				Total	1/465 (0.22%)	Mean 0.23%	SD 0.68%
na			•••••				
					0/49 (0%)	0/48 (0%)	0/48 (0%)
					0/50 (0%)	0/75 (0%)	0/49 (0%)
					0/49 (0%)	0/49 (0%)	1/48 (2%)
				Total	1/465 (0.22%)	Mean 0.23%	SD 0.69%
		•••••	•••••	•••••			
		0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
	0/50 (0%)	1/87 (1%)	0/50 (0%)		0/50 (0%)	0/87 (0%)	0/50 (0%)
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	1/436 (0.23%)	Mean 0.14%	SD 0.41%	Total	0/486 (0%)	Mean 0%	SD 0%
	a na	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/87 (1%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 1/87 (1%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Total Total Total O/50 (0%) 0/49 (0%) O/50 (0%) 1/87 (1%) 0/50 (0%) O/50 (0%) 0/50 (0%)	a O/49 (0%) O/50 (0%) O/49 (0%) Total 1/465 (0.22%) O/49 (0%) O/50 (0%) O/49 (0%) Total 1/465 (0.22%) Total 1/465 (0.22%) O/50 (0%)	a O/49 (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

Report Date: 11/18/2022

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Species: MICE Strain: B6C3F1/N Length of Study: CHRONIC

Vehicle: ALL VEHICLES

			Male				Female	
Parathyroid Gland:								
			0/40 (0%)	0/32 (0%)		0/41 (0%)	0/43 (0%)	0/21 (0%)
		0/36 (0%)	0/68 (0%)	0/40 (0%)		0/36 (0%)	0/60 (0%)	0/37 (0%)
Overall Incidence	Total	0/44 (0%)	1/42 (2%)	0/38 (0%)	Total	0/45 (0%)	0/43 (0%)	0/35 (0%)
Overali incidence	Total	1/340 (0.29%)	Mean 0.3%	SD 0.84%	Total	0/361 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma	stalis or Unspec	ified Site:						
			0/48 (0%)	0/45 (0%)		2/49 (4%)	1/49 (2%)	0/47 (0%)
		0/50 (0%)	0/86 (0%)	0/48 (0%)		4/50 (8%)	6/80 (8%)	3/47 (6%)
		0/48 (0%)	0/50 (0%)	0/43 (0%)		2/50 (4%)	3/50 (6%)	7/46 (15%)
Overall Incidence	Total	0/418 (0%)	Mean 0%	SD 0%	Total	28/468 (5.98%)	Mean 5.91%	SD 4.34%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspec							
			0/48 (0%)	0/45 (0%)		2/49 (4%)	1/49 (2%)	0/47 (0%)
		0/50 (0%)	0/86 (0%)	0/48 (0%)		4/50 (8%)	6/80 (8%)	3/47 (6%)
		0/48 (0%)	0/50 (0%)	0/43 (0%)		2/50 (4%)	3/50 (6%)	7/46 (15%)
Overall Incidence	Total	0/418 (0%)	Mean 0%	SD 0%	Total	28/468 (5.98%)	Mean 5.91%	SD 4.34%
*Pituitary Gland: Pars Int Adenoma	ermedia:							
			0/48 (0%)	0/45 (0%)		0/49 (0%)	0/49 (0%)	1/47 (2%)
		0/50 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/47 (0%)
		0/48 (0%)	0/50 (0%)	0/43 (0%)		0/50 (0%)	0/50 (0%)	1/46 (2%)
		` '	` '	` '		` '	` '	` '

^{*:} 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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
*Pituitary Gland: Pars Into								
			0/48 (0%)	0/45 (0%)		0/49 (0%)	0/49 (0%)	1/47 (2%)
		0/50 (0%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/47 (0%)
	.	0/48 (0%)	0/50 (0%)	0/43 (0%)	-	0/50 (0%)	0/50 (0%)	1/46 (2%)
Overall Incidence	Total	0/418 (0%)	Mean 0%	SD 0%	Total	2/468 (0.43%)	Mean 0.48%	SD 0.95%
*Pituitary Gland: Pars Into Schwannoma Malignan	ermedia:							
_			0/48 (0%)	0/45 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		1/50 (2%)	0/86 (0%)	0/48 (0%)		0/50 (0%)	0/80 (0%)	0/47 (0%)
		0/48 (0%)	0/50 (0%)	0/43 (0%)		0/50 (0%)	0/50 (0%)	0/46 (0%)
Overall Incidence	Total	1/418 (0.24%)	Mean 0.25%	SD 0.71%	Total	0/468 (0%)	Mean 0%	SD 0%
*Prostate: Hemangiosarcoma								
			0/50 (0%)	0/49 (0%)				
		0/50 (0%)	0/90 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%				
*Prostate: Mast Cell Tumor								•••••
			0/50 (0%)	0/49 (0%)				
		0/50 (0%)	1/90 (1%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%				

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

^{#:} Denominator is number of animals necropsied

0/50

1/439 (0.23%)

(0%)

0/50

Mean 0.14%

(0%)

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** *Salivary Glands: Adenocarcinoma 0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/90 (0%)0/50 (0%)1/50 (2%)0/89 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0.67% **Overall Incidence** Total 0/438 (0%) Mean 0% SD 0% Total 1/488 (0.2%) Mean 0.22% *Salivary Glands: Adenoma or Adenocarcinoma 0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 1/50 (2%)0/89 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/438 (0%) Mean 0% SD 0% Total 1/488 (0.2%) Mean 0.22% SD 0.67% *Salivary Glands: **Mast Cell Tumor** 0/49 0/49 0/49 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/90 (1%)0/50 (0%)0/50 (0%)0/89 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)**Overall Incidence** Total 1/438 (0.23%) Mean 0.14% SD 0.39% 0/488 (0%) SD 0% Total Mean 0% **#Seminal Vesicle: Fibroma** 0/50 (0%)0/49 (0%)0/50 (0%)1/90 (1%)0/50 (0%)

0/50

SD 0.39%

(0%)

Total

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/18/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES Vehicle: ALL VEHICLES

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
		0/50 (00/)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%) 1/50 (2%)	0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	0/50 (0%) Mean 0.25%	SD 0.71%	Total	0/50 (0%) 1/490 (0.2%)	0/50 (0%) Mean 0.22%	0/50 (0%) SD 0.67%
		, ,				` '		
Skeletal Muscle: Osteosarcoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
Skeletal Muscle: Rhabdomyosarcoma								
			0/50 (0%)	0/49 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		2/50 (4%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/439 (0.68%)	Mean 0.75%	SD 1.49%	Total	7/490 (1.43%)	Mean 1.56%	SD 1.33%
Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyom	a						
,		-	0/50 (0%)	0/49 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/90 (0%)	0/50 (0%)		2/50 (4%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/439 (0.68%)	Mean 0.75%	SD 1.49%	Total	7/490 (1.43%)	Mean 1.56%	SD 1.33%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Strain: B6C3F1/N

Length of Study: CHRONIC

Vehicle: ALL VEHICLES

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			Male				Female	
#Skeletal Muscle: Sarcoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (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	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
#Skin: Basal Cell Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	Basosquamou	s Tumor Benign						
	•	•	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba		Fumor Benign, or Trichoe						
•	•	5 /	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	1/50 (2%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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					Male						F	emale		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Aden	oma, Basosqua	mous Tur	mor (benign	, maligna	nt or								
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		0/50 0/50	(0%) (0%)	0/50 0/90 0/50	(0%) (0%) (0%)	0/49 1/50 0/50	(0%) (2%) (0%)		0/50 0/50 0/50	(0%) (0%) (0%)	0/50 0/90 0/50	(0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)
Overall Incidence	Total	1/439 (0.23		Mean 0		SD 0.719		Total	0/490 (0%)	Mea	n 0%	SD	0%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	ıa. Basosg. Tum	or (M or I	3). Basal Ce										
		0/50 0/50	(0%) (0%)	0/50 0/90 0/50	(0%) (0%) (0%)	0/49 1/50 0/50	(0%) (2%) (0%)		0/50 0/50 0/50	(0%) (0%) (0%)	0/50 0/90 0/50	(0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)
Overall Incidence	Total	1/439 (0.23	` ,	Mean 0	` ,	SD 0.719	%	Total	0/490 (0%)	Mea	n 0%	SD	` '
#Skin: Fibroma														
		0/50 0/50	(0%) (0%)	0/50 0/90 0/50	(0%) (0%) (0%)	0/49 0/50 0/50	(0%) (0%) (0%)		0/50 0/50 0/50	(0%) (0%) (0%)	0/50 1/90 0/50	(0%) (1%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)
Overall Incidence	Total	0/439 (0%	` ,	Mean	, ,	SD 0%	` '	Total	1/490 (0	` ,		0.12%	SD 0	, ,
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myx	oma, Myxosarc	oma, Mali	gnant Fibro	us Histio	cytoma, or								
		1/50	(2%)	0/50 1/90	(0%) (1%)	0/49 0/50	(0%) (0%)		1/50 1/50	(2%) (2%)	2/50 6/90	(4%) (7%)	0/50 2/50	(0%) (4%)
Overall Incidence	Total	0/50 4/439 (0.91	(0%) %)	2/50 Mean 0	(4%)	0/50 SD 1.46 ^o	(0%)	Total	1/50 16/490 (3	(2%)	0/50	(0%) 2.96%	3/50 SD 2	(6%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/18/2022

			Male				Female	
#Skin:								
Fibroma, Fibrosarcom	na, Sarcoma, Myx	oma, Myxosarcoma, or N	Malignant Fibrous Hist	iocytoma				
			0/50 (0%)	0/49 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/90 (1%)	0/50 (0%)		1/50 (2%)	6/90 (7%)	2/50 (4%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	4/439 (0.91%)	Mean 0.89%	SD 1.46%	Total	16/490 (3.27%)	Mean 2.96%	SD 2.38%
Skin:								
Fibrosarcoma			2(52 (221)	2/12 (22/)		0.750 (00.4)	0/=0 (00/)	0(50 (50))
		2/22 (224)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	3/90 (3%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.5%	SD 1.41%	Total	7/490 (1.43%)	Mean 1.26%	SD 2.15%
#Skin:								
Fibrosarcoma, Sarcon	na, Myxosarcom	a, or Malignant Fibrous H	listiocytoma					
			0/50 (0%)	0/49 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/90 (1%)	0/50 (0%)		1/50 (2%)	5/90 (6%)	2/50 (4%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	4/439 (0.91%)	Mean 0.89%	SD 1.46%	Total	15/490 (3.06%)	Mean 2.84%	SD 2.19%
¢Skin:								
Hemangioma			0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (00/)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		0/439 (0%)	Mean 0%	SD 0%		0/490 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/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: Hemangiosarcoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	2/90 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/439 (0.68%)	Mean 0.64%	SD 1.41%	Total	4/490 (0.82%)	Mean 0.69%	SD 1.04%
#Skin: Lipoma								
-			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	1/90 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.14%	SD 0.39%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
#Skin: Liposarcoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Skin: Malignant Fibrous Histi				•••••				
•	•		0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/90 (1%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/439 (0.46%)	Mean 0.39%	SD 0.76%	Total	4/490 (0.82%)	Mean 0.89%	SD 1.45%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/18/2022

Contract/Lab: All Laboratories

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

Route: ALL ROUTES
Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Skin: Melanoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/90 0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Mean 0% Mean 0.22% SD 0.67% **Overall Incidence** Total 0/439 (0%) SD 0% Total 1/490 (0.2%) #Skin: Osteosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)1/90 (1%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/439 (0%) Mean 0% SD 0% Total 1/490 (0.2%) Mean 0.12% SD 0.37% #Skin: Pilomatrixoma 0/49 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/90 (1%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)(0%)**Overall Incidence** 1/439 (0.23%) Mean 0.14% SD 0.39% 0/490 (0%) SD 0% Total Total Mean 0% #Skin: Sarcoma 0/50 (0%)0/49 (0%)(2%)0/50 0/50 1/50 (0%)(0%)0/50 (0%)0/90 (0%) 0/50 (0%)1/50 (2%)2/90 (2%)0/50 (0%)

0/50

SD 0%

(0%)

Total

0/50

4/490 (0.82%)

(0%)

0/50

(0%)

Mean 0.69%

0/50

SD 1.04%

(0%)

Total

0/50

0/439 (0%)

(0%)

0/50

Mean 0%

.....

(0%)

Overall Incidence

^{*:} 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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Spinal Cord: Schwannoma Malignant								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/490 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
-			0/50 (0%)	1/48 (2%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
		1/50 (2%)	0/87 (0%)	1/50 (2%)		1/50 (2%)	0/86 (0%)	0/50 (0%)
		4/49 (8%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	9/433 (2.08%)	Mean 2.28%	SD 2.76%	Total	3/484 (0.62%)	Mean 0.67%	SD 1.01%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/18/2022

Contract/Lab: All Laboratories

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

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Stomach, Forestomach: **Mast Cell Tumor Malignant** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/439 (0.23%) Mean 0.25% SD 0.71% Total 0/490 (0%) SD 0% #Stomach, Forestomach: **Squamous Cell Carcinoma or Papilloma Squamous** 1/50 (2%)2/49 (4%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 1/50 (2%)0/90 (0%)1/50 (2%)1/50 (2%)1/90 (1%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)Mean 1.26% Mean 1.01% **Overall Incidence** Total 5/439 (1.14%) SD 1.51% Total 5/490 (1.02%) SD 1% #Stomach, Forestomach: Squamous Cell Papilloma 2/49 1/50 (2%)(4%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/90 (0%)1/50 (2%)1/50 (2%)1/90 (1%)0/50 (0%)0/50 (0%)0/50 (2%)0/50 0/50 (0%)(0%)1/50 1/50 (2%)(0%)**Overall Incidence** 5/439 (1.14%) Mean 1.26% SD 1.51% 5/490 (1.02%) SD 1% Total Total Mean 1.01% #Stomach, Glandular: Adenoma 0/50 (0%)0/49 (0%)(0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)

0/50

SD 0%

(0%)

0/50

Total

1/490 (0.2%)

(0%)

0/50

(0%)

Mean 0.22%

0/50

SD 0.67%

(0%)

Total

0/50

0/439 (0%)

(0%)

.....

0/50

Mean 0%

(0%)

Overall Incidence

^{*:} 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

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Report Date:

Report Date: 11/18/2022

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
*Testis: Adenoma								
			0/50 (0%)	0/49 (0%)				
		0/50 (0%)	2/90 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	3/439 (0.68%)	Mean 0.53%	SD 0.98%				
Testis: Hemangioma								
			0/50 (0%)	1/49 (2%)				
		0/50 (0%)	0/90 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/439 (0.23%)	Mean 0.26%	SD 0.72%				
*Thymus: Hemangiosarcoma								
U			0/45 (0%)	0/45 (0%)		0/48 (0%)	0/45 (0%)	0/48 (0%)
		0/48 (0%)	0/75 (0%)	0/41 (0%)		0/50 (0%)	0/85 (0%)	0/49 (0%)
		0/45 (0%)	0/46 (0%)	1/46 (2%)		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	1/391 (0.26%)	Mean 0.27%	SD 0.77%	Total	0/469 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 11/18/2022

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

			Male				Female	
Thymus: Thymoma Benign								
			0/45 (0%)	0/45 (0%)		0/48 (0%)	0/45 (0%)	0/48 (0%)
		0/48 (0%)	0/75 (0%)	0/41 (0%)		0/50 (0%)	0/85 (0%)	0/49 (0%)
		0/45 (0%)	0/46 (0%)	0/46 (0%)		0/49 (0%)	0/48 (0%)	1/47 (2%)
verall Incidence	Total	0/391 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.24%	SD 0.71%
Thyroid Gland: C-Cell: Carcinoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
		0/50 (0%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	1/86 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/438 (0%)	Mean 0%	SD 0%	Total	2/480 (0.42%)	Mean 0.35%	SD 0.73%
Гhyroid Gland: C-Cell: Carcinoma or Adenoma								
			0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/48 (0%)
		0/50 (0%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	1/86 (1%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/438 (0%)	Mean 0%	SD 0%	Total	2/480 (0.42%)	Mean 0.35%	SD 0.73%
Thyroid Gland: Follicular Cell Adenoma	:							
			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/48 (2%)
		0/50 (0%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	0/86 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	0/438 (0%)	Mean 0%	SD 0%	Total	3/481 (0.62%)	Mean 0.68%	SD 1.03%

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

^{#:} Denominator is number of animals necropsied

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Report Date: 11/18/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

		Male				Female			
Thyroid Gland: Follicular Co	ell:								
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	0/86 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	1/438 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/481 (0.21%)	Mean 0.22%	SD 0.67%	
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma									
			0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	1/48 (2%)	
		0/50 (0%)	0/89 (0%)	0/50 (0%)		0/50 (0%)	0/86 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/49 (2%)	0/49 (0%)	1/49 (2%)	
Overall Incidence	Total	1/438 (0.23%)	Mean 0.25%	SD 0.71%	Total	4/481 (0.83%)	Mean 0.91%	SD 1.08%	
#Tongue: Squamous Cell Carcinoma	or Papillom	na Squamous							
·	•	•	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (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	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	
#Tongue: Squamous Cell Papilloma							•••••		
•			0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/90 (0%)	0/50 (0%)		0/50 (0%)	0/90 (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	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 0.22%

SD 0.67%

Report Date: 11/18/2022

Contract/Lab: All Laboratories

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

Route: ALL ROUTES Vehicle: ALL VEHICLES

Length of Study: CHRONIC Male **Female** #Tooth: Odontoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/90 0/50 (0%)0/50 (0%)0/90 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/439 (0.23%) Mean 0.25% SD 0.71% Total 0/490 (0%) SD 0% *Urinary Bladder: **Mast Cell Tumor** 0/50 (0%)0/49 (0%)0/50 (0%)0/48 0/50 (0%)(0%)0/50 0/50 (0%)1/87 (1%)0/50 (0%)0/50 (0%)0/86 (0%)(0%)(0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 1/435 (0.23%) Mean 0.14% SD 0.41% Total 0/482 (0%) Mean 0% SD 0% #Uterus: Adenocarcinoma or Adenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/90 (0%)0/50 (0%)(0%)(2%)0/50 0/50 (0%)1/50 **Overall Incidence** 1/490 (0.2%) Mean 0.22% SD 0.67% Total **#Uterus:** Adenoma 0/50 0/50 0/50 (0%)(0%)(0%)0/50 (0%)0/90 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)

Total

1/490 (0.2%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/18/2022

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
#Uterus: Fibroma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%) 0/50 (0%)	1/90 (1%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/490 (0.2%)	Mean 0.12% SD 0.37%	
#Uterus:				
Granular Cell Tumor Benign		1/50 (2%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/90 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22% SD 0.67%	
#Uterus:				
Hemangioma		1/50 (2%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/90 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/490 (0.2%)	Mean 0.22% SD 0.67%	
#Uterus: Hemangiosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
		1/50 (2%)	0/90 (0%) 0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	0/50 (0%) 0/50 (0%) Mean 0.44% SD 0.88%	
Overall incidence		2/490 (0.41%)		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for S

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/18/2022

Route: ALL ROUTES
Vehicle: ALL VEHICLES

	Male		Female			
#Uterus: Leiomyoma						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	1/90 (1%)	0/50 (0%)		
Overall Incidence	Tota	0/50 (0%) al 2/490 (0.41%)	0/50 (0%) Mean 0.35%	0/50 (0%) SD 0.72%		
#Uterus: Polyp Stromal						
		1/50 (2%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Tota		Mean 0.67%	SD 1%		
#Uterus: Sarcoma						
		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Tota	(,	Mean 0.22%	SD 0.67%		
#Uterus: Sarcoma Stromal or Polyp Stromal						
•		1/50 (2%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/90 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Tota	d 3/490 (0.61%)	Mean 0.67%	SD 1%		

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

^{#:} Denominator is number of animals necropsied

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				
#Vagina: Hemangioma					
			0/50 (0%)	1/50 (2%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied