Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: ORAL Vehicle: WATER

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	052000904	11/09/04	730	50(1)	24(645)	57.1	beta-Picoline
Battelle Columbus Laboratory	059601406	09/26/06	730	50(1)	25(660)	55.9	Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Columbus Laboratory	052000904	11/08/04	729	50(5)	38(702)	67.4	beta-Picoline
Battelle Columbus Laboratory	059601406	09/25/06	729	50(5)	30(680)	63.5	Water disinfection byproducts (Bromodichloroacetic acid)

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 113

			Male			Female			
#All Organs: Benign Tumors									
		36/50 (72%)	43/50 (86%)			40/50 (80%)	36/50 (72%)		
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 9.9%	Total	76/100 (76%)	Mean 76%	SD 5.66%	
#All Organs: Malignant Tumors									
		36/50 (72%)	30/50 (60%)			29/50 (58%)	31/50 (62%)		
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 8.49%	Total	60/100 (60%)	Mean 60%	SD 2.83%	
#All Organs: Malignant and Benign T	umors	48/50 (96%)	48/50 (96%)			43/50 (86%)	45/50 (90%)		
Overall Incidence	Total	96/100 (96%)	Mean 96%	SD 0%	Total	88/100 (88%)	Mean 88%	SD 2.83%	
#All Organs: Hemangioma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma								•••••	
		6/50 (12%)	5/50 (10%)			3/50 (6%)	6/50 (12%)		
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	9/100 (9%)	Mean 9%	SD 4.24%	
#All Organs: Hemangiosarcoma or He	emangioma								
		7/50 (14%)	5/50 (10%)		_	3/50 (6%)	6/50 (12%)		
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	9/100 (9%)	Mean 9%	SD 4.24%	

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

^{#:} Denominator is number of animals necropsied

#All Organs:

#All Organs:

#All Organs:

Overall Incidence

Overall Incidence

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Histiocytic Sarcoma

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Mesothelioma: Benign

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER Male **Female** 1/50 (2%)1/50 (2%)2/50 (4%)Mean 1% SD 1.41% Total 3/100 (3%) Mean 3% SD 1.41% Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)14/50 (28%)6/50 (12%) Mean 0% SD 0% Total 20/100 (20%) Mean 20% SD 11.31%

O/EO

(00/)

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O/EO

O/EO

(00/)

(00/)

SD 1.41%

Report Date: 11/11/2014

		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs:

Mesothelioma: Benign, Malignant, NOS

		1/30 (2%)	1/30 (2%)			0/30 (0%)	0/30 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs:

Mesothelioma: Malignant

		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs: Osteoma

		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (19/.)	Moon 19/

(00/)

(20/)

1 /EO

*: Denominator is number of animals with tissues examined microscopically

Total

Total

0/50

1/100 (1%)

0/50

0/100 (0%)

1/E0

(0%)

(0%)

(20/)

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/11/2014

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male			Female			
#All Organs: Osteosarcoma									
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%	
#All Organs: Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
*Adrenal Cortex: Adenoma									
		2/49 (4%)	2/50 (4%)			0/49 (0%)	0/49 (0%)		
Overall Incidence	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%	Total	0/98 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign						4/40 (00/)	0/50 (00/)		
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	
*Adrenal Medulla: Pheochromocytoma Maligna	ant								
_		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benig	n, Complex	x, Malignant, NOS 0/49 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	

^{*:} 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

Page: 116

Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male			Female			
#Blood Vessel: Hemangioma		0/50 (0%)	0/50 (05)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Bone Marrow: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
Bone Marrow: Hemangiosarcoma									
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	
Bone Marrow: Mast Cell Tumor Malignant		, ,	0/50 (0%)			` '	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
Bone Marrow: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
Bone: Fibroma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 117

			Male				Female			
#Bone: Hemangiosarcoma		0/50 (00/)	0/50 (00/)				0/50 (00)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Bone: Osteoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
#Bone: Osteosarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%		
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
#Bone: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Brain: Granular Cell Tumor Benign										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 118

			Male				Female			
*Brain: Meningioma Malignant	Total	0/50 (0%)	1/50 (2%)	CD 4 449/	Total	0/50 (0%)	0/49 (0%) Mean 0%	CD 00/		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)		SD 0%		
*Brain: Meningioma: Benign, Ma	lignant, NOS	-4								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%		
*Brain: Oligodendroglioma Malig		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Brain: Oligodendroglioma, Glio			0/50 (0%)			0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Hemangioma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 119

			Male				Female	
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		5/50 (10%)	6/50 (12%)	OD		2/50 (4%)	5/50 (10%)	00 10101
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	7/100 (7%)	Mean 7%	SD 4.24%
#Harderian Gland: Carcinoma								
		2/50 (4%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma or Adenoma		7/50 (149/)	6/50 /429/\			A/50 (89/\	5/50 (10%)	
Overall Incidence	Total	7/50 (14%) 13/100 (13%)	6/50 (12%) Mean 13%	SD 1.41%	Total	4/50 (8%) 9/100 (9%)	5/50 (10%) Mean 9%	SD 1.41%
Overall illiciation	ıvıaı	13/100 (13/6)	IVICALI 13/0	JD 1.41/0	ı ulaı	ا (۵/۵)	IVICALI 3/0	3D 1.4170

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 120

			Male			Female			
*Heart: Hemangiosarcoma									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Large: Cecum: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma or Adenoma						0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Large: Cecum: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Small: Duodenum: Adenoma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 121

			Male				Female	
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 122

			Male				Female	
#Intestine Small: Site Un	specified:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Una Carcinoma	specified:							
		2/50 (4%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Un Carcinoma or Adenom	•	- 1						
		2/50 (4%)	3/50 (6%)	00		0/50 (0%)	0/50 (0%)	25 20 /
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Una Leiomyosarcoma	specified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/49 (2%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/97 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 123

			Male			0/49 (0%) 0/50 (0%) ttal 0/99 (0%) Mean 0% SD 0% 0/49 (0%) 0/50 (0%) ttal 0/99 (0%) Mean 0% SD 0% ttal 0/49 (0%) 0/50 (0%) ttal 0/99 (0%) Mean 0% SD 0% 0/49 (0%) 0/50 (0%)			
*Islets, Pancreatic: Carcinoma or Adenoma			0.000 (0.000)			2/22 /227			
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	()	(/	SD 0%	
*Kidney: Pelvis and Transition	onal Epitheliu	ım:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%	
*Kidney: Pelvis and Transition Carcinoma or Adenoma		ım:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	, ,	` '	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma			2/50 /40/			0/40 /00/	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/49 (0%) 0/99 (0%)	0/50 (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

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Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
*Kidney: Renal Tubule: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/49 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/50 (00/)	0(50 (00))			0/40 (00/)	0/40 (00/)	
Overell Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/49 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Weari 0%	SD 0%	I Olai	0/98 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		5/50 (10%)	1/50 (2%)			2/49 (4%)	2/49 (4%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	4/98 (4.08%)	Mean 4.08%	SD 0%
*Liver: Hepatoblastoma								
		6/50 (12%)	4/50 (8%)			1/49 (2%)	0/49 (0%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 2.83%	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%
*Liver: Hepatocellular Adenoma								
-		33/50 (66%)	39/50 (78%)			38/49 (78%)	33/49 (67%)	
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	71/98 (72.45%)	Mean 72.45%	SD 7.22%

^{*:} 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: ORAL

Report Date: 11/11/2014

Page: 125

Species: MICE Strain: B6C3F1

Vehicle: WATER

			Male				Female	
*Liver: Hepatocellular Carcinor	ma							
		26/50 (52%)	12/50 (24%)			11/49 (22%)	9/49 (18%)	
Overall Incidence	Total	38/100 (38%)	Mean 38%	SD 19.8%	Total	20/98 (20.41%)	Mean 20.41%	SD 2.89%
*Liver: Hepatocellular Carcinor	na or Hepatobla	astoma						
-	-	26/50 (52%)	15/50 (30%)			12/49 (24%)	9/49 (18%)	
Overall Incidence	Total	41/100 (41%)	Mean 41%	SD 15.56%	Total	21/98 (21.43%)	Mean 21.43%	SD 4.33%
*Liver: Hepatocellular Carcinor	na or Hepatoce	ellular Adenoma 45/50 (90%)	42/50 (84%)			40/49 (82%)	36/49 (73%)	
Overall Incidence	Total	87/100 (87%)	Mean 87%	SD 4.24%	Total	76/98 (77.55%)	Mean 77.55%	SD 5.77%
*Liver:		ular Adenoma, or Hepatob 45/50 (90%) 87/100 (87%)		SD 4.24%	Total	40/49 (82%) 76/98 (77.55%)	36/49 (73%) Mean 77.55%	SD 5.77%
*Liver: Hepatocholangiocarcin		2/50 (4%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/98 (0%)	Mean 0%	SD 0%
			•••••					
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (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

Report Date: 11/11/2014

Page: 126

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male			Female		
*Liver: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Adend								
Overall Incidence	Total	6/50 (12%) 19/100 (19%)	13/50 (26%) Mean 19%	SD 9.9%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%
*Lung: Alveolar/Bronchiolar Carcir								
Overall Incidence	Total	9/50 (18%) 16/100 (16%)	7/50 (14%) Mean 16%	SD 2.83%	Total	7/50 (14%) 9/100 (9%)	2/50 (4%) Mean 9%	SD 7.07%
*Lung: Alveolar/Bronchiolar Carcir		/eolar/Bronchiolar Adenor 14/50 (28%)				11/50 (22%)	5/50 (10%)	
Overall Incidence	Total	33/100 (33%)	Mean 33%	SD 7.07%	Total	16/100 (16%)	Mean 16%	SD 8.49%
*Lung: Hemangiosarcoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 127

			Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant							0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%) 1/100 (1%) Mean 1% SD 1.41%	
_		0/50 (0%)	0/50 (0%)			` '	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			, ,	, ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenoma, Ca	rcinoma, oı							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER

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Length of Study: CHRONIC

Page: 128

			Male				Female	
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Mesentery: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Overall Incidence

Overall Incidence

Cystadenocarcinoma

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 129

Report Date: 11/11/2014

			Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Papilloma Squamous or Papilloma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary	ynx, Tooth, Gingiva):								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Oral Mucosa: Squamous Cell Carcin	oma	•••••								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Ovary: Choriocarcinoma										
						0/40 (00/)	0 (= 0 (0 0 ()			

Total

Total

0/49

0/49

0/99 (0%)

0/99 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0%

SD 0%

SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 130

Report Date: 11/11/2014

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Cystadenoma 3/49 (6%)1/50 (2%)**Overall Incidence** Total 4/99 (4.04%) Mean 4.06% SD 2.92% *Ovary: **Granulosa Cell Tumor Benign** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Hemangioma 0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/99 (0%) Mean 0% *Ovary: Hemangiosarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% *Ovary: Luteoma

0/49

0/99 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 131

			Male				Female	
*Ovary: Sarcoma						0/40 (00%)	0/50 (00/)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		•••••					•••••	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma								
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	4/50 (8%) 6/99 (6.06%)	2/49 (4%) Mean 6.04%	SD 2.77%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 132

			Male				Female	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		fied Site:						
		0/47 (0%)	0/50 (0%)			4/50 (8%)	2/49 (4%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	6/99 (6.06%)	Mean 6.04%	SD 2.77%
Pituitary Gland: Pars Inte	ermedia:							
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inte Carcinoma or Adenoma	ermedia:							
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma	1							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Mean 0%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Page: 133

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
*Salivary Glands: Myxoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma		0/50 (0%)	0/50 /02/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma		0/50 (09/)	0/50 (0%)			0/50 (09/)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

SD 0%

0/100 (0%)

Total

Mean 0%

SD 0%

Total

0/100 (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

Route: ORAL

Report Date: 11/11/2014

Page: 134

Species: MICE Strain: B6C3F1

Vehicle: WATER

			Male				Female	
#Skin:		- T / 1 1	201					
Basai Celi Carcinoma d	or Basosquamou	s Tumor (malignant or NC 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tum	or (benign, malignan	t or				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/100 (0%)		a, SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		oma, Myxosarcoma, or Fik	1/50 (2%)			2/50 (4%)	4/50 (8%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytoma				0/50 /40/	4/50 (00/)	
• " ' '	T	1/50 (2%)	1/50 (2%)	OD 00/	T	2/50 (4%)	4/50 (8%)	00.0004
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%

^{*:} 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

Page: 135

Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Fibrous Histiocytoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Granular Cell Tumor Benig								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma		1/50 (2%)	1/50 (2%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 136

		Male				Female		
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
	` ,				, ,			
	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)		
Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	
	0/50 (00)					0/50 (00)		
Total	` '	` '	SD 0%	Total	` '	` ,	SD 0%	
	Total	Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%)	0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%	O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% O/50 (0%) O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0% Total O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total O/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total O/50 (0%) Mean 0% SD 0% Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/50 (0%) O/50 (0%) SD 0% Total 1/50 (2%) Total O/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) Total O/100 (0%) Mean 0% SD 0% Total O/100 (0%) O/50 (0%) Mean 0% SD 0% Total O/100 (0%)	O/50 (0%) Mean 0% SD 0% Total O/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% Mean 1% Total O/100 (0%) 0/50 (0%) 0	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 137

			Male				Female					
#Skin: Neurofibroma or Schwannoma benign												
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma or \$	Schwannoma (m	alignant or NOS)										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%				
		0/50 (0%)	lignant or NOS) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%				
Overall Incidence	Total	0/100 (0%)	IVICALI U/0	30 070	i Otal	3/100 (3/0)	IVICALI 370	OD 4.2470				
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
#Skin: Osteosarcoma	Total		0/50 (0%) Mean 0%	SD 0%	Total			SD 0%				
#Skin:	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%					
#Skin: Osteosarcoma Overall Incidence #Skin: Sarcoma	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%)					
#Skin: Osteosarcoma Overall Incidence #Skin: Sarcoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% 1/50 (2%)	SD 0%				
#Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 1/50 (2%)	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

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Report Date: 11/11/2014

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Schwannoma Malignar	nt							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Squamous Cell Carcin or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	0/100 (0%)	iviean 0%		10tai			
#Skin: Squamous Cell Papillo	oma or Papilloma		0.750 (001)			2/22 (221)	2/52 (224)	
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma, S	equamous Cell Carcinoma		a				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma, o		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	, ,	` ,	SD 0%	Total	, ,	, ,	SD 0%
Squamous Cell Papillo Overall Incidence	Total	0/100 (0%) or Keratoacanthoma 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% SD 0%	Total Total	0/100 (0%) 0/50 (0%) 0/100 (0%)		Mean 0% 0/50 (0%) Mean 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 139

			Male				Female				
#Spinal Cord: Hemangiosarcoma											
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
Spleen: Hemangiosarcoma											
		1/46 (2%)	2/50 (4%)			1/46 (2%)	0/49 (0%)				
Overall Incidence	Total	3/96 (3.12%)	Mean 3.09%	SD 1.29%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%			
*Spleen: Mast Cell Tumor Malignant		0/46 (0%)	0/50 (0%)			0/46 (0%)	0/49 (0%)				
Overall Incidence	Total	0/46 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/46 (0%)	0/49 (0%) Mean 0%	SD 0%			
		, ,									
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Carcinoma o		a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Stomach, Forestomach: Squamous Cell Papilloma		(65)	(0.5)			(00)					
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	1/50 (2%)	05 / ////			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 140

			Male				Female			
#Stomach, Glandular: Adenoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00)	0/50 (00/)			0/50 (001)	0/50 (00)			
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/		
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Testes: Adenoma		0/50 (001)	(00)							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%						
*Testes: Hemangioma										
		0/50 (0%)	0/50 (0%)							
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%						
*Thymus: Neoplasm NOS		0/44 (00/)	0/45 (00/)			0/45 (00/)	0/50 (00)			
Overell Incidence	Total	0/41 (0%)	0/45 (0%)	CD 00/	Total	0/45 (0%)	0/50 (0%)	CD 00/		
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/95 (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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 141

			Male				Female		
*Thymus: Thymoma Benign									
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thymus: Thymoma Malignant									
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/41 (0%)	0/45 (0%)			0/45 (0%)	0/50 (0%)		
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma						0/40 (00/)	0/40 (00/)		
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma		•••••							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/40 (00/)	0/50 (0%)			0/40 (00/)	0/40 (09/)		
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell Adenoma	:							
		1/49 (2%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		1/49 (2%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/97 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma c		na Squamous						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date: 11/11/2014
RAL

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			Male				Female		
#Tooth: Odontoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Urethra: Hemangiosarcoma									
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma		-4							
	-	0/45 (0%)	0/50 (0%)	OD 00/	-	0/44 (0%)	0/50 (0%)	00.00/	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma						1/50 (2%)	0/50 (0%)		
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Uterus: Carcinoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangioma									
• " ' '					-	0/50 (0%)	0/50 (0%)	OD 00/	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Hemangiosarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 2/50 (4%)4/50 (8%) **Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% **#Uterus:** Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% **#Uterus:** Sarcoma Stromal or Polyp Stromal 2/50 (4%)4/50 (8%)**Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 145

			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied