

NTP Historical Controls Report

By Route and Vehicle

MICE

2006

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.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
M3
M4
M5
Female
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.

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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: GAVAGE Vehicle: CORN OIL Page: 4

Report Date: 06/03/2022

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		
Southern Research Institute	059302307	07/25/97	729	50(1)	44(721)	57.3	2,4-Hexadienal
					Female		
Southern Research Institute	059302307	07/25/97	732	50(5)	42(717)	64.2	2,4-Hexadienal

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: GAVAGE Vehicle: CORN OIL Page: 5

			Male			Female				
#All Organs: Benign Tumors										
		37/50 (74%)				27/50 (54%)				
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	27/50 (54%)	Mean 54%	SD 0%		
#All Organs: Malignant Tumors										
		23/50 (46%)				17/50 (34%)				
Overall Incidence	Total	23/50 (46%)	Mean 46%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%		
#All Organs: Malignant and Benign T										
		45/50 (90%)				39/50 (78%)				
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%		
#All Organs: Hemangioma		1/50 (2%)								
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma	•••••									
		4/50 (8%)				1/50 (2%)				
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs: Hemangiosarcoma or He	emangioma									
		5/50 (10%)				1/50 (2%)				
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

				Male			Female			
#All Organs: Histiocytic Sarcoma	T	0/50	(0%)		OD 004		1/50 (2%)	M 00/	0D 0V	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Malignant Lymphoma: Histi	ocytic, Lymp			Undifferentiated Ce	ell Type					
	-		(4%)	14	OD 00/	T	4/50 (8%)	14 00/	05.00/	
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	
#All Organs: Mesothelioma: Benign, Mali	gnant, NOS	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Malignant		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteoma										
		0/50	(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Osteosarcoma		4/50	(00/)				0/50 /00/			
Overell Incidence	Total	1/50	(2%)	Maan 20/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male			Female				
#All Organs: Osteosarcoma or Osteoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	%) Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Cortex: Adenoma										
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	%) Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Carcinoma		0/50 /05	20			0/50 (00/)				
Overall Incidence	Total	0/50 (09 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Sarcoma		0/50 (09	%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Benigr										
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	%) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Malign	ant	0/40 /00	27.)			0/50 (0%)				
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	%) Mean 0%	SD 0%	Total	0/50 (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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

				Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%) 1/50 (2%) Overall Incidence Total 0/49 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0%												
Overall Incidence	Total	0/49 (0%)	` ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Bone Marrow: Hemangiosarcoma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Bone Marrow: Mast Cell Tumor Malignant		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(-,-)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chondroma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chondrosarcoma or Chondr	roma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Bone: Fibrosarcoma		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(3,0)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page**: 9

				Male			Female			
#Bone: Osteoma										
Overall Institutes	Tatal	0/50	(0%)	Mana 00/	CD 00/	Tatal	1/50 (2%)	Maan 20/	CD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Bone: Osteosarcoma										
		1/50	(2%)	••	05 00/		0/50 (0%)	••	05.00/	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma										
		1/50	(2%)	••	05 00/		1/50 (2%)	••	05.00/	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Bone: Sarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Malignant		0/50	(00()				(00)			
	-	0/50	(0%)		OD 00/	-	0/50 (0%)	NA 00/	00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Maligr	nant, NOS									
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male			Female			
*Brain: Oligodendroglioma Beniç	gn	-1							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma Malig	ınant				•••••				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glior	ma, or Astrocy	toma 0/50 (0%	.)			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Sarcoma	Total	0/50 (0% 0/50 (0%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall incidence		` '				0/50 (0%)		3D 0%	
*Clitoral/Preputial Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%				0/47 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Page: 11

Report Date: 06/03/2022

Contract/Lab: All Laboratories

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

Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
		0/30 (0/6)				0/47 (078)		3D 070		
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)				0/47 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Squamous Cell Carcinoma										
		0/50 (0%)		25. 22/		0/47 (0%)		00.00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%		
#Coagulating Gland: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Ear: Neural Crest Tumor, Maligna										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Epididymis: Hemangiosarcoma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 12

			Male				Female	
*Epididymis: Sarcoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/40 (00/)				0/44 (00)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%
		0/40 (0/0)						
*Gallbladder: Sarcoma		0/48 (0%)				0/44 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		7/50 (14%)				7/50 (14%)		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
#Harderian Gland: Carcinoma								
O	T-1-1	2/50 (4%)	Marana 407	OD 00/	Taral	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female			
#Harderian Gland: Carcinoma or Adenoma										
Overall Incidence	Total	9/50 (18%) 9/50 (18%)	Mean 18%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%		
*Heart: Hemangiosarcoma		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Heart: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma Malignant		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

				Male				Female	
#Intestine Large: Cecum: Leiomyoma									
•		0/50 (0	%)			0/50	(0%)		
Overall Incidence	Total	0/50 (0%)	Mean		O% Tota		(0%) Me	an 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma									
		0/50 (0	%)			0/50	(0%)		
Overall Incidence	Total	0/50 (0%)	Mean	0% SD	O% Tota	al 0/50	(0%) Me	an 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous						- 1			
		,	%)			0/50	` '		
Overall Incidence	Total	0/50 (0%)	Mean			al 0/50	(0%) Me	an 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyoma	m:								
		0/50 (0	%)			0/50	(0%)		
Overall Incidence	Total	0/50 (0%)	Mean		O% Tota		` '	an 0%	SD 0%
#Intestine Small: Duodenum: Adenoma									
		0/50 (0	%)			0/50	(0%)		
Overall Incidence	Total	0/50 (0%)	Mean	0% SD	0% Tota	al 0/50	(0%) Me	an 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma									
		,	%)			0/50	(0%)		
Overall Incidence	Total	0/50 (0%)	Mean	0% SD	0% Tota	al 0/50	(0%) Me	an 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: GAVAGE Vehicle: CORN OIL **Page:** 15

				Male			Female			
#Intestine Small: Duodenum: Hemangioma										
-		`	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Hemangiosarcoma										
		•	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50	00()				4/50 /00/			
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
		, ,								
#Intestine Small: Ileum: Carcinoma		- 1								
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		` ,					0/50 (0%)		3D 0%	
#Intestine Small: Jejunum: Adenoma										
		•	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma										
		`	2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male				Female	
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%	s)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:							
		0/50 (0%	5)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	cified:							
		1/50 (2%	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:							
		1/50 (2%	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Hemangioma								
_		0/50 (0%	o)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Hemangiosarcoma	cified:							
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Page: 17

Report Date: 06/03/2022

SD 0%

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: **Polyp Adenomatous** 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% *Islets, Pancreatic: Adenoma 2/50 (4%)1/47 (2%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 1/47 (2.13%) Mean 2.13% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%)0/47 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/47 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 2/50 (4%)1/47 (2%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 1/47 (2.13%) Mean 2.13% SD 0% *Kidney: Renal Tubule: Adenoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma

SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

Total

0/50

0/50 (0%)

(0%)

Mean 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: GAVAGE Vehicle: CORN OIL **Page:** 18

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,						
*Liver: Hemangioma		2(72 (224)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incluence		` '				` '		3D 0%
*Liver: Hemangiosarcoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma								
		2/50 (4%)		05 00/		0/50 (0%)		05.00/
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

2000

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female				
*Liver: Hepatocellular Adenoma											
•		23/50 (46%)				11/50 (22%)					
Overall Incidence	Total	23/50 (46%)	Mean 46%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%			
*Liver: Hepatocellular Carcinoma											
		8/50 (16%)				3/50 (6%)					
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%			
*Liver: Hepatocellular Carcinoma o	r Hepatobla	astoma 10/50 (20%)				3/50 (6%)					
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%			
*Liver: Hepatocellular Carcinoma o						13/50 (26%)					
Overall Incidence	Total	31/50 (62%)	Mean 62%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%			
*Liver: Hepatocellular Carcinoma, I						13/50 (26%)					
Overall Incidence	Total	31/50 (62%)	Mean 62%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%			
*Liver: Hepatocholangiocarcinoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female				
*Liver: Ito Cell Tumor Malignant											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Sarcoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Adenoma						0/40 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
		, ,									
*Lung: Alveolar/Bronchiolar Ad	enoma										
Overall Incidence	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca											
		9/50 (18%)				0/49 (0%)					
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca	rcinoma or Alve	eolar/Bronchiolar Adenor 19/50 (38%)				2/49 (4%)					
Overall Incidence	Total	19/50 (38%)	Mean 38%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	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: GAVAGE Vehicle: CORN OIL Page: 21 Report Date: 06/03/2022

		Male			Female			
	0/50 (0%)				0/49 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
					0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	Total Total Total	Total 0/50 (0%) Total 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0%	O/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 7 Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) 0/49 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/49 (2%) 1/49 (2.04%) Total 0/50 (0%) Mean 0% SD 0% Total 1/49 (2.04%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 1/49 (2%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 1/49 (2.04%) Mean 2.04% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 22

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma		0/50 (09/)				1/50 /29/\		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Page: 23

			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
		, ,						
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma	0/50 (09/)				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mesentery: Fibrosarcoma						(201)		
• " ' '	-	1/50 (2%)		OD 00/	-	0/50 (0%)	14 00/	00.00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24 Report Date: 06/03/2022

			Male				Female			
#Mesentery: Fibrous Histiocytoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: Hemangioma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		` '				` '				
#Mesentery: Leiomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mesentery: Sarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Nose: Carcinoma										
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05 00/		0/50 (0%)	••	00.007		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Report Date: 06/03/2022

Page: 25

Species: MICE Strain: B6C3F1/N Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female			
*Nose: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Nose: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Papilloma Squamous o		ynx, Tooth, Gingiva): 0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Squamous Cell Carcine	sa, Tongue, Phary	ynx, Tooth, Gingiva):								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary					0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Mucosa: Squamous Cell Carcin						0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 26

			Male	Female				
#Oral Mucosa: Squamous Cell Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
						1/49 (2%)		
Overall Incidence					Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Ovary: Granulosa Cell Tumor Bel	nign					0/40 (00/)		
Overall Incidence					Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
·····							······	
*Ovary: Granulosa Cell Tumor: Be	nign, Maligna	ant, NOS						
One will be add a second					Tatal	0/49 (0%)	M 00/	OD 00/
Overall Incidence					Total	0/49 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma								
· ·						0/49 (0%)		
Overall Incidence					Total	0/49 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma								
						0/49 (0%)		
Overall Incidence					Total	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

Page: 27

Report Date: 06/03/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** *Ovary: Luteoma 1/49 (2%)**Overall Incidence** Total 1/49 (2.04%) Mean 2.04% SD 0% *Ovary: Teratoma Benign 0/49 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% *Ovary: Thecoma Benign 0/49 (0%)Overall Incidence Total 0/49 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 0/49 (0%)**Overall Incidence** SD 0% Total 0/49 (0%) Mean 0% *Pancreas: Hemangioma 0/50 (0%)0/47 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/47 (0%) Mean 0% SD 0% *Pancreas: Sarcoma

SD 0%

0/47

0/47 (0%)

Total

(0%)

Mean 0%

SD 0%

Total

0/50

0/50 (0%)

(0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Report Date: 06/03/2022

Page: 28

			Male				Female	
*Pituitary Gland: Pars Dista Adenoma	llis or Unspecif	fied Site:						
		0/48 (0%)				2/46 (4%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	2/46 (4.35%)	Mean 4.35%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma								
Gai Girioinia		0/48 (0%)				0/46 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma								
		0/48 (0%)				2/46 (4%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	2/46 (4.35%)	Mean 4.35%	SD 0%
*Pituitary Gland: Pars Inter								
		0/48 (0%)				2/46 (4%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	2/46 (4.35%)	Mean 4.35%	SD 0%
*Pituitary Gland: Pars Interi Carcinoma or Adenoma								
		0/48 (0%)				2/46 (4%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	2/46 (4.35%)	Mean 4.35%	SD 0%
*Prostate: Adenoma		0/49 (0%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%				
Overall illulation	I Ulai	U/49 (U70)	IVICALI U70	3D 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: GAVAGE Vehicle: CORN OIL Page: 29

				Male				Female	
*Prostate: Carcinoma or Adenoma									
Overall Incidence	Total	0/49 0/49 (0%)	(0%)	Mean 0%	SD 0%				
		0, 10 (0,0)							
*Prostate: Hemangiosarcoma									
			(0%)						
Overall Incidence	Total	0/49 (0%)		Mean 0%	SD 0%				
*Salivary Glands: Carcinoma		0/50	(00()				0/40 /00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma							0/40 (09/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma									
			(0%)						
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%				
#Seminal Vesicle: Carcinoma		0/50	(00()						
Overall Incidence	Total	0/50 0/50 (0%)	(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: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male	Female				
#Skeletal Muscle: Hemangioma		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 31

	Male						Female				
#Skin:	_										
Basal Cell Adenoma or	r Basosquamous	•	(00()				0/50 (00/)				
		0/50	(0%)		OD 00/	.	0/50 (0%)		00.00/		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin:											
Basal Cell Adenoma, B	Basosquamous Tu	ımor Benign, o	r Trichoepith	nelioma							
·	•	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
									•••••		
#Skin:											
Basal Cell Carcinoma		0/50	(00()				0/50 (00/)				
Overell Institutes	Tatal	0/50	(0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin:											
Basal Cell Carcinoma	or Basosquamous	s Tumor (maliq	nant or NOS)							
				,			0.1=0 (00.1)				
Basar Gen Garenionia (ouoooquuou.	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total		` '	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
	-	0/50	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
	-	0/50	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
Overall Incidence #Skin: Basal Cell Carcinoma,	Total Basal Cell Adeno	0/50 0/50 (0%)				Total	` '	Mean 0%	SD 0%		
Overall Incidence #Skin:	Total Basal Cell Adeno	0/50 0/50 (0%) oma, Basosquai	mous Tumor			Total	0/50 (0%)	Mean 0%	SD 0%	•••••	
Overall Incidence #Skin: Basal Cell Carcinoma,	Total Basal Cell Adeno	0/50 0/50 (0%)	mous Tumor			Total Total	` '	Mean 0% Mean 0%	SD 0% SD 0%		
Overall Incidence #Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence	Total Basal Cell Adeno ioma	0/50 0/50 (0%) oma, Basosquar 0/50	mous Tumor	(benign, maligna	ant or SD 0%		0/50 (0%)				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total Basal Cell Adeno ioma Total noma, Carcinoma	0/50 0/50 (0%) oma, Basosquar 0/50 0/50 (0%)	(0%) or (M or B), I	Mean 0%	ant or SD 0%		0/50 (0%)				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence	Total Basal Cell Adeno ioma Total noma, Carcinoma	0/50 0/50 (0%) oma, Basosquar 0/50 0/50 (0%)	(0%) or (M or B), I	Mean 0%	ant or SD 0%		0/50 (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: GAVAGE Vehicle: CORN OIL **Page:** 32

			Male				Female	
#Skin: Fibroma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma,								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall illelidelide	ı olal	1/30 (2/0)	IVICALI Z/0	JD 070	ı Olai	0/30 (0/0)	IVICALI U70	30 070

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 33

			Male	Female				
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Keratoacanthoma				•••••				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignar								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Route: GAVAGE

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: CORN OIL

Length of	Study: CHRONIC	

			Male				Female					
#Skin: Myxosarcoma 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Neural Crest Tumor		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma or						1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#Skin: Neurofibrosarcoma, Ne		Schwannoma (benign, ma 0/50 (0%) 0/50 (0%)		SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35

			Male				Female	
#Skin: Schwannoma Malignant		,						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma Overall Incidence	Basal Cell C	0/50 (0%)	nous Tumor (malignar Mean 0%	nt or NOS),	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma o		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, I	Papilloma, S	quamous Cell Carcino 2/50 (4%)	ma or Keratoacanthoi	ma		0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	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 SystemTumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Species: MICE Strain: B6C3F1/N

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female					
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 2/50 (4%) 0/50 (0%)												
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Spleen: Hemangioma		0/49 (0%)				0/48 (0%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%				
*Spleen: Hemangiosarcoma												
Overall Incidence	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%				
*Spleen: Mast Cell Tumor Malignar	nt	0/49 (0%)				0/48 (0%)						
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (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: GAVAGE Vehicle: CORN OIL Report Date: 06/03/2022

Page: 37

			Male		0/50 (0%) 0% Total 0/50 (0%) Mean 0% SD 0 2/50 (4%) 0% Total 2/50 (4%) Mean 4% SD 0				
#Stomach, Forestomach: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total		Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinom	a	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papilloma	a Squamous 2/50 (4%)				2/50 (4%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma Overall Incidence		2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	` '	Mean 4%	SD 0%	
#Stomach, Glandular: Adenoma		0/50 (0%)				0/50 (0%)			
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence	TOtal	0/00 (0/0)							
Overall Incidence #Stomach, Glandular: Carcinoma	Total	0/50 (0%)				0/50 (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

#: Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 38

				Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		1/50	(20/)						
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%				
*Testes: Hemangioma		0/50	(0%)						
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%				
*Testes: Hemangiosarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign, N	lalignant, NOS		(00()						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Maligna	ant	0/50	(00/)						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%				

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: GAVAGE Vehicle: CORN OIL **Page:** 39

			Male				Female	
*Thymus: Hemangioma		0/44 (00/)				0/44 (00/)		
Overall Incidence	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/44 (0%)				0/44 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/44 (0%)				0/44 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligi		0/44 (0%)				0/44 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/44 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (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: GAVAGE Vehicle: CORN OIL Page: 40

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50	(00()				0/40 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		0/50	(0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma			(2%)				1/49 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%
#Tissue NOS: Sarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(= /0)	Mean 0%	SD 0%	Total	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

Route: GAVAGE

Vehicle: CORN OIL

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

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			Male				Female						
#Tongue: Squamous Cell Carcinoma 0/50 (0%) 0/50 (0%)													
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
						0/00 (0/0)	······						
#Tongue: Squamous Cell Carcinoma	or Papillom	•				-4							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Tooth: Odontoma	•••••	0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Tooth: Sarcoma	•••••	2/22 (221)				(20)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%					
*Urinary Bladder: Carcinoma or Papilloma													
		0/50 (0%)	••	05.00		0/48 (0%)		00.00					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (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: GAVAGE Vehicle: CORN OIL Page: 42

			Male				Female	
*Urinary Bladder: Hemangioma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 43

	Male			Female	
#Uterus: Deciduoma Benign		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0/50 (0%) Total 0/50 (0%) Mean 0% SD			
Overall Incidence		Total	` '	Mean 0%	SD 0%
#Uterus: Hemangioma					
Overall Incidence		Total		Mean 0%	SD 0%
#Uterus: Hemangiosarcoma			0/50 (00/)		
Overall Incidence			, ,	Mean 0%	SD 0%
#Uterus: Leiomyoma			0/50 (00)		
Overall Incidence			0/50 (0%)		SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence			0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	0/50 (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 SystemTumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL Page: 44

			Male				Female	
#Uterus: Sarcoma						4/50 (00/)		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Sarcoma Stromal						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp \$	Stromal					0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Schwannoma Malignant						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 45

			Male		70/50 (0%) 0% Total 0/50 (0%) Mean 0% SD 0			
#Zymbal's Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date: 06/03/2022

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		
Southern Research Institute	059100508	07/10/00	729	50(1)	35(693)	53.6	Methylene blue trihydrate
					Female		
Southern Research Institute	059100508	07/10/00	732	50(5)	29(695)	63.5	Methylene blue trihydrate

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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female		
#All Organs: Benign Tumors									
•		37/50 (74%)				25/50 (50%)			
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	25/50 (50%)	Mean 50%	SD 0%	
#All Organs: Malignant Tumors									
		26/50 (52%)				26/50 (52%)			
Overall Incidence	Total	26/50 (52%)	Mean 52%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%	
#All Organs: Malignant and Benign Tu	umors	46/50 (92%)				39/50 (78%)			
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Hemangiosarcoma									
		6/50 (12%)				3/50 (6%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	6/50 (12%)				4/50 (8%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	4/50 (8%)	Mean 8%	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: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male		6/50 (12%) 0% Total 6/50 (12%) Mean 12% SD 0% 0/50 (0%) 0% Total 0/50 (0%) Mean 0% SD 0%			
#All Organs: Histiocytic Sarcoma									
•		0/50	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%		, ,		SD 0%
#All Organs: Malignant Lymphoma: His	tiocvtic. Lvm								
			(4%)		71.		6/50 (12%)		
Overall Incidence	Total	2/50 (4%)	()	Mean 4%	SD 0%	Total	` ,	Mean 12%	SD 0%
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS		(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant							0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#All Organs: Osteoma					•••••				
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50	(004)				(00)		
			(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Adenoma								
		5/48 (10%)				0/50 (0%)		
Overall Incidence	Total	5/48 (10.42%)	Mean 10.42%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma								
		0/48 (0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma						0/50 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
		0/48 (0%)				1/50 (2%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maligna	ant	- (S-1)				(20)		
		0/48 (0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male				Female			
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/48 (0%) 1/50 (2%) Overall Incidence Total 0/48 (0%) Noan 0% SD 0% Total 1/50 (2%) Noan 2% SD 0%											
Overall Incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Bone Marrow: Hemangiosarcoma			(201)				(704)				
Overall Incidence	Total	1/50 (1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Bone Marrow: Mast Cell Tumor Malignan	t	0/50 ((0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Chondroma			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Bone: Chondrosarcoma or Chon											
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Bone: Fibrosarcoma		0/50 ((0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(U /0)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
					10tai	0/30 (0 /6)		
#Bone: Osteosarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Bone: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maligr	nant, NOS							
O	T-1-1	0/50 (0%)	M 00/	OD 00/	Tatal	0/50 (0%)	Marana 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Brain: Oligodendroglioma Beni	i gn Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mali						2.00 (0.0)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glic						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (00)				0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (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

Page: 53 Tumor Incidence for Selected Control Animal Groups Report Date: 06/03/2022

Route: GAVAGE Vehicle: METHYLCELLULOSE

			Male				Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (0%)				0/48 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)				0/48 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)				0/48 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
#Coagulating Gland: Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Ear: Neural Crest Tumor, Malign	ant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Epididymis: Hemangiosarcoma		0/50 (0%)								
Overall Incidence	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Epididymis: Sarcoma		2(20)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma								
Overall Incidence	Total	0/40 (0%) 0/40 (0%)	Mean 0%	SD 0%	Total	0/42 (0%) 0/42 (0%)	Mean 0%	SD 0%
*Gallbladder: Sarcoma		0/40 (0%)				0/42 (0%)		
Overall Incidence	Total	0/40 (0%)	Mean 0%	SD 0%	Total	0/42 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%
#Harderian Gland: Carcinoma		0(50 (00))				0/50 (00/)		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (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/N

#Harderian Gland:

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Carcinoma

Overall Incidence

Overall Incidence

#Intestine Large: Cecum: Carcinoma or Adenoma

......

Schwannoma Malignant

#Intestine Large: Cecum:

*Heart:

*Heart: Sarcoma

*Heart:

Hemangiosarcoma

Length of Study: CHRONIC

Carcinoma or Adenoma

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Male **Female** 4/50 (8%) Mean 22% SD 0% Total 4/50 (8%) Mean 8% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) 0/50 (0%)Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

Page: 55

Report Date: 06/03/2022

SD 0%

Total

Total

Total

Total

Total

Total

11/50

11/50 (22%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

1/50

1/50 (2%)

1/50

1/50 (2%)

(22%)

(0%)

(0%)

(0%)

(2%)

(2%)

Mean 2%

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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female			
Total		(0%)	Moan 0%	SD 0%	Total	0/50 (0%)	Moon 0%	SD 0%	
	` '				10tai	0/30 (0 /0)	ivicali 070		
		(0%)				` ,			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
tum:		(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
:									
	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
:	0/50	(00/)				1/50 (39/)			
Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
	Total tum: Total :	Total 0/50 (0%) 0/50 Total 0/50 (0%) 0/50 Total 0/50 (0%) tum: 0/50 Total 0/50 (0%) : 0/50 Total 0/50 (0%) :	Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) tum: 0/50 (0%) Total 0/50 (0%) : 0/50 (0%) : 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% tum: 0/50 (0%) Total 0/50 (0%) Mean 0% : 0/50 (0%) Total 0/50 (0%) Mean 0% : 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	O/50 (0%) Total O/50 (0%) Mean 0% SD 0% O/50 (0%) Total O/50 (0%) Mean 0% SD 0% O/50 (0%) Total O/50 (0%) Mean 0% SD 0% SD 0% Total O/50 (0%) Total O/50 (0%) Total O/50 (0%) Total O/50 (0%) Mean 0% SD 0% SD 0% SD 0% Hum: O/50 (0%) Total O/50 (0%) Mean 0% SD 0% SD 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 1.	Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% turn: 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% : 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Small: Duodenum: Hemangioma		0/50 /00/				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Hemangiosarcoma		2/22 (22)				(00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male				Female	
#Intestine Small: Jejunum: Polyp Adenomatous									
		0/50 (0	%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mea	ո 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Adenoma	cified:								
		1/50 (2	! %)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mea	າ 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:	/-							
		,	l%)		OD		1/50 (2%)		25. 20/
Overall Incidence	Total	0/50 (0%)		า 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unspectarcinoma or Adenoma	cified:								
		,	!%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		า 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unspe Hemangioma									
•		0/50 (0	1%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mea	ո 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsper Hemangiosarcoma	cified:								
		,	1%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mea	า 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Small: Site Unspec Polyp Adenomatous	cified:							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2%) 1/46 (2.17%)	Mean 2.17%	SD 0%
*Islets, Pancreatic: Carcinoma		0/50 (00/)				0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)				1/46 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%
*Kidney: Renal Tubule: Adenoma		0/40 /00/				0(40 (004)		
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%) 0/48 (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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma										
		1/49 (2%)				0/48 (0%)				
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Hemangiosarcoma										
		0/49 (0%)				0/48 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
*Liver: Cholangiocarcinoma		0/50 (00)				0/50 (00/)				
	-	0/50 (0%)	14 00/	00.00/	+	0/50 (0%)		OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hemangiosarcoma										
		2/50 (4%)				0/50 (0%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hepatoblastoma		2/50 (4%)				0/50 (0%)				
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Moon 0%	SD 0%		
Overall incluence	Total					0/50 (0%)	Mean 0%	3D 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management SystemTumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N Length of Study: CHRONIC Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Liver: Hepatocellular Adenoma								
		28/50 (56%)				15/50 (30%)		
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	15/50 (30%)	Mean 30%	SD 0%
*Liver: Hepatocellular Carcinoma								
		13/50 (26%)				5/50 (10%)		
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobla	astoma 15/50 (30%)				5/50 (10%)		
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Liver: Hepatocellular Carcinoma Overall Incidence			Mean 74%	SD 0%	Total	19/50 (38%) 19/50 (38%)	Mean 38%	SD 0%
*Liver: Hepatocellular Carcinoma,		ılar Adenoma, or Hepatob 38/50 (76%)				19/50 (38%)		
Overall Incidence	Total	38/50 (76%)	Mean 76%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
*Liver: Hepatocholangiocarcinom						0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Moon 00/	SD 0%
	Total	0/50 (0%)				0/50 (0%)	Mean 0%	

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female			
*Liver: Ito Cell Tumor Malignant									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Adenoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		• •			·····				
*Lung: Alveolar/Bronchiolar Ade	noma								
		11/50 (22%)		05.00/		1/50 (2%)		00.00	
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Lung: Alveolar/Bronchiolar Card	cinoma								
		1/50 (2%)				5/50 (10%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
*Lung: Alveolar/Bronchiolar Card	cinoma or Alv		na						
		12/50 (24%)				6/50 (12%)			
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%)	Mean 12%	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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male	•		Female			
*Lung: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node: Hemangiosarcoma		0/50 /00				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node: Sarcoma		0/50 (0%				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Bronchial: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%	6)			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Report Date: 06/03/2022

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				Male			Female			
#Lymph Node, Mediastinal: Hemangiosarcoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Fibrous Histiocytoma		2/72	(20()				(00)			
	.	0/50	(0%)		OD 00/	-	0/50 (0%)	14 00/	00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangioma		2/72	(22()				2(72)			
	.	0/50	(0%)		OD 00/	-	0/50 (0%)	14 00/	00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma		2/72	(22()				2(72)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Moon 09/	SD 0%	
	10tai	0/50 (0%)		iviean 0%	3D 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignan	t									
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Sarcoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (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: 06/03/2022

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female			
#Mammary Gland: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Carcinoma		0/50 (0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Mammary Gland: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Mammary Gland: Fibroma, Fibroadenoma o						0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Fibroma, Fibroadenoma, (Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Mesentery: Fibrosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female			
#Mesentery: Fibrous Histiocytoma	Total	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	M 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Leiomyosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Nose: Carcinoma		0/50 (0%)				0/50 (09/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female					
*Nose: Hemangioma												
·		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Nose: Sarcoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucosa Papilloma Squamous or		nx, Tooth, Gingiva): 0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucosa Squamous Cell Carcinol	, Tongue, Phary											
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	, Tongue, Phary	nx, Tooth, Gingiva):				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%)				0/50 (09/)						
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/				
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)		OD 00/		0/50 (0%)		OD 004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	2/47 (4%) 2/47 (4.26%)	Mean 4.26%	SD 0%
*Ovary: Granulosa Cell Tumor Beni	gn				•••••	0/47 (00/)		
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
'Ovary: Granulosa Cell Tumor: Ben		ant, NOS			•••••			
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
Ovary: Hemangioma								
_						0/47 (0%)		
Overall Incidence					Total	0/47 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma								
Overall Incidence					Total	1/47 (2%) 1/47 (2.13%)	Mean 2.13%	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: GAVAGE
Vehicle: METHYLCELLULOSE

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			Male				Female	
*Ovary: Luteoma								
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Benign						0/47 (00/)		
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma						0/47 (0%)		
Overall Incidence					Total	0/47 (0%)	Mean 0%	SD 0%
*Pancreas: Hemangioma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%
*Pancreas: Sarcoma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma												
		0/50 (0%)				1/46 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%				
*Pituitary Gland: Pars Dis Carcinoma	talis or Unspecit	fied Site:										
		0/50 (0%)				0/46 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%				
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspecit			•••••		•••••						
		0/50 (0%)				1/46 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%				
*Pituitary Gland: Pars Inte Adenoma												
		0/50 (0%)				1/46 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%				
*Pituitary Gland: Pars Inte Carcinoma or Adenoma	rmedia:											
		0/50 (0%)				1/46 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%				
*Prostate: Adenoma		0/40 (00/)										
O	Total	0/49 (0%)	M 00/	OD 00/								
Overall Incidence	Total	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/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male **Female** *Prostate: Carcinoma or Adenoma 0/49 (0%)0/49 (0%) SD 0% **Overall Incidence** Total Mean 0% *Prostate: Hemangiosarcoma 0/49 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% 0/50 (0%) **#Seminal Vesicle:** Adenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Carcinoma 0/50 (0%)**Overall Incidence** Total 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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skeletal Muscle: Hemangioma		0(50 (00())				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

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Report Date: 06/03/2022

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benign						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, B	asosquamous Tu	ımor Benign, or Trichoe	pithelioma					
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:			• • • • • • • • • • • • • • • • • • • •			•••••		
Basal Cell Carcinoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:		s Tumor (malignant or N						
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:				• • • • • • • • • • • • • • • • • • • •				
Basal Cell Carcinoma, NOS), or Trichoepitheli		ma, Basosquamous Tu	mor (benign, maligna	ant or				
,,		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
	noma, Carcinoma	ı, Basosq. Tumor (M or atoacanthoma, Trichoe	B), Basal Cell Adeno			1/50 (2%)		
Overell Incidence	Total	` '	Maan 00/	CD 00/	Total	` '	Maan 20/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 3/50 (6%) Total 3/50 (6%) Mean 6% SD 0% 3/50 (6%) Mean 6% SD 0% 3/50 (6%) Total 3/50 (6%) Mean 6% SD 0%			
#Skin: Fibroma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Skin:								
Fibroma, Fibrosarcoma,	Sarcoma, Myxo	oma, Myxosarcoma, or 1/50 (2%)	Fibrous Histiocytoma			3/50 (6%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	` '	Mean 6%	SD 0%
#Skin: Fibrosarcoma		2/22 (22)				(00)		
	.	0/50 (0%)		OD 00/	T	` '		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	I otal	3/50 (6%)	Mean 6%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma	, or Fibrous Histiocytor	na					
,		1/50 (2%)				3/50 (6%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Skin: Fibrous Histiocytoma		•••••						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		0/50 (00/)				4/50 (00()		
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	1/50 (2%)	Maan 20/	CD 00/
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male					
#Skin: Hemangiosarcoma		4/50 (00/)				4/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)		
#Skin: Keratoacanthoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	(,	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		` '				` '		35 0%
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0%		
#Skin: Myxosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or \$	Schwannoma (m	nalignant or NOS) 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne	urofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	alignant or NOS)			` '		
Occasional International	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (00/)	Moon Oo/	OD 00/
Overall Incidence		` '				(,		SD 0%
#Skin: Osteosarcoma								SD 0%
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)		
#Skin:	Total					······································		SD 0%
#Skin: Osteosarcoma		0/50 (0%)				0/50 (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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		Female 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0% 1/50 (0%) Mean 0% SD 0% 1/50 (2%) Mean 2% SD 0% 0/50 (0%) Mean 0% SD 0%			
#Skin: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	(,	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma Overall Incidence	Basal Cell C	0/50 (0%) 0/50 (0%)	ous Tumor (malignar Mean 0%	nt or NOS), SD 0%	Total	` '	Mean 2%	SD 0%
#Skin: Squamous Cell Papilloma		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma o	or Papilloma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, S	quamous Cell Carcinon 0/50 (0%)	na or Keratoacanthor	ma		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0% 0/47 (0%) Mean 0% SD 0%		
#Skin: Squamous Cell Papilloma, I	Papilloma, c	or Keratoacanthoma				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (09				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (09	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma Overall Incidence	Total	0/49 (0%)	%) Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma	i Olai	2/49 (49		۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰۰	i otai	0/47 (0%)	ivicali U/0	30 0/6
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Spleen: Mast Cell Tumor Malignant		0/49 (09	%)			0/47 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/47 (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: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male			Female 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0%		
#Stomach, Forestomach: Hemangioma									
		0/50	(0%)				` ,		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		- /	,						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
······									
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma	a Squamous 0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma									
	Total		(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #Stomach, Glandular: Adenoma		0/50 (0%)	(0%)				0/50 (0%)		
Overall Incidence #Stomach, Glandular:	Total Total	0/50 (0%)	•••••	Mean 0% Mean 0%	SD 0%	Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0%
Overall Incidence #Stomach, Glandular: Adenoma		0/50 (0%)	•••••				0/50 (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

Vehicle: METHYLCELLULOSE

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Route: GAVAGE

Length of Study: CHRONIC

Male **Female** #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% *Testes: Adenoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Testes: Hemangioma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Testes: Hemangiosarcoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Testes:

i estes.

Seratoli Tumor: Benign, Malignant, NOS

0/50 (0%)

Overall Incidence Total 0/50 (0%) Mean 0% SD 0%

*Testes:

Sertoli Cell Tumor Malignant

0/50 (0%)

Overall Incidence Total 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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Total 0/43 (0%) Mean 0% SD 0% Total 0/43 (0%) Mean 0% SD 0%		
*Thymus: Hemangioma		0/38 (0%)				0/42 (09/)		
Overall Incidence	Total	0/38 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/38 (0%)				0/43 (0%)		
Overall Incidence	Total	0/38 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/38 (0%)				0/43 (0%)		
Overall Incidence	Total	0/38 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	ınant, NOS	0/38 (0%)				` '		
Overall Incidence	Total	0/38 (0%)	Mean 0%	SD 0%	Total	0/43 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma		0/50 (0%)				0/46 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/46 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (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: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male			Total 0/46 (0%) Mean 0% SD 0% 1/46 (2%) Total 1/46 (2.17%) Mean 2.17% SD 0% 0/46 (0%) Total 0/46 (0%) Mean 0% SD 0% 1/46 (2%) Total 1/46 (2.17%) Mean 2.17% SD 0%			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma										
		0/50	(0%)				` '			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%		` ,		SD 0%	
*Thyroid Gland: Follicular Cell: Adenoma										
			(6%)				` '			
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	
*Thyroid Gland: Follicular Cell: Carcinoma										
		0/50	(0%)		00.007		` '	••	22. 22/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	l otal	0/46 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
			(6%)				` ,			
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%		, ,			
#Tissue NOS: Sarcoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Schwannoma Malignant										
		0/50	(0%)		05.00/		0/50 (0%)		22 22/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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				Male			0/50 (0%) al 0/50 (0%) Mean 0% SD 0% 0/50 (0%) al 0/50 (0%) Mean 0% SD 0% 0/50 (0%)				
#Tongue: Squamous Cell Carcinoma 0/50 (0%)											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Tongue:	Danillana								••••••		
Squamous Cell Carcinon	na or Papilloma		(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Tongue: Squamous Cell Papillom	а	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Tooth: Odontoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
#Tooth: Sarcoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Carcinoma or Papilloma		0/48	(0%)				0/45 (0%)				
Overall Incidence	Total	0/48 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/45 (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

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Report Date: 06/03/2022

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			0/45 (0%) 0/45 (0%) Mean 0% SD 0% 0/45 (0%)			
*Urinary Bladder: Hemangioma									
J		0/48 (0%)				0/45 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma									
		1/48 (2%)				` ,			
Overall Incidence	Total	1/48 (2.08%)	Mean 2.08%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Papilloma									
		0/48 (0%)				` ,			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	, ,			
*Urinary Bladder: Sarcoma									
		0/48 (0%)				0/45 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma									
						1/50 (2%)			
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Carcinoma									
						0/50 (0%)			
Overall Incidence					Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

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	Male			Female	
#Uterus: Deciduoma Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma			(201)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Leiomyoma			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal			0/50 (00/)		
Overall Incidence		Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE Page: 86

Female	
Mean 0%	SD 0%

			Male				Female		
#Uterus: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal or Poly	p Stromal					0/50 (00/)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Schwannoma Malignant						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Squamous Cell Carcinom									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Zymbal's Gland: Adenoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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: 06/03/2022

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 88

Report Date: 06/03/2022

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	055021503	03/04/97	730	50(1)	38(707)	53.4	Acrylonitrile
Battelle Columbus Laboratory	058812207	07/01/97	730	50(1)	39(702)	52.5	Elmiron (sodium pentosanpolysulfate)
Battelle Columbus Laboratory	058805006	10/16/95	729	49(1)	35(704)	50.6	Methacrylonitrile
Southern Research Institute	050516106	03/20/96	729	50(1)	39(696)	51.4	Riddelliine
					Female		
Battelle Columbus Laboratory	055021503	03/03/97	729	50(5)	39(709)	62.7	Acrylonitrile
Battelle Columbus Laboratory	058812207	06/30/97	729	50(5)	37(692)	62.9	Elmiron (sodium pentosanpolysulfate)
Battelle Columbus Laboratory	058805006	10/17/95	731	50(5)	35(700)	58.1	Methacrylonitrile
Southern Research Institute	050516106	03/20/96	735	50(5)	34(674)	59.5	Riddelliine

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: GAVAGE Vehicle: WATER **Page:** 89

			Male				Female	
#All Organs: Benign Tumors								
		34/50 (68%) 32/50 (64%)	29/50 (58%)	29/49 (59%)		29/50 (58%) 15/50 (30%)	17/50 (34%)	24/50 (48%)
Overall Incidence	Total	124/199 (62.31%)	Mean 62.3%	SD 4.6%	Total	85/200 (42.5%)	Mean 42.5%	SD 12.9%
#All Organs: Malignant Tumors								
		29/50 (58%) 29/50 (58%)	24/50 (48%)	24/49 (49%)		24/50 (48%) 21/50 (42%)	17/50 (34%)	20/50 (40%)
Overall Incidence	Total	106/199 (53.27%)	Mean 53.24%	SD 5.51%	Total	82/200 (41%)	Mean 41%	SD 5.77%
#All Organs: Malignant and Benign To	umors	45/50 (90%) 44/50 (88%)	38/50 (76%)	40/49 (82%)		39/50 (78%) 31/50 (62%)	29/50 (58%)	34/50 (68%)
Overall Incidence	Total	167/199 (83.92%)	Mean 83.91%	SD 6.37%	Total	133/200 (66.5%)	Mean 66.5%	SD 8.7%
#All Organs: Hemangioma		2/50 (4%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0,00 (0,0)	0/10 (0/0)		0/50 (0%)	0,00 (0,0)	2/00 (1/0)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 2%
#All Organs: Hemangiosarcoma								
		3/50 (6%) 3/50 (6%)	6/50 (12%)	3/49 (6%)		4/50 (8%) 0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	15/199 (7.54%)	Mean 7.53%	SD 2.98%	Total	7/200 (3.5%)	Mean 3.5%	SD 3.42%

^{*:} 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: 90 Report Date: 06/03/2022

Species: MICE Strain: B6C3F1/N Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
All Organs: Hemangiosarcoma or He	mangioma							
		5/50 (10%) 3/50 (6%)	6/50 (12%)	3/49 (6%)		4/50 (8%) 0/50 (0%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	17/199 (8.54%)	Mean 8.53%	SD 2.97%	Total	9/200 (4.5%)	Mean 4.5%	SD 4.12%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#All Organs: Malignant Lymphoma: Hi	istiocytic, Lyn	nphocytic, Mixed, NOS, or 3/50 (6%)	r Undifferentiated Cel 3/50 (6%)	I Type 2/49 (4%)		4/50 (8%)	7/50 (14%)	9/50 (18%)
Malignant Lymphoma: Hi	i stiocytic, Lyn Total	3/50 (6%) 3/50 (6%)			Total	4/50 (8%) 7/50 (14%) 27/200 (13.5%)	7/50 (14%) Mean 13.5%	9/50 (18%) SD 4.12%
Malignant Lymphoma: Hi Overall Incidence #All Organs:	Total	3/50 (6%) 3/50 (6%) 11/199 (5.53%)	3/50 (6%)	2/49 (4%)	Total	7/50 (14%)	,	,
	Total	3/50 (6%) 3/50 (6%) 11/199 (5.53%)	3/50 (6%)	2/49 (4%)	Total	7/50 (14%)	,	,
Malignant Lymphoma: Hi Overall Incidence #All Organs: Mesothelioma: Benign, M	Total	3/50 (6%) 3/50 (6%) 11/199 (5.53%) 5 0/50 (0%)	3/50 (6%) Mean 5.52%	2/49 (4%) SD 0.96%	Total Total	7/50 (14%) 27/200 (13.5%) 0/50 (0%)	Mean 13.5%	SD 4.12%
Malignant Lymphoma: Hi Overall Incidence #All Organs: Mesothelioma: Benign, M Overall Incidence	Total lalignant, NOS Total	3/50 (6%) 3/50 (6%) 11/199 (5.53%) 5 0/50 (0%) 0/50 (0%) 0/199 (0%)	3/50 (6%) Mean 5.52% 0/50 (0%) Mean 0%	2/49 (4%) SD 0.96% 0/49 (0%) SD 0%		7/50 (14%) 27/200 (13.5%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 13.5% 0/50 (0%) Mean 0%	SD 4.12% 0/50 (0%) SD 0%
Malignant Lymphoma: Hi Overall Incidence #All Organs: Mesothelioma: Benign, M Overall Incidence	Total lalignant, NOS Total	3/50 (6%) 3/50 (6%) 11/199 (5.53%) 5 0/50 (0%) 0/50 (0%)	3/50 (6%) Mean 5.52% 0/50 (0%)	2/49 (4%) SD 0.96% 0/49 (0%)		7/50 (14%) 27/200 (13.5%) 0/50 (0%) 0/50 (0%)	Mean 13.5% 0/50 (0%)	SD 4.12% 0/50 (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: GAVAGE Vehicle: WATER **Page:** 91

			Male				Female	
#All Organs: Osteoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Adrenal Cortex: Adenoma								
		3/50 (6%) 3/49 (6%)	2/50 (4%)	5/49 (10%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	13/198 (6.57%)	Mean 6.58%	SD 2.6%	Total	0/198 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/198 (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: GAVAGE Vehicle: WATER **Page:** 92

			Male				Female	
*Adrenal Cortex: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ben						0/50 (09/)	0/40 (00/)	0/40 (09/)
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Mal								
		0/50 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Be	nign, Complex	, Malignant, NOS						
		0/50 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
		2/50 (4%) 1/50 (2%)	2/50 (4%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 1.91%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 93

			Male				Female	
*Bone Marrow: Mast Cell Tumor Malignant								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chondroma								
		0/50 (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	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Chond	Iroma	0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Bone: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER **Page:** 94

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Bone: Sarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Meningioma: Benign, Maligi	nant, NOS							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	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: GAVAGE Vehicle: WATER Page: 95

			Male				Female	
Brain: Oligodendroglioma Benig	n							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Oligodendroglioma Maligr								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
Brain: Sarcoma		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/49 (0%) 1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	Total	0/188 (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: GAVAGE Vehicle: WATER **Page:** 96

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 1/49 (2%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/188 (0.53%)	Mean 0.51%	SD 1.02%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/49 (0%) 1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 1/49 (2%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	Total	1/188 (0.53%)	Mean 0.51%	SD 1.02%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	1/49 (2%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/188 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/188 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER **Page:** 97

			Male				Female	
Ear: Neural Crest Tumor, Ma	alignant							
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Epididymis: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Epididymis: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Eye: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Gallbladder: Adenoma								
		0/50 (0%) 0/44 (0%)	0/40 (0%)	0/46 (0%)		0/50 (0%) 0/45 (0%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	0/180 (0%)	Mean 0%	SD 0%	Total	0/184 (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: GAVAGE Vehicle: WATER Page: 98

			Male				Female	
*Gallbladder: Sarcoma								
		0/50 (0%) 0/44 (0%)	0/40 (0%)	0/46 (0%)		0/50 (0%) 1/45 (2%)	0/39 (0%)	0/50 (0%)
Overall Incidence	Total	0/180 (0%)	Mean 0%	SD 0%	Total	1/184 (0.54%)	Mean 0.56%	SD 1.11%
#Harderian Gland: Adenoma								
		5/50 (10%) 4/50 (8%)	6/50 (12%)	3/49 (6%)		10/50 (20%) 2/50 (4%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	18/199 (9.05%)	Mean 9.03%	SD 2.53%	Total	18/200 (9%)	Mean 9%	SD 7.57%
#Harderian Gland: Carcinoma								
		1/50 (2%) 2/50 (4%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 2/50 (4%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%
#Harderian Gland: Carcinoma or Adenoma								
		6/50 (12%) 6/50 (12%)	6/50 (12%)	3/49 (6%)		11/50 (22%) 4/50 (8%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	21/199 (10.55%)	Mean 10.53%	SD 2.94%	Total	23/200 (11.5%)	Mean 11.5%	SD 7%
*Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER **Page**: 99

			Male				Female	
*Heart: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

^{*:} 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: GAVAGE Vehicle: WATER **Page:** 100

			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma	:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Duodenum: Carcinoma	:				•••••			
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
#Intestine Small: Duodenum: Hemangioma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 3.41%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unsp Carcinoma	ecified:							
		2/50 (4%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 3.41%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unsp Carcinoma or Adenoma								
		2/50 (4%) 0/50 (0%)	4/50 (8%)	3/49 (6%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	9/199 (4.52%)	Mean 4.53%	SD 3.43%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} 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: GAVAGE Vehicle: WATER **Page:** 103

			Male				Female	
#Intestine Small: Site Uns Hemangioma	specified:							
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		2/50 (4%) 3/49 (6%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/50 (0%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.55%	SD 2.56%	Total	0/195 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/195 (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: GAVAGE Vehicle: WATER **Page:** 104

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%) 3/49 (6%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/50 (0%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.55%	SD 2.56%	Total	0/195 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/197 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/197 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/48 (0%)	1/50 (2%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/197 (0.51%)	Mean 0.5%	SD 1%

^{*:} 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: 06/03/2022

Page: 105

Species: MICE Strain: B6C3F1/N Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Cholangiocarcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
		2/50 (4%) 2/50 (4%)	2/50 (4%)	1/49 (2%)		2/50 (4%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%
Liver: Hepatoblastoma								
		0/50 (0%) 3/50 (6%)	1/50 (2%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 2.51%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		23/50 (46%) 16/50 (32%)	19/50 (38%)	17/49 (35%)		14/50 (28%) 9/49 (18%)	7/50 (14%)	9/50 (18%)
Overall Incidence	Total	75/199 (37.69%)	Mean 37.67%	SD 6.07%	Total	39/199 (19.6%)	Mean 19.59%	SD 5.94%

^{*:} 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: GAVAGE Vehicle: WATER Report Date: 06/03/2022

Page: 106

			Male				Female	
Liver: Hepatocellular Carcinor	ma							
		14/50 (28%) 23/50 (46%)	11/50 (22%)	13/49 (27%)		7/50 (14%) 8/49 (16%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	61/199 (30.65%)	Mean 30.63%	SD 10.56%	Total	20/199 (10.05%)	Mean 10.08%	SD 6%
Liver: Hepatocellular Carcinor								
	-	14/50 (28%) 24/50 (48%)	12/50 (24%)	14/49 (29%)		7/50 (14%) 8/49 (16%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	64/199 (32.16%)	Mean 32.14%	SD 10.77%	Total	20/199 (10.05%)	Mean 10.08%	SD 6%
Hepatocellular Carcinor Overall Incidence	ma or Hepatoce	ellular Adenoma 32/50 (64%) 36/50 (72%) 115/199 (57.79%)	23/50 (46%) Mean 57.74%	24/49 (49%) SD 12.34%	Total	20/50 (40%) 16/49 (33%) 56/199 (28.14%)	10/50 (20%) Mean 28.16%	10/50 (20%) SD 9.89%
Liver:								
	na. Hepatocell	ular Adenoma, or Hepato	blastoma					
	ma, Hepatocell	ular Adenoma, or Hepato 32/50 (64%) 36/50 (72%)	blastoma 24/50 (48%)	24/49 (49%)		20/50 (40%) 16/49 (33%)	10/50 (20%)	10/50 (20%)
Hepatocellular Carcinor	ma, Hepatocell Total	32/50 (64%)		24/49 (49%) SD 11.73%	Total	\ /	10/50 (20%) Mean 28.16%	10/50 (20%) SD 9.89%
Hepatocellular Carcinor Overall Incidence	Total	32/50 (64%) 36/50 (72%) 116/199 (58.29%)	24/50 (48%) Mean 58.24%	SD 11.73%	Total	16/49 (33%) 56/199 (28.14%)	Mean 28.16%	SD 9.89%
Hepatocellular Carcinor Overall Incidence *Liver:	Total	32/50 (64%) 36/50 (72%)	24/50 (48%)	,	Total	16/49 (33%)	,	(,

^{*:} 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: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
*Liver: Ito Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/49 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Lung: Alveolar/Bronchiolar A	denoma							
		10/50 (20%) 12/50 (24%)	10/50 (20%)	2/49 (4%)		4/50 (8%) 1/50 (2%)	2/50 (4%)	6/50 (12%)
Overall Incidence	Total	34/199 (17.09%)	Mean 17.02%	SD 8.83%	Total	13/200 (6.5%)	Mean 6.5%	SD 4.43%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		4/50 (8%) 7/50 (14%)	5/50 (10%)	4/49 (8%)		2/50 (4%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	20/199 (10.05%)	Mean 10.04%	SD 2.79%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 108

			Male				Female	
*Lung: Alveolar/Bronchiolar Ca	rcinoma or Al	veolar/Bronchiolar Adeno	ma					
		14/50 (28%) 18/50 (36%)	14/50 (28%)	6/49 (12%)		6/50 (12%) 2/50 (4%)	3/50 (6%)	6/50 (12%)
Overall Incidence	Total	52/199 (26.13%)	Mean 26.06%	SD 9.95%	Total	17/200 (8.5%)	Mean 8.5%	SD 4.12%
*Lung: Hemangiosarcoma				2/12 /22/		2/52 (221)	- ()	2/-2 /22/
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma	•••••			•••••				
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	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: GAVAGE Vehicle: WATER **Page:** 109

			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
-		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
-		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 110

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligr						0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 111

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Fibrosarcoma		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 112 Report Date: 06/03/2022

			Male				Female	
#Mesentery: Hemangioma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Mesentery: Leiomyosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Nose: Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER **Page:** 113

			Male				Female	
*Nose: Hemangioma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
	Oilia	0/50 (00/)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
oquamous son surem		0/50 (0%) 0/50 (0%)	0,00 (0,0)	0/10 (0/0)		0/50 (0%)	, ,	
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Overall Incidence #Oral Cavity (Oral Mucos	sa, Tongue, Phary	0/50 (0%) 0/199 (0%)	,	,	Total	` ,	Mean 0%	SD 0%
Overall Incidence #Oral Cavity (Oral Mucos	sa, Tongue, Phary	0/50 (0%) 0/199 (0%) ynx, Tooth, Gingiva):	,	,	Total	` ,	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: GAVAGE Vehicle: WATER Page: 114

			Ma	ale						F	emale		
#Oral Mucosa: Squamous Cell Carcinoma						,							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	,	SD 0%		Total	0/200 (0%)	Mear	า 0%	SD	0%
#Oral Mucosa: Squamous Cell Papilloma		2/22 /22/	2.5			(224)		- /	(224)	- /	(004)		(224)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%)	SD 0%		Total	1/200 (0		Mean	0.5%	SD	1%
*Ovary: Cystadenoma								8/50	(16%)	1/47	(2%)	2/50	(4%)
Overall Incidence							Total	1/49 12/196 (6	(2%) 5.12%)	Mean	6.04%	SD 6	5.7%
*Ovary: Granulosa Cell Tumor Beni	gn						•••••						
								0/50 0/49	(0%) (0%)	0/47	(0%)	0/50	(0%)
Overall Incidence							Total	0/196 (0%)	Mear	า 0%	SD	0%
*Ovary: Granulosa Cell Tumor: Ben	ign, Maligna	ant, NOS											
								0/50 0/49	(0%) (0%)	0/47	(0%)	0/50	(0%)
Overall Incidence							Total	0/196 (` '	Mear	ո 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: GAVAGE Vehicle: WATER **Page:** 115

	Male			Female	
*Ovary: Hemangioma					
			0/50 (0%) 0/49 (0%)	0/47 (0%)	2/50 (4%)
Overall Incidence		Γotal	2/196 (1.02%)	Mean 1%	SD 2%
*Ovary:					
Hemangiosarcoma			0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	٦	Γotal	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
			0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	٦	Γotal	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Benign					
-			0/50 (0%) 0/49 (0%)	0/47 (0%)	1/50 (2%)
Overall Incidence		Γotal	1/196 (0.51%)	Mean 0.5%	SD 1%
*Ovary: Thecoma Benign					
-			0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	٦	Γotal	0/196 (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: GAVAGE Vehicle: WATER **Page:** 116 Report Date: 06/03/2022

			Male				Female	
*Ovary: Tubulostromal Adenoma								
						0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence					Total	0/196 (0%)	Mean 0%	SD 0%
*Pancreas: Hemangioma		•••••	•••••					
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Pancreas: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/49 (2%)	0/46 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Pituitary Gland: Pars Distali Adenoma	is or Unspec	ified Site:						
		0/49 (0%) 1/49 (2%)	0/47 (0%)	0/48 (0%)		2/48 (4%) 5/48 (10%)	2/48 (4%)	2/49 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.51%	SD 1.02%	Total	11/193 (5.7%)	Mean 5.71%	SD 3.14%
*Pituitary Gland: Pars Distali Carcinoma		ified Site:	•••••					
		0/49 (0%) 0/49 (0%)	0/47 (0%)	0/48 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/193 (0%)	Mean 0%	SD 0%	Total	0/193 (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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Dista Carcinoma or Adenoma	alis or Unspec	ified Site:						
		0/49 (0%) 1/49 (2%)	0/47 (0%)	0/48 (0%)		2/48 (4%) 5/48 (10%)	2/48 (4%)	2/49 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.51%	SD 1.02%	Total	11/193 (5.7%)	Mean 5.71%	SD 3.14%
*Pituitary Gland: Pars Inter Adenoma	media:							
		1/49 (2%) 0/49 (0%)	0/47 (0%)	0/48 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	2/49 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.51%	SD 1.02%	Total	2/193 (1.04%)	Mean 1.02%	SD 2.04%
*Pituitary Gland: Pars Inter Carcinoma or Adenoma								
		1/49 (2%) 0/49 (0%)	0/47 (0%)	0/48 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	2/49 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.51%	SD 1.02%	Total	2/193 (1.04%)	Mean 1.02%	SD 2.04%
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (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: GAVAGE

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: WATER

Length of Study: CHRONIC

			Male		Female
*Prostate: Hemangiosarcoma					
- -		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	
*Salivary Glands: Carcinoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/49 (0%) 0/48 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/197 (0%) Mean 0% SD 0%
*Salivary Glands: Carcinoma or Adenoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/49 (0%) 0/48 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/197 (0%) Mean 0% SD 0%
#Seminal Vesicle: Adenoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	
#Seminal Vesicle: Carcinoma					
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	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: GAVAGE Vehicle: WATER **Page**: 119

			Male				Female	
#Skeletal Muscle: Hemangioma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rh	abdomyoma							
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	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: GAVAGE Vehicle: WATER Report Date: 06/03/2022

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			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign						
	-	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Basal Cell Adenoma, Bas	osquamous T Total	umor Benign, or Trichoep 0/50 (0%) 0/50 (0%) 0/199 (0%)	ithelioma 0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
#Skin: Basal Cell Carcinoma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or	Basosquamou	s Tumor (malignant or NO	DS)					
	•	0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male			Female
#Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelic	Basal Cell Aden	oma, Basosquamous Tui	nor (benign, malignant or			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 1/5 0/50 (0%)	50 (2%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0		1/200 (0.5%) N	Mean 0.5% SD 1%
#Skin: Basal or Sq. Cell Carcin	oma. Carcinom	a, Basosq. Tumor (M or l ratoacanthoma, Trichoep 0/50 (0%)	3). Basal Cell Adenoma.		0/50 (0%) 1/5	50 (2%) 0/50 (0%)
Overall leadelance	Tatal	0/50 (0%)	Mana 0.540/ CD 4.0	200/ T-+-I	0/50 (0%)	Acces 0.50/ CD 40/
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51% SD 1.0)2% Total	1/200 (0.5%) N	Mean 0.5% SD 1%
#Skin: Fibroma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/5 0/50 (0%)	50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0	% Total	` '	Mean 0% SD 0%
#Skin: Fibroma, Fibrosarcoma,	, Sarcoma, Myx	oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma 0/50 (0%) 0/49	(0%)	3/50 (6%) 3/5 3/50 (6%)	50 (6%) 2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0	% Total	` '	Mean 5.5% SD 1%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%) 0/49	0%)	2/50 (4%) 0/5	50 (0%) 2/50 (4%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0% SD 0	% Total	0/50 (0%) 4/200 (2%)	Mean 2% SD 2.31%

^{*:} 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: GAVAGE Vehicle: WATER

. GE Page: 122

			Male				Female	
#Skin:		,						
Fibrosarcoma, Sarcoma,	Myxosarcoma	i, or Fibrous Histiocytoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		3/50 (6%) 3/50 (6%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	11/200 (5.5%)	Mean 5.5%	SD 1%
Skin: Fibrous Histiocytoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
≄Skin: Hemangioma			•••••			•••••	•••••	
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
-		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Keratoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 123

			Male				Female	
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								0/50 (00/)
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Melanoma Malignant								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
≇Skin: Myxosarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 124 Report Date: 06/03/2022

			Male				Female	
#Skin: Neural Crest Tumor								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or								
	,	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Neurofibrosarcoma, No Overall Incidence	eurofibroma, or S	Schwannoma (benign, ma 0/50 (0%) 0/50 (0%) 0/199 (0%)	alignant or NOS) 0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 2/200 (1%)	0/50 (0%) Mean 1%	2/50 (4%) SD 2%
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		` ` `						
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
	Total	0/199 (0%)		SD 0%		0/200 (0%)	Mean 0%	SD 0%
Overall Incidence #Skin: Sarcoma Overall Incidence	Total Total	0/199 (0%)				0/200 (0%)	Mean 0% 3/50 (6%) Mean 3.5%	SD 0% 0/50 (0%) SD 3%

^{*:} 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: GAVAGE Vehicle: WATER

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			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Squamous Cell Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma or Carcinoma	, Dasar och (zaremoma, basosquamo	us rumor (mangnam)	or NOS),				
or Carcinoma	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		0/50 (0%) 0/200 (0%)	Mean 0%	,
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%) 0/199 (0%) 0/50 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/199 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/49 (0%) SD 0% 0/49 (0%)		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% 0/50 (0%)	SD 0% 0/50 (0%)
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence #Skin:	Total Total	0/50 (0%) 0/50 (0%) 0/199 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/49 (0%) SD 0% 0/49 (0%)		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% 0/50 (0%)	SD 0% 0/50 (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: GAVAGE Vehicle: WATER Page: 126 Report Date: 06/03/2022

			Male				Female	
#Skin: Squamous Cell Papillor	na, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthom	a				
	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor		or Keratoacanthoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
≴Skin: Sebaceous Gland: Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma	ı							
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/196 (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: GAVAGE Vehicle: WATER Page: 127

			Male				Female	
*Spleen: Hemangiosarcoma								
		1/50 (2%) 1/49 (2%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/47 (0%)	1/50 (2%)
Overall Incidence	Total	3/197 (1.52%)	Mean 1.52%	SD 1.01%	Total	1/196 (0.51%)	Mean 0.5%	SD 1%
*Spleen: Mast Cell Tumor Malignant								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Hemangioma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillom	na Squamous						
	-	3/50 (6%) 1/50 (2%)	0/50 (0%)	1/49 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 2.51%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

^{*:} 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: GAVAGE Vehicle: WATER Page: 128

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		3/50 (6%) 1/50 (2%)	0/50 (0%)	1/49 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 2.51%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%
#Stomach, Glandular: Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma		0/50 /00/	0/50 (00)	0/40 /00/				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (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: GAVAGE Vehicle: WATER **Page:** 129

			Male		Female
*Testes: Hemangioma					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	
*Testes: Hemangiosarcoma					
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
*Testes: Seratoli Tumor: Benign, M					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	
*Testes: Sertoli Cell Tumor Malign	ant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	
*Thymus: Hemangioma					
-		0/47 (0%) 0/42 (0%)	0/40 (0%)	0/40 (0%)	0/50 (0%) 0/43 (0%) 0/47 (0%) 0/49 (0%)
Overall Incidence	Total	0/169 (0%)	Mean 0%	SD 0%	Total 0/189 (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: 06/03/2022

Page: 130

Species: MICE Strain: B6C3F1/N Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma Benign								
		0/47 (0%) 0/42 (0%)	0/40 (0%)	0/40 (0%)		0/50 (0%) 0/49 (0%)	0/43 (0%)	0/47 (0%)
Overall Incidence	Total	0/169 (0%)	Mean 0%	SD 0%	Total	0/189 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/47 (0%) 0/42 (0%)	0/40 (0%)	0/40 (0%)		0/50 (0%) 0/49 (0%)	0/43 (0%)	0/47 (0%)
Overall Incidence	Total	0/169 (0%)	Mean 0%	SD 0%	Total	0/189 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malignar	nt, NOS							
		0/47 (0%) 0/42 (0%)	0/40 (0%)	0/40 (0%)		0/50 (0%) 0/49 (0%)	0/43 (0%)	0/47 (0%)
Overall Incidence	Total	0/169 (0%)	Mean 0%	SD 0%	Total	0/189 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/194 (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: GAVAGE Vehicle: WATER Page: 131

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/194 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Adenoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		2/50 (4%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	2/194 (1.03%)	Mean 1%	SD 2%
*Thyroid Gland: Follicular Cell Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/194 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		0/50 (0%) 0/49 (0%)	0/48 (0%)	1/49 (2%)		2/50 (4%) 0/49 (0%)	0/46 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	2/194 (1.03%)	Mean 1%	SD 2%
#Tissue NOS: Sarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 132

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o Overall Incidence	or Papilloma	a Squamous 0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
≠Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (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: GAVAGE Vehicle: WATER Page: 133

			Male				Female	
#Tooth: Sarcoma								
		0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/193 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/193 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/43 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/193 (0.52%)	Mean 0.5%	SD 1%
'Urinary Bladder: Papilloma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/193 (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: GAVAGE Vehicle: WATER Report Date: 06/03/2022

Page: 134

			Male				Female	
*Urinary Bladder: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/193 (0.52%)	Mean 0.5%	SD 1%
#Uterus: Adenoma								
						0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma								
<u>-</u>						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (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: GAVAGE Vehicle: WATER Page: 135

	Male			F	emale		
Uterus: Hemangiosarcoma							
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	To	tal 0/200	(0%)	Mear	า 0%	SD	0%
Uterus: Leiomyoma							
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	To	,	•	Mean		SD	
Uterus: Leiomyosarcoma							
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	To	tal 1/200 (0.5%)	Mean		SD	
Uterus: Polyp Stromal							
		0/50 0/50	(0%) (0%)	3/50	(6%)	0/50	(0%)
Overall Incidence	To	tal 3/200 (1.5%)	Mean	1.5%	SD	3%
Uterus: Sarcoma							
		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	To			Mean	0.5%	SD	1%

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 06/03/2022

Page: 136

					Male						F	emale		
#Uterus: Sarcoma Stromal							·							
									0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	0/200	` '		า 0%	SD	0%
fUterus: Sarcoma Stromal or Polyp S														
									0/50 0/50	(0%) (0%)	3/50	(6%)	0/50	(0%)
Overall Incidence								Total	3/200 (1	•	Mean		SD	
#Uterus: Schwannoma Malignant											0/50			(00/)
									0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	0/200	(0%)		ո 0%	SD	
fVagina: Squamous Cell Carcinoma														
									0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	0/200	(0%)	Mea	า 0%	SD	0%
≠Zymbal's Gland: Adenoma														
			(0%) (0%)	0/50	(0%)	0/49	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/199 (0%)	(-/0)	Mean	0%	SD 0%		Total	0/200	. ,	Mea	า 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: GAVAGE Vehicle: WATER Page: 137

			Male			Female					
#Zymbal's Gland: Carcinoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Zymbal's Gland: Carcinoma or Adenoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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Report Date: 06/03/2022

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

Route: INHALATION Vehicle: AIR

Strain: B6C3F1/N Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	059601106	06/11/01	729	50(5)	38(709)	53.9	Cumene
Battelle Northwest	059302606	08/28/97	733	50(5)	40(701)	54.4	Decalin
Battelle Northwest	058800406	09/27/99	729	50(5)	41(702)	52.2	Divinylbenzene
Battelle Northwest	058812404	01/25/96	733	50(5)	37(711)	51.6	Indium phosphide
Battelle Northwest	059700602	06/05/00	729	50(5)	40(709)	53.2	Methyl isobutyl ketone
Battelle Northwest	058800604	07/30/01	729	50(5)	35(698)	54.9	alpha-Methylstyrene
Battelle Northwest	059000406	09/29/97	729	50(5)	35(703)	54.3	Propylene glycol mono-t-butyl ether
Battelle Northwest	059600106	12/21/98	729	50(5)	34(690)	53.2	Stoddard solvent (type IIC)
Battelle Northwest	056142708	01/13/97	729	50(5)	39(710)	55.4	Vanadium pentoxide
					Female		
Battelle Northwest	059601106	06/11/01	731	50(5)	37(685)	60.7	Cumene
Battelle Northwest	059302606	08/28/97	735	49(5)	37(708)	61.5	Decalin
Battelle Northwest	058800406	09/27/99	731	50(5)	33(681)	63.0	Divinylbenzene
Battelle Northwest	058812404	01/25/96	735	50(5)	42(713)	54.8	Indium phosphide
Battelle Northwest	059700602	06/05/00	731	50(5)	35(695)	60.3	Methyl isobutyl ketone
Battelle Northwest	058800604	07/30/01	731	50(5)	39(701)	58.6	alpha-Methylstyrene
Battelle Northwest	059000406	09/29/97	731	50(5)	39(718)	59.8	Propylene glycol mono-t-butyl ether
Battelle Northwest	059600106	12/21/98	731	50(5)	36(702)	54.6	Stoddard solvent (type IIC)
Battelle Northwest	056142708	01/13/97	731	50(5)	38(692)	58.7	Vanadium pentoxide

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 06/03/2022

SD 1.06%

Mean 1.12%

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** #All Organs: **Benign Tumors** 43/50 (86%)32/50 (64%)35/50 (70%)34/50 (68%)28/49 (57%)28/50 (56%)29/50 (58%)27/50 (54%)35/50 (70%)25/50 (50%)29/50 (58%)26/50 (52%)30/50 (60%)32/50 (64%)31/50 (62%)25/50 (50%)27/50 (54%)19/50 (38%)**Overall Incidence** Total 294/450 (65.33%) Mean 65.33% SD 9.33% Total 241/449 (53.67%) Mean 53.68% SD 8.04% #All Organs: **Malignant Tumors** 27/50 (54%)23/50 (46%)26/50 (52%)26/50 (52%)22/49 (45%)22/50 (44%)(42%)(58%)29/50 21/50 29/50 19/50 (38%)20/50 (40%)30/50 (60%)(58%)22/50 (44%)23/50 (46%)27/50 (54%)23/50 (46%)19/50 (38%)17/50 (34%)**Overall Incidence** Total 217/450 (48.22%) Mean 48.22% SD 6.59% Total 208/449 (46.33%) Mean 46.32% SD 8.83% #All Organs: **Malignant and Benign Tumors** 48/50 (96%)43/50 (86%)43/50 (86%)42/50 (84%)39/49 (80%)40/50 (80%)41/50 (82%)45/50 (90%)43/50 (86%)35/50 (70%)42/50 (84%)40/50 (80%)(82%)42/50 (74%)39/50 41/50 (84%)42/50 (84%)37/50 (78%)32/50 (64%)**Overall Incidence** 388/450 (86.22%) Mean 86.22% SD 4.41% 346/449 (77.06%) SD 6.62% Total Total Mean 77.07% **#All Organs:** Hemangioma 1/50 (2%)0/50 (0%)0/50 (0%)(0%)(2%)1/50 (2%)0/50 1/49 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)

SD 1.05%

5/449 (1.11%)

Total

Total

4/450 (0.89%)

Mean 0.89%

.....

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date: 06/03/2022

SD 6.8%

Mean 20.05%

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Male **Female** #All Organs: Hemangiosarcoma 0/50 (0%)1/50 (2%)6/50 (12%)1/50 (2%)1/49 (2%)1/50 (2%)3/50 (6%)3/50 (6%)4/50 (8%) 3/50 (6%)3/50 (6%)4/50 (8%)(2%) 3/50 (6%)1/50 1/50 (2%)1/50 (2%)1/50 (2%)2/50 (4%)22/450 (4.89%) Mean 4.89% **Overall Incidence** Total SD 3.76% Total 17/449 (3.79%) Mean 3.78% SD 2.33% **#All Organs:** Hemangiosarcoma or Hemangioma 1/50 (2%)1/50 (2%)6/50 (12%)1/50 (2%)2/49 (4%)2/50 (4%)3/50 (6%)4/50 (8%)4/50 (8%)4/50 (8%)3/50 (6%)5/50 (10%)4/50 (8%)2/50 (4%)1/50 (2%)1/50 (2%)2/50 (4%)2/50 (4%)Mean 5.78% **Overall Incidence** Total 26/450 (5.78%) SD 3.53% Total 22/449 (4.9%) Mean 4.9% SD 2.66% #All Organs: **Histiocytic Sarcoma** 0/50 1/50 (0%)0/50 (0%)(2%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)3/50 (6%)1/50 (2%)(0%)0/50 (2%)0/50 0/50 (0%)(0%)1/50 2/50 (4%)3/50 (6%)**Overall Incidence** 2/450 (0.44%) Mean 0.44% SD 0.88% 12/449 (2.67%) Mean 2.67% SD 2.24% Total Total **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type (4%)3/50 (6%)(2%)(14%)11/49 (22%)2/50 1/50 7/50 (22%)11/50 1/50 (2%)1/50 (2%)0/50 (0%)8/50 (16%)13/50 (26%)15/50 (30%)3/50 (6%)3/50 (6%)2/50 (4%)13/50 (26%)5/50 (10%)7/50 (14%)

SD 2.19%

90/449 (20.04%)

Total

Total

16/450 (3.56%)

Mean 3.56%

.....

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Mesothelioma: Benign, M	lalignant, NOS							
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%

^{*:} 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#All Organs:														,
Osteosarcoma or Osteoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%	,	Mean		SD 0%		Total	1/449 (0.	,		0.22%	SD 0	
*Adrenal Cortex: Adenoma														
		1/50	(2%)	2/49	(4%)	3/49	(6%)		0/50	(0%)	1/49	(2%)	0/50	(0%)
		2/50	(4%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		1/48	(2%)	4/49	(8%)	1/50	(2%)		0/49	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	16/445 (3.6	,	Mean 3		SD 2.45°		Total	3/448 (0.	67%)	Mean	0.67%	SD 1	.01%
*Adrenal Cortex: Carcinoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/48	(0%)	0/49	(0%)	0/50	(0%)		1/49	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/445 (0%	,	Mean		SD 0%		Total	1/448 (0.	,	Mean	0.23%	SD 0	.68%
*Adrenal Cortex: Sarcoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/48	(0%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/445 (0%	o)	Mean	0%	SD 0%		Total	0/448 (0%)	Mea	ın 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: INHALATION Vehicle: AIR

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	nign							
		0/50 (0%)	0/49 (0%)	2/49 (4%)		0/50 (0%)	2/48 (4%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/49 (4%)	2/50 (4%)	2/50 (4%)
		0/47 (0%)	0/48 (0%)	0/50 (0%)		0/47 (0%)	1/49 (2%)	2/49 (4%)
Overall Incidence	Total	2/443 (0.45%)	Mean 0.45%	SD 1.36%	Total	11/441 (2.49%)	Mean 2.49%	SD 1.98%
*Adrenal Medulla: Pheochromocytoma Ma	lignant							
	_	0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/47 (0%)	0/48 (0%)	0/50 (0%)		0/47 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	1/443 (0.23%)	Mean 0.22%	SD 0.67%	Total	1/441 (0.23%)	Mean 0.23%	SD 0.68%
*Adrenal Medulla: Pheochromocytoma: Be								
		0/50 (0%)	0/49 (0%)	2/49 (4%)		0/50 (0%)	2/48 (4%)	0/49 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/49 (4%)	2/50 (4%)	2/50 (4%)
		0/47 (0%)	0/48 (0%)	0/50 (0%)		0/47 (0%)	2/49 (4%)	2/49 (4%)
Overall Incidence	Total	3/443 (0.68%)	Mean 0.68%	SD 1.44%	Total	12/441 (2.72%)	Mean 2.71%	SD 2.03%
*Bone Marrow: Hemangiosarcoma								
-		0/50 (0%)	1/49 (2%)	2/50 (4%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	4/446 (0.9%)	Mean 0.9%	SD 1.46%	Total	2/445 (0.45%)	Mean 0.44%	SD 0.88%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Bone Marrow: Mast Cell Tumor Maligna	ınt							
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/446 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/445 (0%)	Mean 0%	SD 0%
#Bone: Chondroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Bone: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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Report Date: 06/03/2022

			Male				Female	
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	alianant NOS							
Werningionia. Denign, We	alignant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Beni								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mali								
-	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (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: INHALATION Vehicle: AIR

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Report Date: 06/03/2022

			Male				Female	
Brain: Oligodendroglioma, Glion	na, or Astroc	ytoma						
.		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
*Brain: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma						•••••		
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/41 (0%)	0/40 (0%)	0/47 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/45 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/42 (0%)	0/40 (0%)	0/39 (0%)
Overall Incidence	Total	0/446 (0%)	Mean 0%	SD 0%	Total	0/382 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/41 (0%)	0/40 (0%)	0/47 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/45 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/42 (0%)	0/40 (0%)	0/39 (0%)
Overall Incidence	Total	0/446 (0%)	Mean 0%	SD 0%	Total	0/382 (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: INHALATION Vehicle: AIR

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					Male						F	emale		
*Clitoral/Preputial Gland: Carcinoma or Adenoma														
		0/49 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)		0/41 0/45	(0%) (0%)	0/40 0/45	(0%) (0%)	0/47 0/43	(0%) (0%)
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/42	(0%)	0/40	(0%)	0/39	(0%)
Overall Incidence	Total	0/446 (0%)		Mean		SD 0%		Total	0/382	` '		า 0%	SD	
*Clitoral/Preputial Gland: Hemangiosarcoma														
		0/49	(0%)	0/49	(0%)	0/50	(0%)		0/41	(0%)	0/40	(0%)	0/47	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/45	(0%)	0/45	(0%)	0/43	(0%)
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/42	(0%)	0/40	(0%)	0/39	(0%)
Overall Incidence	Total	0/446 (0%))	Mean	0%	SD 0%		Total	0/382	(0%)	Mea	ո 0%	SD	0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma														
		0/49	(0%)	0/49	(0%)	0/50	(0%)		0/41	(0%)	0/40	(0%)	0/47	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/45	(0%)	0/45	(0%)	1/43	(2%)
		0/50	(0%)	0/49	(0%)	0/49	(0%)		0/42	(0%)	0/40	(0%)	0/39	(0%)
Overall Incidence	Total	0/446 (0%))	Mean	0%	SD 0%		Total	1/382 (0	.26%)		0.26%	SD 0.	.78%
#Coagulating Gland: Adenoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/450 (0.22%	6)	Mean 0	22%	SD 0.679	%	Total	0/449	(0%)	Mear	า 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: INHALATION Vehicle: AIR

Report Date: 06/03/2022

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			Male				Female	
#Ear:				,				
Neural Crest Tumor, Mal	ignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
Epididymis: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%				
*Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%				
#Eye: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%

^{*:} 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: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** *Gallbladder: Adenoma 0/43 (0%)0/42 (0%)1/42 (2%)0/38 (0%)0/41 (0%)0/45 (0%)0/43 (0%)0/43 (0%)0/42 (0%)0/46 (0%)0/42 (0%)0/47 (0%)0/38 (0%)0/39 (0%)0/42 (0%)0/40 (0%)0/40 (0%)0/46 (0%)Mean 0% **Overall Incidence** Total 1/374 (0.27%) Mean 0.26% SD 0.79% Total 0/385 (0%) SD 0% *Gallbladder: Sarcoma 0/43 (0%)0/42 (0%)0/42 (0%)0/38 (0%)0/41 0/45 (0%)(0%)0/43 (0%)0/43 (0%)0/42 (0%)0/46 (0%)0/42 (0%)0/47 (0%)0/38 (0%)0/39 (0%)0/42 (0%)0/40 (0%)0/40 (0%)0/46 (0%)**Overall Incidence** Total 0/374 (0%) Mean 0% SD 0% Total 0/385 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 8/50 (16%)6/50 (12%)5/50 (10%)8/50 (16%)3/49 (6%)4/50 (8%)1/50 (2%)5/50 (10%)10/50 (20%)3/50 (6%)6/50 (12%)3/50 (6%)(12%)6/50 7/50 (14%)8/50 (16%)3/50 (6%)4/50 (8%)2/50 (4%)**Overall Incidence** 56/450 (12.44%) Mean 12.44% SD 5.08% 36/449 (8.02%) SD 3.73% Total Total Mean 8.01% #Harderian Gland: Carcinoma 4/50 (8%) 3/50 (6%)1/50 (2%)(10%)1/49 (2%)2/50 (4%)5/50 0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)

0/50

SD 2.83%

(0%)

0/50

Total

11/449 (2.45%)

(0%)

1/50

(2%)

Mean 2.45%

0/50

SD 3.13%

(0%)

Total

1/50

12/450 (2.67%)

(2%)

0/50

Mean 2.67%

.....

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N Length of Study: CHRONIC **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		11/50 (22%)	9/50 (18%)	6/50 (12%)		12/50 (24%)	4/49 (8%)	6/50 (12%)
		1/50 (2%)	7/50 (14%)	11/50 (22%)		3/50 (6%)	7/50 (14%)	4/50 (8%)
		7/50 (14%)	7/50 (14%)	8/50 (16%)		3/50 (6%)	5/50 (10%)	2/50 (4%)
Overall Incidence	Total	67/450 (14.89%)	Mean 14.89%	SD 6.01%	Total	46/449 (10.24%)	Mean 10.24%	SD 6.03%
*Heart: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/450 (0.89%)	Mean 0.89%	SD 1.45%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
*Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.23%	SD 0.68%
#Intestine Large: Cecum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%

^{*:} 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: INHALATION

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Cecum: Polyp Adenomatous								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/450 (0.44%)	Mean 0.44%	SD 0.88%	Total	0/449 (0%)	Mean 0%	SD 0%
fintestine Large: Colon/Re Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
fintestine Small: Duodenu Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
fintestine Small: Duodenu Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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				Male						F	emale		
#Intestine Small: Duodenum: Hemangioma													
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	0/449 (,		ın 0%	SD	
#Intestine Small: Duodenum: Hemangiosarcoma													
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	0/449 (0%)	Mea	ın 0%	SD	0%
#Intestine Small: Duodenum: Polyp Adenomatous													
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	1/449 (0.	,		0.22%	SD 0	.67%
#Intestine Small: Ileum: Carcinoma													
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/450 (0.22%)	Mean	0.22%	SD 0.679	%	Total	1/449 (0.	22%)	Mean	0.22%	SD 0	.67%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/450 (1.33%)	Mean 1.33%	SD 2.24%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:			•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/450 (0.44%)	Mean 0.44%	SD 0.88%	Total	1/449 (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
Route: INHALATION

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Un	specified:							
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/450 (1.56%)	Mean 1.56%	SD 2.19%	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%
Intestine Small: Site Un Carcinoma or Adenom	specified:							
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	9/450 (2%)	Mean 2%	SD 2%	Total	3/449 (0.67%)	Mean 0.67%	SD 1%
fintestine Small: Site Un Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Un Hemangiosarcoma	specified:							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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

Vehicle: AIR

Route: INHALATION

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Report Date: 06/03/2022

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspe Polyp Adenomatous	cified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/	()	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/:	` ,	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/	()	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%		(0.22%)	Mean 0.22%	SD 0.67%
*Islets, Pancreatic: Adenoma								
		0/50 (0%)	1/49 (2%)	1/49 (2%)	1/-	19 (2%)	1/49 (2%)	0/48 (0%)
		3/50 (6%)	1/49 (2%)	0/50 (0%)	0/	50 (0%)	0/50 (0%)	0/49 (0%)
		2/48 (4%)	0/48 (0%)	1/50 (2%)	1/-	49 (2%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	9/443 (2.03%)	Mean 2.03%	SD 2.02%		3 (0.9%)	Mean 0.91%	SD 1.08%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)	0/-	49 (0%)	0/49 (0%)	1/48 (2%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)	0/	50 (0%)	0/50 (0%)	0/49 (0%)
		0/48 (0%)	0/48 (0%)	0/50 (0%)	0/-	19 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/443 (0.23%)	Mean 0.22%	SD 0.67%		(0.23%)	Mean 0.23%	SD 0.69%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%)	1/49 (2%)	1/-	19 (2%)	1/49 (2%)	1/48 (2%)
		3/50 (6%)	1/49 (2%)	1/50 (2%)	0/	50 (0%)	0/50 (0%)	0/49 (0%)
		2/48 (4%)	0/48 (0%)	1/50 (2%)	1/-	19 (2%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	10/443 (2.26%)	Mean 2.25%	SD 1.87%	Total 5/443	(1.13%)	Mean 1.14%	SD 1.08%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/446 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%	Total	0/446 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/449 (0.67%)	Mean 0.67%	SD 1.41%	Total	0/446 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
-		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	0/446 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Liver: Cholangiocarcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/447 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/450 (0.67%)	Mean 0.67%	SD 1%	Total	1/447 (0.22%)	Mean 0.22%	SD 0.67%
*Liver: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		2/50 (4%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	15/450 (3.33%)	Mean 3.33%	SD 2.65%	Total	2/447 (0.45%)	Mean 0.44%	SD 0.88%
Liver: Hepatoblastoma								
-		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	1/447 (0.22%)	Mean 0.22%	SD 0.67%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Liver: Hepatocellular Adenom	a							
		34/50 (68%)	22/50 (44%)	22/50 (44%)		18/50 (36%)	7/49 (14%)	17/49 (35%)
		17/50 (34%)	17/50 (34%)	24/50 (48%)		12/50 (24%)	13/50 (26%)	10/50 (20%)
		18/50 (36%)	23/50 (46%)	15/50 (30%)		14/49 (29%)	9/50 (18%)	6/50 (12%)
Overall Incidence	Total	192/450 (42.67%)	Mean 42.67%	SD 11.4%	Total	106/447 (23.71%)	Mean 23.73%	SD 8.46%
*Liver: Hepatocellular Carcinor								
		13/50 (26%)	10/50 (20%)	13/50 (26%)		10/50 (20%)	4/49 (8%)	5/49 (10%)
		11/50 (22%)	12/50 (24%)	10/50 (20%)		6/50 (12%)	6/50 (12%)	3/50 (6%)
		9/50 (18%)	16/50 (32%)	14/50 (28%)		4/49 (8%)	6/50 (12%)	6/50 (12%)
Overall Incidence	Total	108/450 (24%)	Mean 24%	SD 4.47%	Total	50/447 (11.19%)	Mean 11.17%	SD 3.98%
*Liver: Hepatocellular Carcinor								
		14/50 (28%)	10/50 (20%)	13/50 (26%)		10/50 (20%)	4/49 (8%)	5/49 (10%)
		11/50 (22%)	12/50 (24%)	10/50 (20%)		6/50 (12%)	6/50 (12%)	3/50 (6%)
		9/50 (18%)	16/50 (32%)	14/50 (28%)		4/49 (8%)	6/50 (12%)	6/50 (12%)
Overall Incidence	Total	109/450 (24.22%)	Mean 24.22%	SD 4.63%	Total	50/447 (11.19%)	Mean 11.17%	SD 3.98%
*Liver: Hepatocellular Carcinor								
•	·	40/50 (80%)	28/50 (56%)	30/50 (60%)		25/50 (50%)	11/49 (22%)	19/49 (39%)
		26/50 (52%)	27/50 (54%)	28/50 (56%)		18/50 (36%)	17/50 (34%)	13/50 (26%)
		25/50 (50%)	34/50 (68%)	26/50 (52%)		18/49 (37%)	13/50 (26%)	12/50 (24%)
Overall Incidence	Total	264/450 (58.67%)	Mean 58.67%	SD 9.64%	Total	146/447 (32.66%)	Mean 32.66%	SD 8.91%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
Liver:								
Hepatocellular Carcinom	a, Hepatocell	ular Adenoma, or Hepato	blastoma					
		41/50 (82%)	28/50 (56%)	30/50 (60%)		25/50 (50%)	11/49 (22%)	19/49 (39%)
		26/50 (52%)	27/50 (54%)	28/50 (56%)		18/50 (36%)	17/50 (34%)	13/50 (26%)
		25/50 (50%)	34/50 (68%)	26/50 (52%)		18/49 (37%)	13/50 (26%)	12/50 (24%)
Overall Incidence	Total	265/450 (58.89%)	Mean 58.89%	SD 10.2%	Total	146/447 (32.66%)	Mean 32.66%	SD 8.91%
Liver: Hepatocholangiocarcino								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	1/49 (2%)
		0/50 (0%)	5/50 (10%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/450 (1.33%)	Mean 1.33%	SD 3.32%	Total	2/447 (0.45%)	Mean 0.45%	SD 0.89%
Liver: Ito Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/447 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/447 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar A	Adenoma							
		13/50 (26%)	8/50 (16%)	12/49 (24%)		1/50 (2%)	1/49 (2%)	4/50 (8%)
		13/50 (26%)	9/50 (18%)	8/50 (16%)		3/50 (6%)	4/50 (8%)	1/50 (2%)
		13/50 (26%)	6/50 (12%)	13/50 (26%)		2/50 (4%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	95/449 (21.16%)	Mean 21.17%	SD 5.61%	Total	19/449 (4.23%)	Mean 4.23%	SD 2.53%
*Lung: Alveolar/Bronchiolar C								
		9/50 (18%)	8/50 (16%)	5/49 (10%)		3/50 (6%)	6/49 (12%)	2/50 (4%)
		6/50 (12%)	5/50 (10%)	5/50 (10%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		6/50 (12%)	7/50 (14%)	12/50 (24%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	63/449 (14.03%)	Mean 14.02%	SD 4.67%	Total	14/449 (3.12%)	Mean 3.14%	SD 3.96%
*Lung: Alveolar/Bronchiolar C	Carcinoma or Al	veolar/Bronchiolar Adeno	ma					
		19/50 (38%)	15/50 (30%)	16/49 (33%)		4/50 (8%)	7/49 (14%)	6/50 (12%)
		18/50 (36%)	14/50 (28%)	13/50 (26%)		4/50 (8%)	4/50 (8%)	2/50 (4%)
		17/50 (34%)	13/50 (26%)	22/50 (44%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	147/449 (32.74%)	Mean 32.74%	SD 5.99%	Total	33/449 (7.35%)	Mean 7.37%	SD 3.94%

^{*:} 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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Mean 0%

SD 0%

Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/449 (0.22%) Mean 0.22% SD 0.67% Total 0/449 (0%) SD 0% *Lung: Sarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/449 (0%) Mean 0% SD 0% Total 0/449 (0%) Mean 0% SD 0% #Lymph Node: Hemangiosarcoma 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)**Overall Incidence** Total 0/450 (0%) Mean 0% SD 0% 0/449 (0%) Mean 0% SD 0% Total **#Lymph Node:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/449 (0%)

Total

0/450 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node, Mesenteric: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	5/449 (1.11%)	Mean 1.12%	SD 1.06%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	5/449 (1.11%)	Mean 1.12%	SD 1.06%
#Mammary Gland: Fibroma, Fibroadenoma								
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland:		,				,		
Fibroma, Fibroadenoma	a, Carcinoma, or	· Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	5/449 (1.11%)	Mean 1.12%	SD 1.06%
#Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Mesentery: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
#Mesentery: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
*Nose: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	0/447 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Nose: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	1/447 (0.22%)	Mean 0.22%	SD 0.67%
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	1/447 (0.22%)	Mean 0.23%	SD 0.68%
#Oral Cavity (Oral Muco								
Papilloma Squamous	or Papilloma							
Papilloma Squamous	or Papilloma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Papilloma Squamous	or Papilloma	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Papilloma Squamous	or Papilloma	` '	` ,	` ,		` ,	` '	` ,
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/450 (0.22%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total sa, Tongue, Phar	0/50 (0%) 0/50 (0%) 1/450 (0.22%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence #Oral Cavity (Oral Muco	Total sa, Tongue, Phar	0/50 (0%) 0/50 (0%) 1/450 (0.22%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence #Oral Cavity (Oral Muco	Total sa, Tongue, Phar	0/50 (0%) 0/50 (0%) 1/450 (0.22%) rynx, Tooth, Gingiva):	0/50 (0%) 0/50 (0%) Mean 0.22%	0/50 (0%) 1/50 (2%) SD 0.67%	Total	0/50 (0%) 0/50 (0%) 0/449 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Overall Incidence #Oral Cavity (Oral Muco	Total sa, Tongue, Phar	0/50 (0%) 0/50 (0%) 1/450 (0.22%) 	0/50 (0%) 0/50 (0%) Mean 0.22%	0/50 (0%) 1/50 (2%) SD 0.67%	Total	0/50 (0%) 0/50 (0%) 0/449 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (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: INHALATION Vehicle: AIR

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			Male				Female	
Oral Cavity (Oral Mucosa Squamous Cell Carcino		ynx, Tooth, Gingiva): Squamous, or Papilloma						
•	•	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/450 (0.67%)	Mean 0.67%	SD 1%	Total	2/449 (0.45%)	Mean 0.45%	SD 0.89%
#Oral Mucosa: Squamous Cell Carcino								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
#Oral Mucosa: Squamous Cell Papillor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma			•••••			•••••		
-,						5/48 (10%)	1/49 (2%)	3/48 (6%)
						0/47 (0%)	0/49 (0%)	2/48 (4%)
						2/50 (4%)	1/49 (2%)	1/48 (2%)
Overall Incidence					Total	15/436 (3.44%)	Mean 3.44%	SD 3.29%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Mal	le		Female	
*Ovary: Granulosa Cell Tumor Benign				
•		0/48 (0%)	1/49 (2%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
Outrall Indidense	Tatal	0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/436 (0.23%)	Mean 0.23%	SD 0.68%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/48 (0%)	1/49 (2%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/436 (0.23%)	Mean 0.23%	SD 0.68%
*Ovary:				
Hemangioma				
•		0/48 (0%)	1/49 (2%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
		0/50 (0%)	1/49 (2%)	0/48 (0%)
Overall Incidence	Total	2/436 (0.46%)	Mean 0.45%	SD 0.9%
*Ovary:				
Hemangiosarcoma				
··-··		0/48 (0%)	0/49 (0%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/436 (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: INHALATION Vehicle: AIR

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Ma	ale		Female	
*Ovary: Luteoma		0/48 (0%) 1/49 (2%) 1/48 (2%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 2/50 (4%) 0/49 (0%) 0/48 (0%) otal 4/436 (0.92%) Mean 0.9% SD 1.47% 1/48 (2%) 0/49 (0%) 0/48 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 0/50 (0%) 1/49 (2%) 0/48 (0%) otal 2/436 (0.46%) Mean 0.46% SD 0.91% 0/48 (0%) 0/49 (0%) 0/48 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%)		
		0/48 (0%)	1/49 (2%)	1/48 (2%)
		` '	` ,	` '
		, ,	` '	` ,
Overall Incidence	Total			
*Ovary: Teratoma Benign				
		1/48 (2%)	0/49 (0%)	0/48 (0%)
		` ,	0/49 (0%)	0/48 (0%)
		0/50 (0%)	1/49 (2%)	0/48 (0%)
Overall Incidence	Total			
*Ovary: Thecoma Benign				
		0/48 (0%)	0/49 (0%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/436 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma				
		0/48 (0%)	0/49 (0%)	0/48 (0%)
		0/47 (0%)	0/49 (0%)	0/48 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/436 (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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** *Pancreas: Hemangioma 0/50 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/444 (0%) Mean 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/443 (0%) SD 0% *Pancreas: Sarcoma 0/50 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/48 (0%)(0%)0/49 0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/444 (0%) Mean 0% SD 0% Total 0/443 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/48 1/48 (2%)1/48 (2%)(0%)8/50 (16%)13/49 (27%)8/47 (17%)0/48 (0%)0/50 (0%)0/48 (0%)10/50 (20%)7/50 (14%)4/50 (8%)0/43 (0%)1/50 (19%)0/49 (0%)(2%)9/48 10/47 (21%)8/49 (16%)**Overall Incidence** Total 3/432 (0.69%) Mean 0.69% SD 1.03% 77/440 (17.5%) Mean 17.55% SD 5.12% Total *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/48 (0%)0/48 (0%)0/48 (0%)0/50 (0%)0/49 (0%)0/47 (0%)

0/48

1/50

SD 0.67%

(0%)

(2%)

Total

0/50

0/48

0/440 (0%)

(0%)

(0%)

0/50

0/47

(0%)

(0%)

Mean 0%

0/50

0/49

SD 0%

(0%)

(0%)

Total

0/48

0/43

1/432 (0.23%)

(0%)

(0%)

0/50

0/49

Mean 0.22%

(0%)

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1/N Route: INHALATION Vehicle: AIR

			Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma										
		1/48 (2%)	1/48 (2%)	0/48 (0%)		8/50 (16%)	13/49 (27%)	8/47 (17%)		
		0/48 (0%)	0/50 (0%)	0/48 (0%)		10/50 (20%)	7/50 (14%)	4/50 (8%)		
		0/43 (0%)	0/49 (0%)	2/50 (4%)		9/48 (19%)	10/47 (21%)	8/49 (16%)		
Overall Incidence	Total	4/432 (0.93%)	Mean 0.91%	SD 1.47%	Total	77/440 (17.5%)	Mean 17.55%	SD 5.12%		
Pituitary Gland: Pars Int Adenoma										
		0/48 (0%)	0/48 (0%)	0/48 (0%)		2/50 (4%)	1/49 (2%)	1/47 (2%)		
		0/48 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/43 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%)	0/47 (0%)	0/49 (0%)		
Overall Incidence	Total	1/432 (0.23%)	Mean 0.23%	SD 0.69%	Total	4/440 (0.91%)	Mean 0.91%	SD 1.47%		
Pituitary Gland: Pars Int Carcinoma or Adenom	ermedia:				•					
		0/48 (0%)	0/48 (0%)	0/48 (0%)		2/50 (4%)	1/49 (2%)	1/47 (2%)		
		0/48 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/43 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%)	0/47 (0%)	0/49 (0%)		
Overall Incidence	Total	1/432 (0.23%)	Mean 0.23%	SD 0.69%	Total	4/440 (0.91%)	Mean 0.91%	SD 1.47%		
Prostate: Adenoma										
		0/50 (0%)	0/48 (0%)	0/48 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		1/49 (2%)	0/46 (0%)	0/50 (0%)						
Overall Incidence	Total	1/441 (0.23%)	Mean 0.23%	SD 0.68%						

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	0/48 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Occupation of days a	T-1-1	1/49 (2%)	0/46 (0%)	0/50 (0%)				
Overall Incidence	Total	1/441 (0.23%)	Mean 0.23%	SD 0.68%				
*Prostate: Hemangiosarcoma								
_		0/50 (0%)	0/48 (0%)	0/48 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/49 (0%)	0/46 (0%)	0/50 (0%)				
Overall Incidence	Total	0/441 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma				•••••				
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	1/448 (0.22%)	Mean 0.22%	SD 0.67%
*Salivary Glands: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%	Total	1/448 (0.22%)	Mean 0.22%	SD 0.67%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%				
#Seminal Vesicle: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/450 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/449 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or l	Rhabdomyoma							
•	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Basal Cell Adenoma o	r Basosquamous	Tumor Benign						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, E	Basosquamous T	umor Benign, or Trichoep	oithelioma					
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin:								
-	or Basosquamou	s Tumor (malignant or NO	OS)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
Overall incluence	i Otal	0/430 (0%)	IVICALI U%	3D 0%	iolai	0/449 (0%)	iviean 0%	3D 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: INHALATION Vehicle: AIR

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					Male						F	emale		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquar	nous Tur	nor (benign	, malignar	nt or								
Overall Incidence	Total	0/50 0/50 0/50 0/450 (0%)	(0%) (0%) (0%)	0/50 0/50 0/50 Mean	(0%) (0%) (0%) 0%	0/50 0/50 0/50 SD 0%	(0%) (0%) (0%)	Total	0/50 0/50 0/50 0/449 ((0%) (0%) (0%) 0%)	0/49 0/50 0/50 Mea	(0%) (0%) (0%) n 0%	0/50 0/50 0/50 SD	(0%) (0%) (0%) 0%
#Skin:														
Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	a, Basosq. Tumo ratoacanthoma,	or (M or E Trichoep	B), Basal Ce oithelioma	II Adenom	na,								
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		1/50	(2%)	0/49	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	,	Mean	0%	SD 0%		Total	3/449 (0.	67%)	Mean	0.67%	SD	1%
#Skin: Fibroma														
														(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0/0)
			(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)		0/50 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)	0/50 0/50	(0%)
		0/50	` ,		` '		` ,			` ,		` ,		` '
	Total	0/50 0/50 0/450 (0%)	(0%) (0%)	0/50 0/50 Mean	(0%) (0%)	0/50	(0%)	Total	0/50 0/50 0/449 ((0%) (0%) 0%)	0/50 0/50 Mea	(0%)	0/50	(0%) (0%)
		0/50 0/50 0/450 (0%)	(0%) (0%)	0/50 0/50 Mean	(0%) (0%)	0/50 0/50	(0%)		0/50 0/50	(0%) (0%) 0%)	0/50 0/50 Mea	(0%) (0%)	0/50 0/50	(0%) (0%)
		0/50 0/50 0/450 (0%)	(0%) (0%)	0/50 0/50 Mean	(0%) (0%) 0%	0/50 0/50	(0%)		0/50 0/50 0/449 ((0%) (0%) 0%)	0/50 0/50 Mea	(0%) (0%)	0/50 0/50	(0%) (0%)
#Skin:		0/50 0/50 0/450 (0%)	(0%) (0%)	0/50 0/50 Mean	(0%) (0%) 0%	0/50 0/50	(0%)		0/50 0/50 0/449 ((0%) (0%) 0%)	0/50 0/50 Mea	(0%) (0%)	0/50 0/50	(0%) (0%)
#Skin:		0/50 0/50 0/450 (0%) oma, Myxosarco	(0%) (0%)) oma, or Fi	0/50 0/50 Mean	(0%) (0%) 0% ocytoma	0/50 0/50 SD 0%	(0%) (0%)		0/50 0/50 0/449 ((0%) (0%) 0%)	0/50 0/50 Mea	(0%) (0%) n 0%	0/50 0/50 SD	(0%) (0%) 0%
Overall Incidence #Skin: Fibroma, Fibrosarcoma		0/50 0/50 0/450 (0%) oma, Myxosarco 2/50 0/50	(0%) (0%)) oma, or Fi (4%)	0/50 0/50 Mean ibrous Histi 0/50	(0%) (0%) 0% ocytoma (0%)	0/50 0/50 SD 0%	(0%) (0%) (6%)		0/50 0/50 0/449 ((0%) (0%) 0%) 	0/50 0/50 Mean 2/49	(0%) (0%) n 0% 	0/50 0/50 SD 1/50	(0%) (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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female			
#Skin: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%		
#Skin:		a, or Fibrous Histiocytom								
	•	2/50 (4%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	2/49 (4%)	1/50 (2%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	4/50 (8%)	6/50 (12%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)		
Overall Incidence	Total	7/450 (1.56%)	Mean 1.56%	SD 2.19%	Total	17/449 (3.79%)	Mean 3.79%	SD 3.93%		
#Skin: Fibrous Histiocytoma										
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	4/450 (0.89%)	Mean 0.89%	SD 1.45%	Total	2/449 (0.45%)	Mean 0.44%	SD 1.33%		
#Skin: Hemangioma										
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%		

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	6/449 (1.34%)	Mean 1.33%	SD 1.41%
#Skin: Keratoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (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
Route: INHALATION

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
≇Skin: Myxosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:						,		
Neurofibrosarcoma or	Schwannoma (n	nalignant or NOS)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma, Ne	eurofibroma, or \$	Schwannoma (benign, ma	alignant or NOS)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma								
Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	2/49 (4%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	6/50 (12%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	3/450 (0.67%)	Mean 0.67%	SD 1%	Total	15/449 (3.34%)	Mean 3.34%	SD 3.61%

^{*:} 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: INHALATION

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: AIR

Length of Study: CHRONIC

			Male			Female				
#Skin: Schwannoma Malignant	t									
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Carcino	ma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%		
	ma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),						
Squamous Cell Carcino	ma, Basal Cell C	Carcinoma, Basosquamou	us Tumor (malignant	or NOS) , 0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)		
Squamous Cell Carcino	ma, Basal Cell C	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Squamous Cell Carcino	ma, Basal Cell (0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		` ,	` ,	0/50 (0%) 0/50 (0%)		
Squamous Cell Carcino or Carcinoma	ma, Basal Cell C	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Squamous Cell Carcino or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Squamous Cell Carcino or Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Squamous Cell Carcino or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/450 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/449 (0.22%)	0/50 (0%) 0/50 (0%) Mean 0.22%	0/50 (0%) 0/50 (0%) SD 0.67%		
or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/450 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/449 (0.22%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0.22%	0/50 (0%) 0/50 (0%) SD 0.67%		

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Squamous Cell Papillo	ma or Papilloma							
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%
#Skin:								
	ma, Papilloma, S	quamous Cell Carcino	na or Keratoacanthoma					
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	3/449 (0.67%)	Mean 0.67%	SD 1%
#Skin:								
Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%
#Skin: Sebaceous Gland Adenoma								
71440114		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
	Total	0/450 (0%)	,	SD 0%	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female #Skin: Sebaceous Gland:** Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)SD 0.67% **Overall Incidence** Total 0/450 (0%) Mean 0% SD 0% Total 1/449 (0.22%) Mean 0.22% *Spleen: Hemangioma 0/50 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/445 (0%) Mean 0% SD 0% Total 0/445 (0%) Mean 0% SD 0% *Spleen: Hemangiosarcoma 0/50 1/49 0/49 (0%)0/49 (0%)(2%)0/49 (0%)1/49 (2%)(0%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)2/48 (4%)0/50 (0%)2/50 0/49 (0%)(0%)0/49 1/49 (2%)(4%)**Overall Incidence** Total 7/445 (1.57%) Mean 1.58% SD 1.7% 6/445 (1.35%) Mean 1.34% SD 1.42% Total *Spleen: **Mast Cell Tumor Malignant** 0/50 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

0/49

0/445 (0%)

Total

(0%)

0/49

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/48

0/445 (0%)

(0%)

.....

0/49

Mean 0%

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Forestomach: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	2/449 (0.45%)	Mean 0.44%	SD 0.88%
#Stomach, Forestomach: Squamous Cell Carcinoma								
·	•	1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	6/450 (1.33%)	Mean 1.33%	SD 1.73%	Total	6/449 (1.34%)	Mean 1.33%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma				•••••				
•		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	5/450 (1.11%)	Mean 1.11%	SD 1.45%	Total	4/449 (0.89%)	Mean 0.89%	SD 1.45%

^{*:} 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: INHALATION Vehicle: AIR

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				Male						F	emale		
#Stomach, Glandular: Adenoma													
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	1/50	(2%)
		0/50 (0%	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	2/449 (0.			0.44%	SD 0	.88%
#Stomach, Glandular: Carcinoma													
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	0/449 (n 0%	SD	
#Stomach, Glandular: Carcinoma or Adenoma													
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/49	(0%)	1/50	(2%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	0/450 (0%)	Mean		SD 0%		Total	2/449 (0.	,		0.44%	SD 0	
*Testes: Adenoma													
		1/50 (2%	%) 0/50	(0%)	1/50	(2%)							
		2/50 (4%	%) 0/50	(0%)	0/50	(0%)							
		2/50 (4%	%) 1/50	(2%)	0/50	(0%)							
Overall Incidence	Total	7/450 (1.56%)	Mean ·	1.56%	SD 1.679	%							

^{*:} 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: INHALATION Vehicle: AIR

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			Male			Female
Testes: Hemangioma					,	
-		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		1/50 (2%)	0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%		
*Testes: Hemangiosarcoma						
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%		
*Testes: Seratoli Tumor: Benigr						
_		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%		
*Testes: Sertoli Cell Tumor Mali						
	-	0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	0/450 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Thymus: Hemangioma								
		0/45 (0%)	0/44 (0%)	0/44 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/35 (0%)	0/42 (0%)	0/41 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/40 (0%)	0/41 (0%)	0/35 (0%)		0/45 (0%)	0/43 (0%)	0/44 (0%)
Overall Incidence	Total	0/367 (0%)	Mean 0%	SD 0%	Total	0/424 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/45 (0%)	0/44 (0%)	0/44 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/35 (0%)	0/42 (0%)	0/41 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/40 (0%)	0/41 (0%)	0/35 (0%)		0/45 (0%)	0/43 (0%)	0/44 (0%)
Overall Incidence	Total	0/367 (0%)	Mean 0%	SD 0%	Total	0/424 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/45 (0%)	0/44 (0%)	0/44 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/35 (0%)	1/42 (2%)	0/41 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/40 (0%)	0/41 (0%)	0/35 (0%)		0/45 (0%)	0/43 (0%)	0/44 (0%)
Overall Incidence	Total	1/367 (0.27%)	Mean 0.26%	SD 0.79%	Total	0/424 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	gnant, NOS							
		0/45 (0%)	0/44 (0%)	0/44 (0%)		0/49 (0%)	0/48 (0%)	0/49 (0%)
		0/35 (0%)	1/42 (2%)	0/41 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/40 (0%)	0/41 (0%)	0/35 (0%)		0/45 (0%)	0/43 (0%)	0/44 (0%)
Overall Incidence	Total	1/367 (0.27%)	Mean 0.26%	SD 0.79%	Total	0/424 (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: INHALATION Vehicle: AIR

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			Male				Female	
*Thyroid Gland: Adenoma								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	0/447 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/447 (0.22%)	Mean 0.22%	SD 0.67%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/439 (0%)	Mean 0%	SD 0%	Total	1/447 (0.22%)	Mean 0.22%	SD 0.67%
*Thyroid Gland: Follicular Co								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		1/50 (2%)	1/49 (2%)	0/49 (0%)
		0/47 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		1/48 (2%)	1/49 (2%)	0/48 (0%)		0/49 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	5/439 (1.14%)	Mean 1.12%	SD 2.03%	Total	7/447 (1.57%)	Mean 1.56%	SD 2.19%

^{*:} 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: INHALATION Vehicle: AIR

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			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	ell:							
		0/50 (0%)	0/48 (0%)	0/49 (0%)		1/50 (2%)	0/49 (0%)	0/49 (0%)
		1/47 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/439 (0.23%)	Mean 0.24%	SD 0.71%	Total	2/447 (0.45%)	Mean 0.44%	SD 0.88%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		2/50 (4%)	1/49 (2%)	0/49 (0%)
		1/47 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	3/50 (6%)
		1/48 (2%)	1/49 (2%)	0/48 (0%)		0/49 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	6/439 (1.37%)	Mean 1.36%	SD 2.01%	Total	9/447 (2.01%)	Mean 2%	SD 2.24%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Tongue: Squamous Cell Carcinom	na							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	1/449 (0.22%)	Mean 0.23%	SD 0.68%
#Tongue: Squamous Cell Carcinom								
•	•	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/450 (0.44%)	Mean 0.44%	SD 0.88%	Total	1/449 (0.22%)	Mean 0.23%	SD 0.68%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/450 (0.22%)	Mean 0.22%	SD 0.67%	Total	0/449 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Tooth: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/49 (0%)
		1/48 (2%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	2/444 (0.45%)	Mean 0.45%	SD 0.9%	Total	0/439 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/444 (0%)	Mean 0%	SD 0%	Total	0/439 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
-		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/444 (0%)	Mean 0%	SD 0%	Total	0/439 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: **Papilloma** 0/50 (0%)0/49 (0%)0/48 (0%)0/48 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/49 (0%)1/48 (2%)0/49 (0%)1/50 (2%)0/50 (0%)0/48 (0%)0/48 (0%)**Overall Incidence** Total 2/444 (0.45%) Mean 0.45% SD 0.9% Total 0/439 (0%) Mean 0% SD 0% *Urinary Bladder: Sarcoma 0/50 (0%)0/49 (0%)0/48 (0%)0/48 (0%)0/49 (0%)0/49 (0%)(0%)0/49 0/50 (0%)0/50 (0%)0/50 0/48 (0%)0/50 (0%)(0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/48 (0%)**Overall Incidence** Total 0/444 (0%) Mean 0% SD 0% Total 0/439 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)(2%)0/50 1/50 0/50 (0%)(0%)**Overall Incidence** 2/449 (0.45%) Mean 0.44% SD 0.88% Total **#Uterus:** Carcinoma 3/50 (6%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/449 (1.11%) Mean 1.12% SD 2.03%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Route: INHALATIO Vehicle: AIR

Length of Study: CHRONIC

	Male		Female	
fUterus: Deciduoma Benign				
		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
	Total	0/449 (0%)	Mean 0%	
tUterus: Hemangioma				
•		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%
Uterus: Hemangiosarcoma				
_		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/449 (0.67%)	Mean 0.67%	SD 1%
Uterus: Leiomyoma				
• • •		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/449 (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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male		Female	
Uterus: Leiomyosarcoma				
		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%
Uterus: Polyp Stromal				
		3/50 (6%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	3/50 (6%)	3/50 (6%)
		0/50 (0%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	14/449 (3.12%)	Mean 3.11%	SD 2.67%
Uterus: Sarcoma				•••••
		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/449 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal				•••••
		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/449 (0.67%)	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: INHALATION Vehicle: AIR

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			Male					Female	
#Uterus: Sarcoma Stromal or Poly	p Stromal								
							3/50 (6%)	0/49 (0%)	1/50 (2%)
							0/50 (0%)	4/50 (8%)	3/50 (6%)
							1/50 (2%)	3/50 (6%)	2/50 (4%)
Overall Incidence						Total	17/449 (3.79%)	Mean 3.78%	SD 2.91%
#Uterus: Schwannoma Malignant									
_							0/50 (0%)	0/49 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/449 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinom									
•							0/50 (0%)	0/49 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
							0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence						Total	0/449 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		•••••					•••••		
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	, ,	Total	0/449 (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: INHALATION Vehicle: AIR

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			Male				Female	
#Zymbal's Gland:		,						
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/450 (0%)	Mean 0%	SD 0%	Total	0/449 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Strain: B6C3F1/N Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	058813804	09/14/99	730	50(1)	44(717)	46.0	Benzophenone
Battelle Columbus Laboratory	055611104	09/24/97	728	100(1)	91(705)	46.0	trans-Cinnamaldehyde
Battelle Columbus Laboratory	055634804	06/19/96	727	100(1)	91(707)	48.4	Citral
Battelle Columbus Laboratory	058812004	01/04/96	733	50(1)	40(705)	46.9	p,p'-Dichlorodiphenyl sulfone
Southern Research Institute	059201206	07/29/98	729	50(1)	43(706)	46.8	2-Methylimidazole
Southern Research Institute	059201306	02/03/00	729	50(1)	45(717)	46.1	4-Methylimidazole
Southern Research Institute	050520309	02/20/96	729	60(1)	52(712)	48.0	o-Nitrotoluene
Southern Research Institute	050520508	11/14/95	729	50(1)	46(722)	47.4	p-Nitrotoluene
					Female		
Battelle Columbus Laboratory	058813804	09/13/99	729	50(5)	40(706)	46.2	Benzophenone
Battelle Columbus Laboratory	055611104	09/25/97	733	100(5)	84(711)	45.6	trans-Cinnamaldehyde
Battelle Columbus Laboratory	055634804	06/20/96	733	99(5)	81(695)	47.7	Citral
Battelle Columbus Laboratory	058812004	01/05/96	734	50(5)	42(717)	46.5	p,p'-Dichlorodiphenyl sulfone
Southern Research Institute	059201206	07/29/98	732	50(5)	46(720)	38.8	2-Methylimidazole
Southern Research Institute	059201306	02/03/00	734	50(5)	42(706)	45.6	4-Methylimidazole
Southern Research Institute	050520309	02/20/96	731	60(5)	52(708)	46.6	o-Nitrotoluene
Southern Research Institute	050520508	11/14/95	732	50(5)	46(727)	41.4	p-Nitrotoluene

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Strain: B6C3F1/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

ontrol Animal Groups Report Date: 06/03/2022

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			Male				Female	
#All Organs: Benign Tumors								
		27/50 (54%)	37/100 (37%)	40/100 (40%)		15/50 (30%)	32/100 (32%)	28/99 (28%)
		16/50 (32%)	23/50 (46%)	26/50 (52%)		15/50 (30%)	13/50 (26%)	18/50 (36%)
		30/60 (50%)	25/50 (50%)			21/60 (35%)	17/50 (34%)	
Overall Incidence	Total	224/510 (43.92%)	Mean 45.13%	SD 7.92%	Total	159/509 (31.24%)	Mean 31.41%	SD 3.46%
#All Organs: Malignant Tumors								
		17/50 (34%)	28/100 (28%)	32/100 (32%)		16/50 (32%)	46/100 (46%)	24/99 (24%)
		21/50 (42%)	20/50 (40%)	15/50 (30%)		12/50 (24%)	12/50 (24%)	20/50 (40%)
		26/60 (43%)	14/50 (28%)			16/60 (27%)	9/50 (18%)	
Overall Incidence	Total	173/510 (33.92%)	Mean 34.67%	SD 6.27%	Total	155/509 (30.45%)	Mean 29.36%	SD 9.39%
#All Organs: Malignant and Benign 1								
		38/50 (76%)	57/100 (57%)	55/100 (55%)		25/50 (50%)	62/100 (62%)	45/99 (45%)
		32/50 (64%)	32/50 (64%)	34/50 (68%)		23/50 (46%)	23/50 (46%)	29/50 (58%)
		45/60 (75%)	31/50 (62%)			33/60 (55%)	21/50 (42%)	
Overall Incidence	Total	324/510 (63.53%)	Mean 65.12%	SD 7.61%	Total	261/509 (51.28%)	Mean 50.56%	SD 7.04%
#All Organs: Hemangioma								
-		0/50 (0%)	3/100 (3%)	2/100 (2%)		0/50 (0%)	4/100 (4%)	1/99 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	0/50 (0%)			3/60 (5%)	1/50 (2%)	
Overall Incidence	Total	6/510 (1.18%)	Mean 0.83%	SD 1.21%	Total	9/509 (1.77%)	Mean 1.5%	SD 2%

^{*:} 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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
#All Organs: Hemangiosarcoma								
		3/50 (6%)	2/100 (2%)	3/100 (3%)		1/50 (2%)	1/100 (1%)	0/99 (0%)
		3/50 (6%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		4/60 (7%)	1/50 (2%)			0/60 (0%)	1/50 (2%)	
Overall Incidence	Total	19/510 (3.73%)	Mean 3.96%	SD 2%	Total	8/509 (1.57%)	Mean 1.88%	SD 2.17%
#All Organs: Hemangiosarcoma or H								
		3/50 (6%)	5/100 (5%)	5/100 (5%)		1/50 (2%)	5/100 (5%)	1/99 (1%)
		3/50 (6%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	3/50 (6%)
		5/60 (8%)	1/50 (2%)			3/60 (5%)	2/50 (4%)	
Overall Incidence	Total	25/510 (4.9%)	Mean 4.79%	SD 2.13%	Total	17/509 (3.34%)	Mean 3.38%	SD 2.13%
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	2/100 (2%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/60 (2%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	4/510 (0.78%)	Mean 0.96%	SD 1.03%	Total	3/509 (0.59%)	Mean 0.5%	SD 0.93%
#All Organs: Malignant Lymphoma:		nphocytic, Mixed, NOS, o						
• , ,	• • •	2/50 (4%)	8/100 (8%)	4/100 (4%)		8/50 (16%)	23/100 (23%)	7/99 (7%)
		3/50 (6%)	2/50 (4%)	3/50 (6%)		6/50 (12%)	6/50 (12%)	7/50 (14%)
		3/60 (5%)	3/50 (6%)	(,		8/60 (13%)	3/50 (6%)	` ,
Overall Incidence	Total	28/510 (5.49%)	Mean 5.38%	SD 1.41%	Total	68/509 (13.36%)	Mean 12.93%	SD 5.29%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#All Organs: Mesothelioma: Benign,	Malignant, NOS							
,	,	0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Maligna								
•		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		1/50 (2%) 1/50 (2%) 0/60 (0%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%)	Mean 0%	SD 0%	Total	4/509 (0.79%)	Mean 0.88%	SD 0.99%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female
#All Organs: Osteosarcoma or Osteoma	a					
		0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	100 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/60 (0%)	1/100 (1%) 0/99 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0% SE		Total 4/509 (0.79%)	Mean 0.88% SD 0.99%
*Adrenal Cortex: Adenoma						
		0/50 (0%) 0/49 (0%) 2/60 (3%)	` '	100 (2%) 4/50 (8%)	1/50 (2%) 0/50 (0%) 1/59 (2%)	0/100 (0%) 0/99 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	13/507 (2.56%)	Mean 2.68% SE		Total 2/508 (0.39%)	Mean 0.46% SD 0.86%
*Adrenal Cortex: Carcinoma						
		0/50 (0%) 0/49 (0%) 0/60 (0%)	` '	100 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 0/99 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/507 (0%)	` '	0%	Total 0/508 (0%)	Mean 0% SD 0%
*Adrenal Cortex: Sarcoma						
		0/50 (0%) 0/49 (0%) 0/60 (0%)	` '	100 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/59 (0%)	0/100 (0%) 0/99 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/507 (0%)	` '	0 0%	Total 0/508 (0%)	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	enign							
		0/50 (0%) 0/49 (0%)	0/99 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/99 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/30 (0 /8)		0/59 (0%)	0/50 (0%)	0/30 (0 /8)
Overall Incidence	Total	0/506 (0%)	Mean 0%	SD 0%	Total	1/507 (0.2%)	Mean 0.25%	SD 0.71%
*Adrenal Medulla: Pheochromocytoma Ma	alignant							
•		0/50 (0%)	0/99 (0%)	0/99 (0%)		0/50 (0%)	1/99 (1%)	1/99 (1%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/49 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/506 (0%)	Mean 0%	SD 0%	Total	4/507 (0.79%)	Mean 0.75%	SD 0.89%
*Adrenal Medulla: Pheochromocytoma: Bo	enign, Complex	., Malignant, NOS						
•		0/50 (0%)	0/99 (0%)	0/99 (0%)		1/50 (2%)	1/99 (1%)	1/99 (1%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/49 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/506 (0%)	Mean 0%	SD 0%	Total	5/507 (0.99%)	Mean 1%	SD 0.93%
*Bone Marrow: Hemangiosarcoma								
· ·		0/49 (0%)	0/100 (0%)	0/100 (0%)		1/50 (2%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	2/509 (0.39%)	Mean 0.5%	SD 0.93%	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%

^{*:} 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: ORAL

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Report Date: 06/03/2022

Length of Study: CHRONIC

Vehicle: FEED

			Male				Female	
*Bone Marrow: Mast Cell Tumor Malign:	ant							
		0/49 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	3/509 (0.59%)	Mean 0.58%	SD 0.85%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Bone: Chondroma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Bone: Fibrosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/99 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.13%	SD 0.36%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Bone: Osteoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) SD 0% #Bone: Osteosarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/100 (1%)0/99 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 3/509 (0.59%) Mean 0.62% SD 0.92% #Bone: Osteosarcoma or Osteoma 0/100 0/100 0/99 0/50 (0%)(0%)(0%)0/50 (0%)1/100 (1%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** 0/510 (0%) Mean 0% SD 0% 3/509 (0.59%) Mean 0.62% SD 0.92% Total Total #Bone: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/100 (0%)0/99 0/50 (0%)(0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% Total

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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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 208

			Male				Female	
*Brain: Meningioma Malignant								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, N	Malignant, NOS							
	-	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Bei	nign							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Ma	lignant							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
*Brain:	omo or Astron	tomo						,
Oligodendroglioma, Glic	oma, or Astrocy	0/50 (0%)	0/100 (0%)	0/100	(0%)	0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)		(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	0/00	(070)	0/60 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Brain: Sarcoma					•••••			
		0/50 (0%)	0/100 (0%)	0/100	(0%)	0/50 (0%)	0/99 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100	(0%)	0/50 (0%)	0/99 (0%)	0/95 (0%)
		0/50 (0%)	0/50 (0%)	0/50	(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/58 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/502 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100	(0%)	0/50 (0%)	1/99 (1%)	1/95 (1%)
		0/50 (0%)	0/50 (0%)		(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)		• ,	0/58 (0%)	0/50 (0%)	,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	2/502 (0.4%)	Mean 0.26%	SD 0.48%

^{*:} 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: ORAL Vehicle: FEED Page: 210 Report Date: 06/03/2022

Mean 0%

SD 0%

Male **Female** *Clitoral/Preputial Gland: Carcinoma or Adenoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/99 (1%)1/95 (1%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/58 (0%)0/50 (0%)SD 0.48% **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 2/502 (0.4%) Mean 0.26% *Clitoral/Preputial Gland: Hemangiosarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/99 (0%)0/95 (0%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/58 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/502 (0%) Mean 0% SD 0% *Clitoral/Preputial Gland: **Squamous Cell Carcinoma** 0/50 0/100 (0%)0/100 0/99 0/95 (0%)(0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/60 0/50 0/58 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/502 (0%) Mean 0% SD 0% #Coagulating Gland: Adenoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)

SD 0%

Total

0/509 (0%)

Total

0/510 (0%)

.....

Mean 0%

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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Ear: **Neural Crest Tumor, Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/60 (2%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.21% SD 0.59% Total 0/509 (0%) Mean 0% SD 0% *Epididymis: Hemangiosarcoma 0/50 (0%)1/100 (1%)0/100 (0%)(0%)0/50 0/50 0/50 (0%)(0%)(0%)(0%)0/60 0/50 **Overall Incidence** Total 1/510 (0.2%) Mean 0.12% SD 0.35% *Epididymis: Sarcoma 0/50 0/100 0/100 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 **Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% #Eye: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0%

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^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Gallbladder: Adenoma 0/45 (0%)0/100 (0%)0/100 (0%)0/49 (0%)0/100 (0%)0/99 (0%)(0%) 0/49 0/49(0%)0/46 0/44 (0%)(0%)0/49 (0%)(0%)0/54 (0%)0/49 (0%)0/54 (0%)0/49 (0%)Mean 0% **Overall Incidence** Total 0/487 (0%) Mean 0% SD 0% Total 0/496 (0%) SD 0% *Gallbladder: Sarcoma 0/45 (0%)0/100 (0%)0/100 (0%)0/49 (0%)0/100 (0%)0/99 (0%)0/49 (0%)0/46 (0%)0/44 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/54 (0%)0/49 (0%)0/54 (0%)0/49 (0%)**Overall Incidence** Total 0/487 (0%) Mean 0% SD 0% Total 0/496 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 4/100 3/99 6/50 (12%)8/100 (8%)(4%)1/50 (2%)2/100 (2%)(3%)5/50 (10%)9/50 (18%)4/50 (8%) 3/50 (6%)3/50 (6%)6/50 (12%)(7%)(7%)4/60 3/50 (6%)4/60 2/50 (4%)**Overall Incidence** 43/510 (8.43%) Mean 9.08% SD 4.35% 24/509 (4.72%) Mean 5.21% SD 3.3% Total Total #Harderian Gland: Carcinoma 1/50 (2%)0/100 (0%)0/100 (0%)(0%)(1%)1/99 (1%)0/50 1/100 0/50 (0%) 1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/60 (2%)0/50 (0%)1/60 (2%)0/50 (0%)SD 0.88% **Overall Incidence** Total 4/510 (0.78%) Mean 0.96% SD 1.03% Total 5/509 (0.98%) Mean 0.96%

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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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	8/100 (8%)	4/100 (4%)		1/50 (2%)	3/100 (3%)	4/99 (4%)
		5/50 (10%)	10/50 (20%)	5/50 (10%)		3/50 (6%)	4/50 (8%)	7/50 (14%)
		5/60 (8%)	3/50 (6%)			5/60 (8%)	2/50 (4%)	
Overall Incidence	Total	47/510 (9.22%)	Mean 10.04%	SD 5%	Total	29/509 (5.7%)	Mean 6.17%	SD 3.89%
*Heart: Hemangiosarcoma								
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/508 (0%)	Mean 0%	SD 0%
*Heart: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/508 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
_		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/508 (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: ORAL Vehicle: FEED Page: 214 Report Date: 06/03/2022

			Male				Female	
#Intestine Large: Cecum: Carcinoma						,		
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Cecum: **Polyp Adenomatous** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Mean 0% Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) SD 0% #Intestine Large: Colon/Rectum: Leiomyoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Adenoma 0/50 0/100 0/100 0/99 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% 0/509 (0%) Mean 0% SD 0% Total #Intestine Small: Duodenum: Carcinoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (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: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%) 1/60 (2%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.21%	SD 0.59%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	2/100 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 1/50 (2%)
Overall Incidence	Total	4/510 (0.78%)	Mean 0.62%	SD 0.92%	Total	2/509 (0.39%)	Mean 0.5%	SD 0.93%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date: 06/03/2022

Length of Study: CHRONIC

Vehicle: FEED

			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/100 (1%)	3/100 (3%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/60 (3%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	7/510 (1.37%)	Mean 1.17%	SD 1.43%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
fintestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Intestine Small: Site Uns Carcinoma	specified:							
		0/50 (0%) 0/50 (0%) 2/60 (3%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	3/100 (3%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	7/510 (1.37%)	Mean 1.17%	SD 1.43%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Intestine Small: Site Uns Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 2/60 (3%)	1/100 (1%) 1/50 (2%) 0/50 (0%)	3/100 (3%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	7/510 (1.37%)	Mean 1.17%	SD 1.43%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Intestine Small: Site Uns Hemangioma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Hemangiosarcoma	specified:							
-		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	1/60 (2%) 1/510 (0.2%)	0/50 (0%) Mean 0.21%	SD 0.59%	Total	0/60 (0%) 0/509 (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: 06/03/2022

Species: MICE
Strain: B6C3F1/N

Route: ORAL Vehicle: FEED

			Male				Female	
#Intestine Small: Site Unspe Polyp Adenomatous	cified:							
		0/50 (0%) 0/50 (0%)	1/100 (1%) 1/50 (2%)	2/100 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 1/50 (2%)
Overall Incidence	Total	0/60 (0%) 4/510 (0.78%)	0/50 (0%) Mean 0.62%	SD 0.92%	Total	0/60 (0%) 2/509 (0.39%)	0/50 (0%) Mean 0.5%	SD 0.93%
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/49 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/49 (0%)
Overall Incidence	Total	0/59 (0%) 1/508 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%	Total	0/60 (0%) 0/507 (0%)	0/49 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/49 (0%)		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/49 (0%)
Overall Incidence	Total	0/59 (0%) 0/508 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 1/507 (0.2%)	0/49 (0%) Mean 0.25%	SD 0.71%
*Islets, Pancreatic: Carcinoma or Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/49 (0%)		0/50 (0%) 1/50 (2%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/49 (0%)
Overall Incidence	Total	0/59 (0%) 1/508 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%	Total	0/60 (0%) 1/507 (0.2%)	0/49 (0%) Mean 0.25%	SD 0.71%

^{*:} 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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/58 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	0/508 (0%)	Mean 0%	SD 0%	Total	0/506 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/58 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	1/508 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/506 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/58 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	1/508 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/506 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/58 (0%)	0/50 (0%)	. ,		0/59 (0%)	0/49 (0%)	. ,
Overall Incidence	Total	0/508 (0%)	Mean 0%	SD 0%	Total	0/506 (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: ORAL Vehicle: FEED Page: 221

Report Date: 06/03/2022

			Male				Female	
*Liver: Cholangiocarcinoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
		0/50 (0%)	0/100 (0%)	2/100 (2%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	1/50 (2%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	7/510 (1.37%)	Mean 1.46%	SD 1.4%	Total	0/507 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.21%	SD 0.59%	Total	0/507 (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: ORAL Vehicle: FEED sups Report Date: 06/03/2022

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			Male				Female	
*Liver: Hepatocellular Adenoma								
		11/50 (22%)	14/100 (14%)	20/100 (20%)		5/50 (10%)	7/99 (7%)	8/99 (8%)
		6/50 (12%)	7/50 (14%)	17/50 (34%)		4/50 (8%)	3/50 (6%)	4/50 (8%)
Overall Incidence	Tatal	18/60 (30%)	14/50 (28%)	CD 0.040/	Tatal	7/60 (12%)	6/49 (12%)	CD 0.040/
	Total	107/510 (20.98%)	Mean 21.75%	SD 8.24%	Total	44/507 (8.68%)	Mean 8.88%	SD 2.21%
*Liver: Hepatocellular Carcinom	a							
-		8/50 (16%)	13/100 (13%)	13/100 (13%)		0/50 (0%)	3/99 (3%)	4/99 (4%)
		9/50 (18%)	4/50 (8%)	10/50 (20%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
		12/60 (20%)	8/50 (16%)			2/60 (3%)	3/49 (6%)	
Overall Incidence	Total	77/510 (15.1%)	Mean 15.5%	SD 4.07%	Total	18/507 (3.55%)	Mean 3.57%	SD 2.01%
*Liver: Hepatocellular Carcinom	a or Hepatob	lastoma						
·	•	8/50 (16%)	13/100 (13%)	13/100 (13%)		0/50 (0%)	3/99 (3%)	4/99 (4%)
		9/50 (18%)	4/50 (8%)	10/50 (20%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
		13/60 (22%)	8/50 (16%)			2/60 (3%)	3/49 (6%)	
Overall Incidence	Total	78/510 (15.29%)	Mean 15.71%	SD 4.37%	Total	18/507 (3.55%)	Mean 3.57%	SD 2.01%
*Liver: Hepatocellular Carcinom			•••••			•••••		
		18/50 (36%)	26/100 (26%)	28/100 (28%)		5/50 (10%)	9/99 (9%)	12/99 (12%)
		15/50 (30%)	10/50 (20%)	23/50 (46%)		6/50 (12%)	4/50 (8%)	5/50 (10%)
		27/60 (45%)	20/50 (40%)	, ,		9/60 (15%)	8/49 (16%)	, ,
Overall Incidence	Total	167/510 (32.75%)	Mean 33.88%	SD 9.39%	Total	58/507 (11.44%)	Mean 11.57%	SD 2.9%

^{*:} 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: ORAL Vehicle: FEED Page: 223

Report Date: 06/03/2022

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver:								
Hepatocellular Carcino	ma, Hepatocell	ular Adenoma, or Hepatol	blastoma					
		18/50 (36%) 15/50 (30%)	26/100 (26%) 10/50 (20%)	28/100 (28%) 23/50 (46%)		5/50 (10%) 6/50 (12%)	9/99 (9%) 4/50 (8%)	12/99 (12%) 5/50 (10%)
		28/60 (47%)	20/50 (40%)	,		9/60 (15%)	8/49 (16%)	, ,
Overall Incidence	Total	168/510 (32.94%)	Mean 34.08%	SD 9.68%	Total	58/507 (11.44%)	Mean 11.57%	SD 2.9%
*Liver:								
Hepatocholangiocarcin	oma							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	2/50 (4%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.5%	SD 1.41%	Total	0/507 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignar								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/49 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/507 (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: ORAL Vehicle: FEED

DRAL

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Report Date: 06/03/2022

			Male				Female	
*Lung: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%
				•••••				
*Lung: Alveolar/Bronchiolar A	Adenoma							
		14/50 (28%)	9/100 (9%)	12/100 (12%)		0/50 (0%)	3/100 (3%)	5/99 (5%)
		6/50 (12%)	11/50 (22%)	8/50 (16%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
		9/60 (15%)	6/50 (12%)			2/60 (3%)	5/50 (10%)	
Overall Incidence	Total	75/510 (14.71%)	Mean 15.75%	SD 6.3%	Total	19/509 (3.73%)	Mean 3.67%	SD 3.81%
*Lung: Alveolar/Bronchiolar C	Carcinoma							
		2/50 (4%)	7/100 (7%)	9/100 (9%)		1/50 (2%)	2/100 (2%)	6/99 (6%)
		7/50 (14%)	6/50 (12%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		5/60 (8%)	2/50 (4%)			3/60 (5%)	1/50 (2%)	
Overall Incidence	Total	40/510 (7.84%)	Mean 7.79%	SD 3.81%	Total	16/509 (3.14%)	Mean 2.88%	SD 2.49%
*Lung: Alveolar/Bronchiolar C	Carcinoma or Al	veolar/Bronchiolar Adeno	ma			•••••		
7.11 COIGH, 21 CHOHIOIGH C	Jan 01110111111 01 711	16/50 (32%)	14/100 (14%)	20/100 (20%)		1/50 (2%)	5/100 (5%)	11/99 (11%)
		13/50 (26%)	14/50 (28%)	9/50 (18%)		0/50 (0%)	4/50 (8%)	3/50 (6%)
		14/60 (23%)	8/50 (16%)	()		5/60 (8%)	6/50 (12%)	(-,0)
Overall Incidence	Total	108/510 (21.18%)	Mean 22.17%	SD 6.25%	Total	35/509 (6.88%)	Mean 6.56%	SD 4.18%

^{*:} 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: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male				Female	
*Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/100 (1%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	0/509 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma		•••••		•••••				
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (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: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
•		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
#Lymph Node, Mesenteric: Hemangioma						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	` ,	(0%) (0%)	0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0% SD 0%		0/509 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma						
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	, ,	(0%) (0%)	0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0% SD 0%		0/509 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligi						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	. ,	(0%) (0%)	0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12% SD 0.35%	Total 0	0/509 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma						
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/100 (0%) 0/50 (0%) 0/50 (0%) 1/60 (2%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	0/50 (0%) Mean 0% SD 0%	Total 1/	1/60 (2%) 0/50 (0%) /509 (0.2%) Mean 0.21%	SD 0.59%

^{*:} 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: ORAL Vehicle: FEED Page: 228

Report Date: 06/03/2022

			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%
				30 0%				
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		1/50 (2%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	3/509 (0.59%)	Mean 0.75%	SD 1.04%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		1/50 (2%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	3/509 (0.59%)	Mean 0.75%	SD 1.04%
#Mammary Gland: Fibroma, Fibroadenoma	ı or Adenoma							
·		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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

Vehicle: FEED

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Report Date: 06/03/2022

Route: ORAL

			Male				Female	
#Mammary Gland:						,		,
Fibroma, Fibroadenoma	, Carcinoma, or	· Adenoma						
		0/50 (0%)	0/100 (0%)	0/100 (0%)		1/50 (2%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	3/509 (0.59%)	Mean 0.75%	SD 1.04%
#Mesentery: Fibrosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Mesentery: Fibrous Histiocytoma								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma								
_		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	. ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

			Male				Female	
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma						•••••		
·		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma						•••••		
		0/50 (0%) 0/50 (0%)	0/96 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/506 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/508 (0%)	0/50 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
*Nose: Hemangioma							
-		0/50 (0%)	0/96 (0%)	0/100 (0%)	0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/506 (0%)	Mean 0%	SD 0%	Total 0/508 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma							
		0/50 (0%)	0/96 (0%)	0/100 (0%)	0/50 (0%)	0/99 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)		0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/506 (0%)	Mean 0%	SD 0%	Total 0/508 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar						
	-	0/50 (0%)	1/100 (1%)	0/100 (0%)	0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)		0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	Total 0/509 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva):					
•		0/50 (0%)	0/100 (0%)	0/100 (0%)	0/50 (0%)	0/100 (0%)	1/99 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)		0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total 1/509 (0.2%)	Mean 0.13%	SD 0.36%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)1/100 (1%) 0/100 (0%)0/50 (0%)0/100 (0%)1/99 (1%)(0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.12% SD 0.35% Total 1/509 (0.2%) Mean 0.13% SD 0.36% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 (0%)0/50 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% **#Oral Mucosa:** Squamous Cell Papilloma 0/100 0/100 0/99 0/50 (0%)1/100 (1%)(0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/60 0/50 (0%)0/60 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.12% SD 0.35% 0/509 (0%) Mean 0% SD 0% Total *Ovary: Cystadenoma 1/49 (2%)2/100 (2%)3/99 (3%)2/50 (4%)0/50 (0%)2/48 (4%)1/59 (2%)3/48 (6%)SD 1.91% **Overall Incidence** Total 14/503 (2.78%) Mean 2.9%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Male	•		Female	
*Ovary: Granulosa Cell Tumor Benign				
		0/49 (0%)	1/100 (1%)	1/99 (1%)
		1/50 (2%)	0/50 (0%)	2/48 (4%)
Overall Incidence	Total	0/59 (0%) 6/503 (1.19%)	1/48 (2%) Mean 1.28%	SD 1.44%
		` ,		
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/49 (0%)	1/100 (1%)	1/99 (1%)
		1/50 (2%)	0/50 (0%)	2/48 (4%)
		0/59 (0%)	1/48 (2%)	
Overall Incidence	Total	6/503 (1.19%)	Mean 1.28%	SD 1.44%
'Ovary: Hemangioma				
·		0/49 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/59 (0%)	1/48 (2%)	
Overall Incidence	Total	2/503 (0.4%)	Mean 0.39%	SD 0.77%
'Ovary: Hemangiosarcoma				
······································		0/49 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/59 (0%)	0/48 (0%)	,
Overall Incidence	Total	1/503 (0.2%)	Mean 0.12%	SD 0.35%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male	Female	
Ovary: Luteoma			
		0/49 (0%) 2/100 (2%) 1/9	` '
		0/50 (0%) 0/50 (0%) 0/46 2/59 (3%) 0/48 (0%)	3 (0%)
Overall Incidence	Total	, ,	1.28%
'Ovary: Teratoma Benign			
-		0/49 (0%) 0/100 (0%) 0/99	` '
		0/50 (0%) 0/50 (0%) 0/40	3 (0%)
Overall Incidence	Total	0/59 (0%) 0/48 (0%) 0/503 (0%) Mean 0% S	D 0%
	Ιοια		
Ovary: Thecoma Benign			
		0/49 (0%) 1/100 (1%) 0/99	` '
		0/50 (0%) 0/50 (0%) 0/4i 0/59 (0%) 0/48 (0%)	3 (0%)
Overall Incidence	Total	1/503 (0.2%) Mean 0.12% SD	0.35%
'Ovary: Tubulostromal Adenoma			
		1/49 (2%) 0/100 (0%) 0/9	9 (0%)
		0/50 (0%) 0/50 (0%) 0/40	3 (0%)
Overell has dense	Tatal	0/59 (0%) 0/48 (0%)	0.700/
Overall Incidence	Total	,	0.72%

^{*:} 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: ORAL Vehicle: FEED Page: 235

Report Date: 06/03/2022

Length of Study: CHRONIC

Male **Female** *Pancreas: Hemangioma 0/50 (0%)1/100 (1%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 0/49 (0%)0/59 (0%)0/50 (0%)0/60 (0%)0/49 (0%)**Overall Incidence** Total 1/508 (0.2%) Mean 0.12% SD 0.35% Total 0/507 (0%) Mean 0% SD 0% *Pancreas: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%)0/49 0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/59 (0%)0/50 0/60 (0%)0/49 (0%)0/507 (0%) **Overall Incidence** Total 0/508 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/98 8/97 0/48 (0%)0/98 (0%)(0%)2/50 (4%)11/97 (11%)(8%)0/49 (0%)0/49 (0%)0/49 (0%)3/48 (6%)1/50 (2%)5/49 (10%)1/53 (2%)3/58 0/46 (0%)(5%)0/45 (0%)**Overall Incidence** Total 1/490 (0.2%) Mean 0.24% SD 0.67% Total 33/494 (6.68%) Mean 5.9% SD 3.93% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/48 (0%)0/98 (0%)0/98 (0%)0/50 (0%)0/97 (0%)0/97 (0%)0/49 (0%)0/49 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/49 (0%)0/53 (0%)0/46 (0%)0/58 (0%)0/45 (0%)**Overall Incidence** Total 0/490 (0%) Mean 0% SD 0% Total 0/494 (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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/48 (0%)0/98 (0%)0/98 (0%)2/50 (4%)11/97 (11%)8/97 (8%)0/49(0%)0/49 (0%)0/49(0%)3/48 (6%)1/50 (2%)(10%)1/53 (2%)0/46 (0%)3/58 (5%)0/45 (0%)**Overall Incidence** Total 1/490 (0.2%) Mean 0.24% SD 0.67% Total 33/494 (6.68%) Mean 5.9% SD 3.93% *Pituitary Gland: Pars Intermedia: Adenoma 0/48 (0%)1/98 (1%)0/98 (0%)0/50 (0%)0/97 (0%)(2%)0/49 (0%)0/49 (0%)0/49 (0%)1/48 (2%)0/50 (0%)0/49 (0%)0/53 (0%)0/46 (0%)0/58 (0%)0/45 (0%)Mean 0.13% **Overall Incidence** Total 1/490 (0.2%) SD 0.36% Total 3/494 (0.61%) Mean 0.52% SD 0.96% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/98 2/97 0/48 (0%)1/98 (1%)(0%)0/50 (0%)0/97 (0%)(2%)0/49 (0%)0/49 (0%)0/49 (0%)1/48 (2%)0/50 (0%)0/49 (0%)0/53 (0%)(0%)0/46 (0%)0/58 0/45 (0%)**Overall Incidence** Total 1/490 (0.2%) Mean 0.13% SD 0.36% 3/494 (0.61%) Mean 0.52% SD 0.96% Total *Prostate: Adenoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/49 (0%) 0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0%

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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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/60 (0%)	0/50 (0%)					
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%				
Prostate: Hemangiosarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)				
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		0/60 (0%)	0/50 (0%)					
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/504 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/98 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/504 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%				
#Seminal Vesicle: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)				
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma			•••••					
·		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/60 (2%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.21%	SD 0.59%
#Skeletal Muscle: Hemangiosarcoma								
-		1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 2/510 (0.39%)	0/50 (0%) Mean 0.5%	SD 0.93%	Total	0/60 (0%) 0/509 (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: 06/03/2022

Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Skeletal Muscle: Rhabdomyosarcoma or								
·	•	0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	1/100 (1%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	1/99 (1%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.13%	SD 0.36%
#Skin: Basal Cell Adenoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (0%)	0/50 (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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benian						
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, B	asosquamous T	umor Benign, or Trichoe <mark>j</mark>	oithelioma					
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or N	OS)					
	•	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	, ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 0/100 (0%)0/100 (0%)0/50 0/99 (0%)(0%)(0%)0/100 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/60 (0%)0/50 (0%) 0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosg. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (0%)0/50 1/100 (1%)0/100 (0%)0/50 (0%)1/100 (1%)0/99 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)1/50 (2%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 2/510 (0.39%) Mean 0.38% SD 0.74% Total 1/509 (0.2%) Mean 0.12% SD 0.35% #Skin: **Fibroma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** 0/510 (0%) Mean 0% SD 0% 0/509 (0%) Mean 0% SD 0% Total Total #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/100 (0%) 1/100 (1%) 0/50 (0%)1/50 (2%)4/100 (4%)2/99 (2%)0/50 (0%)1/50 (2%)0/50 (0%)(2%)0/50 (0%)(4%)1/50 0/60 (0%)0/50 (0%)1/60 (2%)2/50 (4%)**Overall Incidence** Total 2/510 (0.39%) Mean 0.38% SD 0.74% Total 13/509 (2.55%) Mean 2.46% SD 1.43%

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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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

icle: FEED

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Report Date: 06/03/2022

			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 (1%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	4/100 (4%) 0/50 (0%)	0/99 (0%) 1/50 (2%)
Overall Incidence	Total	0/60 (0%) 1/510 (0.2%)	0/50 (0%) Mean 0.12%	SD 0.35%	Total	0/60 (0%) 7/509 (1.38%)	1/50 (2%) Mean 1.25%	SD 1.49%
#Skin:								
Fibrosarcoma, Sarcoma	a, Myxosarcoma	, or Fibrous Histiocytom						
		0/50 (0%)	0/100 (0%)	1/100 (1%)		1/50 (2%)	4/100 (4%)	2/99 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
		0/60 (0%)	0/50 (0%)			1/60 (2%)	2/50 (4%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	13/509 (2.55%)	Mean 2.46%	SD 1.43%
#Skin: Fibrous Histiocytoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
•		0/50 (0%)	2/100 (2%)	1/100 (1%)		0/50 (0%)	1/100 (1%)	1/99 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	()		0/60 (0%)	0/50 (0%)	()
Overall Incidence	Total	3/510 (0.59%)	Mean 0.38%	SD 0.74%	Total	2/509 (0.39%)	Mean 0.25%	SD 0.47%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 1/50 (2%) 1/50 (2%)	0/99 (0%) 2/50 (4%)
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	4/509 (0.79%)	Mean 1%	SD 1.51%
#Skin: Keratoacanthoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 1/50 (2%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%
#Skin: Liposarcoma								
-		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/509 (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/N

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Mean 0%

SD 0%

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC Male **Female** #Skin: **Mast Cell Tumor Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) (0%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% Total 0/509 (0%) SD 0% #Skin: **Melanoma Malignant** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 0/509 (0%) Mean 0% SD 0% #Skin: Myxosarcoma 0/50 0/100 0/100 0/99 (0%)(0%)(0%)0/50 (0%)0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)(0%)0/60 0/50 (0%)0/60 0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% 1/509 (0.2%) Mean 0.25% SD 0.71% Total #Skin: **Neural Crest Tumor** 0/50 (0%)0/100 (0%)0/100 (0%)0/100 (0%)0/99 0/50 (0%)(0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)

SD 0%

.....

Total

0/509 (0%)

Total

0/510 (0%)

Mean 0%

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

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 1/50 (2%)0/100 (0%)0/100 (0%)1/50 (2%)2/100 (2%)0/99 (0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0.25% **Overall Incidence** Total 1/510 (0.2%) SD 0.71% Total 3/509 (0.59%) Mean 0.5% SD 0.93% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/100 0/100 (0%)1/50 (2%)2/100 (2%)0/99 1/50 (2%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% Total 3/509 (0.59%) Mean 0.5% SD 0.93% #Skin: Osteosarcoma 0/50 0/99 (0%)0/100 (0%)0/100 (0%)1/50 0/100 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** 0/510 (0%) SD 0% Mean 0.25% SD 0.71% Total Mean 0% Total 1/509 (0.2%) #Skin: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/100 2/99 0/50 (0%)(0%)(2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/60 (0%)0/50 (0%)1/60 (2%)1/50 (2%)**Overall Incidence** 1/510 (0.2%) Mean 0.25% SD 0.71% Total 5/509 (0.98%) Mean 0.96% SD 1.03% Total

^{*:} 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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Mean 0%

SD 0%

Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** #Skin: Schwannoma Malignant 1/50 (2%)0/100 (0%)0/100 (0%)1/50 (2%)2/100 (2%)0/99 (0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 1/510 (0.2%) Mean 0.25% SD 0.71% Total 3/509 (0.59%) Mean 0.5% SD 0.93% #Skin: Squamous Cell Carcinoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/100 (1%)0/99 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 1/509 (0.2%) Mean 0.12% SD 0.35% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)1/100 (1%)0/99 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 1/509 (0.2%) Mean 0.12% SD 0.35% #Skin: **Squamous Cell Papilloma** 0/50 (0%)1/100 (1%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) 0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)1/50 (2%)0/60 (0%)0/50 (0%)

SD 0.74%

Total

0/509 (0%)

Total

2/510 (0.39%)

Mean 0.38%

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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Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male				Female	
#Skin:				,		,		
Squamous Cell Papillor	na or Papilloma	1						
		0/50 (0%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papillor	na, Papilloma, S	Squamous Cell Carcinor	na or Keratoacanthom	a				
		0/50 (0%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%
#Skin:								
Squamous Cell Papillor	na, Papilloma, c	or Keratoacanthoma						
		0/50 (0%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	1/50 (2%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.38%	SD 0.74%	Total	0/509 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland:								
Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	` ,		0/60 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (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: ORAL Vehicle: FEED

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/97 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		1/60 (2%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	1/509 (0.2%)	Mean 0.21%	SD 0.59%	Total	0/502 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		1/50 (2%)	1/100 (1%)	0/100 (0%)		0/50 (0%)	0/97 (0%)	0/99 (0%)
		1/50 (2%)	1/50 (2%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	2/49 (4%)
		2/60 (3%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	6/509 (1.18%)	Mean 1.29%	SD 1.24%	Total	2/502 (0.4%)	Mean 0.51%	SD 1.44%
*Spleen: Mast Cell Tumor Malignant								
J		0/50 (0%)	0/100 (0%)	1/100 (1%)		0/50 (0%)	0/97 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/60 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	1/509 (0.2%)	Mean 0.12%	SD 0.35%	Total	0/502 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 249

Report Date: 06/03/2022

Length of Study: CHRONIC

Male **Female** #Stomach, Forestomach: Hemangioma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/60 (0%)0/50 (0%)1/60 (2%)0/50 (0%)**Overall Incidence** Total 0/510 (0%) Mean 0% SD 0% Total 1/509 (0.2%) Mean 0.21% SD 0.59% #Stomach, Forestomach: **Squamous Cell Carcinoma** 0/50 (0%)0/100 (0%)0/100 (0%)1/50 (2%)0/100 (0%)0/99 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/60 (0%)0/50 (0%)0/60 (0%)0/50 (0%)Mean 0.25% **Overall Incidence** Total 1/510 (0.2%) SD 0.71% Total 1/509 (0.2%) Mean 0.25% SD 0.71% #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/100 0/100 1/99 1/50 (2%)(0%)(0%)2/50 (4%)1/100 (1%)(1%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/50 (4%)2/50 (4%)0/60 (0%)(2%)0/50 1/50 (2%)1/60 (0%)**Overall Incidence** 3/510 (0.59%) Mean 0.75% SD 1.04% Total 9/509 (1.77%) Mean 1.96% SD 1.78% Total #Stomach, Forestomach: **Squamous Cell Papilloma** 1/50 (2%)0/100 (0%)0/100 (0%)(2%)1/100 (1%)1/99 (1%)1/50 0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)2/50 (4%)2/50 (4%)0/60 (0%)1/50 (2%)1/60 (2%)0/50 (0%)**Overall Incidence** Total 2/510 (0.39%) Mean 0.5% SD 0.93% Total 8/509 (1.57%) Mean 1.71% SD 1.58%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/60 (0%)	0/50 (0%)	00.00/	+	0/60 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%)	0/50 (0%)	SD 0%
overali incidence	Total	0/510 (0%)		3D 0%	Total	0/509 (0%)	Mean 0%	3D 0%
Testes: Adenoma								
		0/50 (0%)	1/100 (1%)	1/100 (1%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/60 (0%)	0/50 (0%)					
Overall Incidence	Total	3/510 (0.59%)	Mean 0.5%	SD 0.76%				

^{*:} 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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male			Female
*Testes:						
Hemangioma		0/50 (00/)	0/400 (00/)	4/400	(40()	
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	1/100 0/50	(1%)	
		0/60 (0%)	0/50 (0%)	0/30	(0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%		
Testes: Hemangiosarcoma						
		0/50 (0%)	1/100 (1%)	0/100	(0%)	
		0/50 (0%)	0/50 (0%)	0/50	(0%)	
		0/60 (0%)	0/50 (0%)			
Overall Incidence	Total	1/510 (0.2%)	Mean 0.12%	SD 0.35%	%	
Testes: Seratoli Tumor: Benigr	n, Malignant, NO	S				
ū	, , ,	0/50 (0%)	0/100 (0%)	0/100	(0%)	
		0/50 (0%)	1/50 (2%)	0/50	(0%)	
		0/60 (0%)	0/50 (0%)			
overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.719		
Testes:						
Sertoli Cell Tumor Mali	ignant	0/50 (00/)	0/400 (00/)	0/400	(00()	
		0/50 (0%)	0/100 (0%)	0/100	(0%)	
		0/50 (0%)	1/50 (2%)	0/50	(0%)	
Overell lesidence	Tatal	0/60 (0%)	0/50 (0%)	OD 0.740	1 /	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.719	%	

^{*:} 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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male		Female			
*Thymus: Hemangioma								
		0/46 (0%) 0/45 (0%)	0/87 (0%) 0/47 (0%)	0/99 (0%) 0/48 (0%)		0/46 (0%) 0/49 (0%)	0/93 (0%) 0/50 (0%)	0/95 (0%) 0/49 (0%)
		0/43 (0%)	0/47 (0%)	0/46 (0 /6)		0/49 (0%)	0/30 (0%)	0/49 (0 /6)
Overall Incidence	Total	0/476 (0%)	Mean 0%	SD 0%	Total	0/487 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/46 (0%)	0/87 (0%)	0/99 (0%)		0/46 (0%)	0/93 (0%)	0/95 (0%)
		0/45 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/57 (0%)	0/47 (0%)	05 00/		0/57 (0%)	0/48 (0%)	05.00/
Overall Incidence	Total	0/476 (0%)	Mean 0%	SD 0%	Total	0/487 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant								
		0/46 (0%)	0/87 (0%)	0/99 (0%)		0/46 (0%)	0/93 (0%)	0/95 (0%)
		0/45 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/57 (0%) 0/476 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/57 (0%) 0/487 (0%)	0/48 (0%) Mean 0%	SD 0%
	TOlai							
*Thymus: Thymoma: Benign, Maliç	gnant, NOS							
		0/46 (0%)	0/87 (0%)	0/99 (0%)		0/46 (0%)	0/93 (0%)	0/95 (0%)
		0/45 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/57 (0%)	0/47 (0%)			0/57 (0%)	0/48 (0%)	
Overall Incidence	Total	0/476 (0%)	Mean 0%	SD 0%	Total	0/487 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
*Thyroid Gland: Adenoma								
		0/50 (0%)	0/99 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/97 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/59 (0%) 0/508 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 1/504 (0.2%)	0/50 (0%) Mean 0.25%	SD 0.71%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/99 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/97 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/59 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/508 (0%)	Mean 0%	SD 0%	Total	0/504 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/99 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/97 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/59 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/508 (0%)	Mean 0%	SD 0%	Total	0/504 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma								
		1/50 (2%)	1/99 (1%)	1/100 (1%)		0/50 (0%)	1/98 (1%)	0/97 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/49 (2%)	0/50 (0%)
		1/59 (2%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	6/508 (1.18%)	Mean 1.21%	SD 0.86%	Total	4/504 (0.79%)	Mean 0.88%	SD 1.46%

^{*:} 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: ORAL Vehicle: FEED Report Date: 06/03/2022

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			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	ell:							
		0/50 (0%)	0/99 (0%)	0/100 (0%)		0/50 (0%)	0/98 (0%)	0/97 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/59 (0%) 0/508 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/504 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '				(,		
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	ell:							
		1/50 (2%)	1/99 (1%)	1/100 (1%)		0/50 (0%)	1/98 (1%)	0/97 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	1/49 (2%)	0/50 (0%)
		1/59 (2%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	6/508 (1.18%)	Mean 1.21%	SD 0.86%	Total	4/504 (0.79%)	Mean 0.88%	SD 1.46%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/60 (3%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	2/510 (0.39%)	Mean 0.42%	SD 1.18%	Total	0/509 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
-		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/509 (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: ORAL Vehicle: FEED

Control Animal Groups Report Date: 06/03/2022

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			Male				Female	
#Tongue: Squamous Cell Carcino	oma							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/99 (1%)
		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/60 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.13%	SD 0.36%
#Tongue: Squamous Cell Carcino		a Squamous						
•	·	0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	1/99 (1%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.13%	SD 0.36%
#Tongue: Squamous Cell Papillo	ma							
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		1/50 (2%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)			0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/510 (0.2%)	Mean 0.25%	SD 0.71%	Total	0/509 (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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male			Female		
#Tooth: Sarcoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/60 (0%)	0/50 (0%)	OD 00/	-	0/60 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	0/509 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/59 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/59 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
verall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/507 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
U		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/59 (0%)	0/50 (0%)			0/59 (0%)	0/49 (0%)	
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%	Total	0/507 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: **Papilloma** 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/59 (0%)0/50 (0%)0/59 (0%)0/49 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 0/507 (0%) Mean 0% SD 0% *Urinary Bladder: Sarcoma 0/50 (0%)0/100 (0%)0/100 (0%)0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/59 (0%)0/50 0/59 (0%)0/49 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0% Total 0/507 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 0/100 0/99 (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/60 (0%)**Overall Incidence** 0/509 (0%) Mean 0% SD 0% Total **#Uterus:** Carcinoma 0/50 (0%)0/100 (0%)0/99 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/60 (0%)0/50 (0%)**Overall Incidence** Total 0/509 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male			Female	
#Uterus: Deciduoma Benign				
		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/509 (0%)	0/50 (0%) Mean 0%	SD 0%
	·····			
#Uterus: Hemangioma				
•		0/50 (0%)	1/100 (1%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/60 (2%)	0/50 (0%)	
Overall Incidence	Total	2/509 (0.39%)	Mean 0.33%	SD 0.64%
#Uterus: Hemangiosarcoma				
.		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	
Overall Incidence	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%
#Uterus: Leiomyoma				
20.0, 02		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/60 (0%)	0/50 (0%)	. ,
Overall Incidence	Total	0/509 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: 2006 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL Vehicle: FEED

	Male	Female	
Uterus: Leiomyosarcoma			
		0/50 (0%) 1/100 (1%)	0/99 (0%)
		0/50 (0%) 0/50 (0%) 0/60 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/509 (0.2%) Mean 0.12%	SD 0.35%
Uterus: Polyp Stromal			
. 21.		4/50 (8%) 1/100 (1%)	2/99 (2%)
		1/50 (2%) 0/50 (0%)	0/50 (0%)
	-	2/60 (3%) 3/50 (6%)	00.0070/
Overall Incidence	Total	13/509 (2.55%) Mean 2.79%	SD 2.87%
Uterus: Sarcoma			
		0/50 (0%) 0/100 (0%)	0/99 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/50 (0%) 0/509 (0%) Mean 0%	SD 0%
	Τοιαι	(11)	
tUterus: Sarcoma Stromal			
		1/50 (2%) 0/100 (0%)	0/99 (0%)
		0/50 (0%) 1/50 (2%)	0/50 (0%)
Normall In addison a	Total	0/60 (0%) 0/50 (0%)	OD 0.000/
Overall Incidence	Total	2/509 (0.39%) Mean 0.5%	SD 0.93%

^{*:} 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: 06/03/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus: Sarcoma Stromal or Po	olyp Stromal							
						5/50 (10%) 1/50 (2%)	1/100 (1%) 1/50 (2%)	2/99 (2%) 0/50 (0%)
Overall Incidence					Total	2/60 (3%) 15/509 (2.95%)	3/50 (6%) Mean 3.29%	SD 3.24%
#Uterus: Schwannoma Malignan				•••••				•••••
ochwannoma mangnan	ıı					0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 1/50 (2%)
Overall Incidence					Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%
#Vagina: Squamous Cell Carcino								
						0/50 (0%) 0/50 (0%) 0/60 (0%)	0/100 (0%) 0/50 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence					Total	0/509 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma				•••••		•••••		•••••
		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/100 (0%) 0/50 (0%)	0/99 (0%) 0/50 (0%)
Overall Incidence	Total	0/60 (0%) 0/510 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/60 (0%) 0/509 (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: 06/03/2022

Species: MICE Strain: B6C3F1/N Route: ORAL Vehicle: FEED

			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)	,		0/60 (0%)	0/50 (0%)	` ,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/100 (0%)	0/100 (0%)		0/50 (0%)	0/100 (0%)	0/99 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/60 (0%)	0/50 (0%)	(,		0/60 (0%)	0/50 (0%)	(11,
Overall Incidence	Total	0/510 (0%)	Mean 0%	SD 0%	Total	1/509 (0.2%)	Mean 0.25%	SD 0.71%

^{*:} 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: 06/03/2022

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

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	058803106	03/19/97	729	50(1)	40(704)	53.9	Dipropylene glycol
Battelle Columbus Laboratory	058800706	08/02/95	727	50(1)	39(708)	51.4	Sodium nitrite
Southern Research Institute	059601804	N/A	N/A	0(0)	0(0)	N/A	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601706	02/23/00	729	49(1)	31(685)	52.5	Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601004	09/30/98	729	50(1)	38(694)	54.1	Water disinfection byproducts (Sodium chlorate)
					Female		
Battelle Columbus Laboratory	058803106	03/18/97	728	50(5)	37(699)	61.4	Dipropylene glycol
Battelle Columbus Laboratory	058800706	08/03/95	728	50(5)	40(702)	58.8	Sodium nitrite
Southern Research Institute	059601804	12/15/98	729	50(5)	36(699)	66.6	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601706	02/23/00	734	50(5)	38(708)	64.3	Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601004	09/30/98	735	50(5)	36(691)	66.5	Water disinfection byproducts (Sodium chlorate)

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: ORAL Vehicle: WATER Page: 263 Report Date: 06/03/2022

			Male				Female	
#All Organs: Benign Tumors								
		27/50 (54%) 25/49 (51%)	28/50 (56%) 34/50 (68%)			22/50 (44%) 29/50 (58%)	13/50 (26%) 38/50 (76%)	34/50 (68%)
Overall Incidence	Total	114/199 (57.29%)	Mean 57.26%	SD 7.45%	Total	136/250 (54.4%)	Mean 54.4%	SD 19.87%
#All Organs: Malignant Tumors								
		19/50 (38%)	27/50 (54%)			18/50 (36%)	12/50 (24%)	43/50 (86%)
Overall Incidence	Total	23/49 (47%) 98/199 (49.25%)	29/50 (58%) Mean 49.23%	SD 8.78%	Total	36/50 (72%) 142/250 (56.8%)	33/50 (66%) Mean 56.8%	SD 25.87%
						` ,		
#All Organs: Malignant and Benign T	umors							
		39/50 (78%)	40/50 (80%)			32/50 (64%)	21/50 (42%)	46/50 (92%)
Overall Incidence	Total	37/49 (76%) 161/199 (80.9%)	45/50 (90%) Mean 80.88%	SD 6.35%	Total	42/50 (84%) 188/250 (75.2%)	47/50 (94%) Mean 75.2%	SD 22.03%
					10tai	100/230 (73.276)	IVIEAIT 73.270	
All Organs: Hemangioma								
		2/50 (4%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	CD 20/	Total	3/50 (6%)	2/50 (4%) Mean 3.2%	CD 2.200/
overali incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	8/250 (3.2%)	iviean 3.2%	SD 2.28%
‡All Organs: Hemangiosarcoma								
-		0/50 (0%)	7/50 (14%)			3/50 (6%)	1/50 (2%)	8/50 (16%)
Overell Incidence	Total	4/49 (8%)	1/50 (2%)	CD 6 240/	Total	1/50 (2%)	3/50 (6%)	CD = 720/
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 6.34%	Total	16/250 (6.4%)	Mean 6.4%	SD 5.73%

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

^{#:} Denominator is number of animals necropsied

: 2006

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 2/50 (4%)7/50 (14%)5/50 (10%)1/50 (2%)8/50 (16%) 4/49 (8%)1/50 (2%)(8%)5/50 (10%)Overall Incidence Total 14/199 (7.04%) Mean 7.04% SD 5.3% Total 23/250 (9.2%) Mean 9.2% SD 5.02% #All Organs: **Histiocytic Sarcoma** (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/250 (0%) Mean 0% SD 0% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 1/50 (2%)1/50 (2%)5/50 (10%)7/50 (14%)(58%)(0%)0/49 3/50 (6%)(54%)23/50 (46%)**Overall Incidence** Total 5/199 (2.51%) Mean 2.5% SD 2.52% Total 91/250 (36.4%) Mean 36.4% SD 22.73% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/250 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 1%

Total

0/250 (0%)

Total

1/199 (0.5%)

.....

Mean 0.5%

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 265

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteon				•••••				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
*Adrenal Cortex: Adenoma								
		0/50 (0%) 3/49 (6%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/49 (6%) 6/199 (3.02%)	3/50 (6%) Mean 3.03%	SD 3.5%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 266

			Male				Female	
Adrenal Cortex: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Adrenal Medulla: Pheochromocytoma Ber	nign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
*Adrenal Medulla: Pheochromocytoma Mal	lignant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)			0/50 (0%)	2/50 (4%)	0/00 (0/0)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
*Adrenal Medulla: Pheochromocytoma: Be	nign, Complex	t, Malignant, NOS						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/49 (2%)	0/49 (0%)			1/50 (2%)	3/50 (6%)	
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	5/250 (2%)	Mean 2%	SD 2.45%
*Bone Marrow: Hemangiosarcoma								
-		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/47 (0%)	0/49 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/196 (1.02%)	Mean 1%	SD 2%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%

^{*:} 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: ORAL Vehicle: WATER Page: 267

			Male				Female	
Bone Marrow: Mast Cell Tumor Malign	ant							
		0/50 (0%) 0/47 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Chondroma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Ch								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 268

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
O	T-1-1	0/49 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00.000/
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
'Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Malig	nant. NOS							
·	,	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Page: 269

			Male				Female	
Brain: Oligodendroglioma Beni	ign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain:								
Oligodendroglioma Mali	gnant							
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glio	oma, or Astrocy	vtoma 0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	ı Olai	0/199 (0%)	iviean 0%	SD 0%	10lai	0/230 (0%)		۵D 0%
*Brain: Sarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	0/48 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/243 (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: ORAL Vehicle: WATER Page: 270

			Male				Female	
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)	0/48 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
ŭ		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma			•••••					
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/48 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Page: 271
Report Date: 06/03/2022

			Male				Female	
#Ear:								
Neural Crest Tumor, Ma	lignant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Epididymis: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)					
		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)					
		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Eye: Sarcoma								
Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	(070)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Gallbladder: Adenoma								
		0/48 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	0/46 (0%)
		0/39 (0%)	0/44 (0%)			0/47 (0%)	0/40 (0%)	
Overall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/231 (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: ORAL Vehicle: WATER Page: 272

			Male				Female	
*Gallbladder: Sarcoma								
		0/48 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	0/46 (0%)
Overall Incidence	Total	0/39 (0%) 0/181 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/231 (0%)	0/40 (0%) Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		2/50 (4%) 3/49 (6%)	4/50 (8%) 6/50 (12%)			1/50 (2%) 9/50 (18%)	0/50 (0%) 11/50 (22%)	3/50 (6%)
Overall Incidence	Total	15/199 (7.54%)	Mean 7.53%	SD 3.4%	Total	24/250 (9.6%)	Mean 9.6%	SD 9.84%
#Harderian Gland: Carcinoma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
Harderian Gland: Carcinoma or Adenoma				•••••				
		3/50 (6%) 3/49 (6%)	4/50 (8%) 6/50 (12%)			1/50 (2%) 10/50 (20%)	0/50 (0%) 12/50 (24%)	4/50 (8%)
Overall Incidence	Total	16/199 (8.04%)	Mean 8.03%	SD 2.8%	Total	27/250 (10.8%)	Mean 10.8%	SD 10.73%
Heart: Hemangiosarcoma								
-		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/249 (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: ORAL Vehicle: WATER Report Date: 06/03/20

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Report	Date:	06/0)3/2()2

			Male				Female	
*Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/49 (2%) 1/199 (0.5%)	0/50 (0%) Mean 0.51%	SD 1.02%	Total	0/249 (0%)	0/49 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (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

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Intestine Large: Cecum: **Polyp Adenomatous** (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Leiomyoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Intestine Small: Duodenum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/250 (0%) Mean 0% SD 0% #Intestine Small: Duodenum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/250 (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: 06/03/2022

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

			Male				Female	
#Intestine Small: Duodenum: Hemangioma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 3/199 (1.51%)	0/50 (0%) Mean 1.5%	SD 1.91%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (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

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Report Date: 06/03/2022

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

Route: ORAL Vehicle: WATER

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%) 0/49 (0%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 8/199 (4.02%)	2/50 (4%) Mean 4%	SD 4.32%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous								
		1/50 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec	cified:					•••••	•••••	
		0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
		1/50 (2%) 0/49 (0%)	5/50 (10%) 2/50 (4%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	8/199 (4.02%)	Mean 4%	SD 4.32%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Unspec Carcinoma or Adenoma								
		1/50 (2%) 0/49 (0%)	5/50 (10%) 3/50 (6%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	9/199 (4.52%)	Mean 4.5%	SD 4.43%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 277

			Male				Female	
#Intestine Small: Site Uns Hemangioma	specified:							
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous		•••••						
		2/50 (4%) 1/49 (2%)	2/50 (4%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 1.91%	Total	0/250 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		•••••						
		0/50 (0%) 0/46 (0%)	3/50 (6%) 1/48 (2%)			2/50 (4%) 1/49 (2%)	0/50 (0%) 0/46 (0%)	3/49 (6%)
Overall Incidence	Total	4/194 (2.06%)	Mean 2.02%	SD 2.83%	Total	6/244 (2.46%)	Mean 2.43%	SD 2.65%
'Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/46 (0%)	0/50 (0%) 0/48 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/46 (0%)	0/49 (0%)
Overall Incidence	Total	0/46 (0%)	0/46 (0%) Mean 0%	SD 0%	Total	0/244 (0%)	0/46 (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: ORAL Vehicle: WATER Page: 278

			Male				Female	
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 0/46 (0%)	3/50 (6%) 1/48 (2%)			2/50 (4%) 1/49 (2%)	0/50 (0%) 0/46 (0%)	3/49 (6%)
Overall Incidence	Total	4/194 (2.06%)	Mean 2.02%	SD 2.83%	Total	6/244 (2.46%)	Mean 2.43%	SD 2.65%
'Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 1/49 (2%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/249 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma						•••••		
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 1/49 (2%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/249 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
-		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/49 (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: ORAL Vehicle: WATER

RAL

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			Male				Female	
Liver: Cholangiocarcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 1/48 (2%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.52%	SD 1.04%	Total	0/248 (0%)	Mean 0%	SD 0%
'Liver: Hemangioma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/48 (0%)			1/50 (2%) 1/49 (2%)	0/50 (0%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	Total	4/248 (1.61%)	Mean 1.62%	SD 1.71%
Liver: Hemangiosarcoma								
-		0/50 (0%) 1/49 (2%)	2/50 (4%) 1/48 (2%)			2/50 (4%) 1/49 (2%)	0/50 (0%) 1/49 (2%)	2/50 (4%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.03%	SD 1.63%	Total	6/248 (2.42%)	Mean 2.42%	SD 1.67%
Liver: Hepatoblastoma							•••••	
		0/50 (0%) 0/49 (0%)	5/50 (10%) 6/48 (13%)			0/50 (0%) 1/49 (2%)	0/50 (0%) 1/49 (2%)	1/50 (2%)
Overall Incidence	Total	11/197 (5.58%)	Mean 5.62%	SD 6.57%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.11%
Liver: Hepatocellular Adenoma								
-		17/50 (34%) 18/49 (37%)	19/50 (38%) 30/48 (63%)			11/50 (22%) 19/49 (39%)	9/50 (18%) 30/49 (61%)	24/50 (48%)
Overall Incidence	Total	84/197 (42.64%)	Mean 42.81%	SD 13.23%	Total	93/248 (37.5%)	Mean 37.6%	SD 17.99%

^{*:} 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: ORAL Vehicle: WATER Page: 280 Report Date: 06/03/2022

			Male				Female	
*Liver: Hepatocellular Carcinor	ma							
		14/50 (28%) 14/49 (29%)	9/50 (18%) 20/48 (42%)			7/50 (14%) 3/49 (6%)	2/50 (4%) 3/49 (6%)	13/50 (26%)
Overall Incidence	Total	57/197 (28.93%)	Mean 29.06%	SD 9.71%	Total	28/248 (11.29%)	Mean 11.25%	SD 9.09%
Liver: Hepatocellular Carcinor	ma or Henatoh	lastoma						
Trepatocendial Caremor	na or riepatos	14/50 (28%) 14/49 (29%)	12/50 (24%) 23/48 (48%)			7/50 (14%) 4/49 (8%)	2/50 (4%) 4/49 (8%)	14/50 (28%)
Overall Incidence	Total	63/197 (31.98%) ´	Mean 32.12%	SD 10.72%	Total	31/248 (12.5%)	Mean 12.47%	SD 9.39%
*Liver: Hepatocellular Carcinor Overall Incidence	ma or Hepatoc Total	ellular Adenoma 29/50 (58%) 28/49 (57%) 122/197 (61.93%)	24/50 (48%) 41/48 (85%) Mean 62.14%	SD 16.16%	Total	17/50 (34%) 22/49 (45%) 110/248 (44.35%)	10/50 (20%) 31/49 (63%) Mean 44.43%	30/50 (60%) SD 18.05%
Liver: Hepatocellular Carcinor	ma. Henatocell	lular Adenoma, or Hepatol	olastoma					
nopatoconala. Caronio.	na, riopaioco	29/50 (58%) 28/49 (57%)	26/50 (52%) 41/48 (85%)			17/50 (34%) 22/49 (45%)	10/50 (20%) 31/49 (63%)	31/50 (62%)
Overall Incidence	Total	124/197 (62.94%)	Mean 63.14%	SD 15.09%	Total	111/248 (44.76%)	Mean 44.83%	SD 18.5%
Liver: Hepatocholangiocarcine	oma							
-		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)			0/50 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 281

			Male				Female	
*Liver: Ito Cell Tumor Maligna	ınt							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)			0/50 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
*Lung: Adenoma								
		0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/250 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar A	Adenoma							
		3/50 (6%) 7/49 (14%)	10/50 (20%) 6/50 (12%)			2/50 (4%) 1/50 (2%)	1/50 (2%) 3/50 (6%)	6/50 (12%)
Overall Incidence	Total	26/199 (13.07%)	Mean 13.07%	SD 5.79%	Total	13/250 (5.2%)	Mean 5.2%	SD 4.15%
*Lung: Alveolar/Bronchiolar C	Carcinoma							
		3/50 (6%) 5/49 (10%)	4/50 (8%) 4/50 (8%)			2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	16/199 (8.04%)	Mean 8.05%	SD 1.72%	Total	5/250 (2%)	Mean 2%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 06/03/2022

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

Route: ORAL Vehicle: WATER

			Male				Female	
Lung: Alveolar/Bronchiolar Ca	rcinoma or Alv	veolar/Bronchiolar Adeno	ma					
		6/50 (12%)	13/50 (26%)			3/50 (6%)	1/50 (2%)	6/50 (12%)
		12/49 (24%)	10/50 (20%)			2/50 (4%)	4/50 (8%)	
Overall Incidence	Total	41/199 (20.6%)	Mean 20.62%	SD 6.29%	Total	16/250 (6.4%)	Mean 6.4%	SD 3.85%
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	OD		0/50 (0%)	0/50 (0%)	00 0000
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Lung: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 283

			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Page: 284

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma	:							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malig	:							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma						•••••		•••••
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 285

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma	ı							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
#Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Fibroma, Fibroadenoma Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 0/50 (0%) 2/250 (0.8%)	0/50 (0%) 0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.79%
#Mesentery: Fibrosarcoma		- (a)	-/ /			2/-2 (221)	(22)	
-		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Fibrosarcoma	Total	,	` ,	SD 0%	Total	` ,	\ /	0/50 (0%) SD 0%
Fibrosarcoma Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence #Mesentery:	Total	0/49 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (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: ORAL Vehicle: WATER Page: 286

			Male				Female	
#Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
#Mesentery: Leiomyosarcoma		0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Nose: Carcinoma								
		0/50 (0%) 0/48 (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	0/198 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: 06/03/2022

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

			Male				Female	
*Nose: Hemangioma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Sarcoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Papilloma Squamous o	Total	0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/50 (2%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva):						
•		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%

^{*:} 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: ORAL Vehicle: WATER Page: 288

			Male				Female	
#Oral Mucosa: Squamous Cell Carcino	ma							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Oral Mucosa: Squamous Cell Papillom	na							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
						0/50 (0%)	0/47 (0%)	4/50 (8%)
Overall Incidence					Total	0/49 (0%) 5/241 (2.07%)	1/45 (2%) Mean 2.04%	SD 3.47%
*Ovary: Granulosa Cell Tumor B	senign							
	-					1/50 (2%) 0/49 (0%)	0/47 (0%) 1/45 (2%)	1/50 (2%)
Overall Incidence					Total	3/241 (1.24%)	Mean 1.24%	SD 1.14%
*Ovary: Granulosa Cell Tumor: E	Benign, Maligna	nt, NOS						
						1/50 (2%) 0/49 (0%)	0/47 (0%) 1/45 (2%)	1/50 (2%)
Overall Incidence					Total	3/241 (1.24%)	Mean 1.24%	SD 1.14%

^{*:} 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: ORAL Vehicle: WATER Page: 289

	Male		Female	
Ovary: Hemangioma				
		0/50 (0%) 0/49 (0%)	0/47 (0%) 0/45 (0%)	0/50 (0%)
Overall Incidence	Tota	0/241 (0%)	Mean 0%	SD 0%
Ovary:				
Hemangiosarcoma		0/50 (0%)	0/47 (0%)	2/50 (4%)
		0/49 (0%)	0/45 (0%)	` '
Overall Incidence	Tota	2/241 (0.83%)	Mean 0.8%	SD 1.79%
Ovary: Luteoma				
Luteoma		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/49 (0%)	3/45 (7%)	(111)
Overall Incidence	Tota		Mean 1.33%	SD 2.98%
Ovary: Teratoma Benign				
Totalonia Bonign		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/49 (0%)	0/45 (0%)	
Overall Incidence	Tota	0/241 (0%)	Mean 0%	SD 0%
Ovary: Thecoma Benign				
3		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/49 (0%)	0/45 (0%)	
Overall Incidence	Tota	0/241 (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: ORAL Vehicle: WATER Page: 290

			Male				Female	
Ovary: Tubulostromal Adenoma	a			,				
						0/50 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence					Total	0/49 (0%) 0/241 (0%)	0/45 (0%) Mean 0%	SD 0%
*Pancreas: Hemangioma								
		0/50 (0%) 0/46 (0%)	0/49 (0%) 0/48 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 0/46 (0%)	0/50 (0%)
Overall Incidence	Total	0/193 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Pancreas: Sarcoma		•••••	•••••					
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/46 (0%) 0/193 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/245 (0%)	0/46 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Dist Adenoma								
		0/49 (0%) 0/45 (0%)	0/49 (0%) 0/47 (0%)			1/49 (2%) 2/47 (4%)	1/48 (2%) 3/46 (7%)	3/49 (6%)
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	10/239 (4.18%)	Mean 4.2%	SD 2.13%
*Pituitary Gland: Pars Dist Carcinoma		fied Site:	•••••					
		0/49 (0%) 0/45 (0%)	0/49 (0%) 0/47 (0%)			0/49 (0%) 0/47 (0%)	0/48 (0%) 0/46 (0%)	0/49 (0%)
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	0/239 (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: ORAL Vehicle: WATER **Page:** 291

			Male				Female	
*Pituitary Gland: Pars Dista Carcinoma or Adenoma	alis or Unspec	ified Site:						
		0/49 (0%) 0/45 (0%)	0/49 (0%) 0/47 (0%)			1/49 (2%) 2/47 (4%)	1/48 (2%) 3/46 (7%)	3/49 (6%)
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	10/239 (4.18%)	Mean 4.2%	SD 2.13%
*Pituitary Gland: Pars Inter Adenoma						•••••		
		1/49 (2%) 0/45 (0%)	0/49 (0%) 0/47 (0%)			0/49 (0%) 1/47 (2%)	0/48 (0%) 0/46 (0%)	2/49 (4%)
Overall Incidence	Total	1/190 (0.53%)	Mean 0.51%	SD 1.02%	Total	3/239 (1.26%)	Mean 1.24%	SD 1.84%
*Pituitary Gland: Pars Inter Carcinoma or Adenoma		1/49 (2%) 0/45 (0%)	0/49 (0%) 0/47 (0%)			0/49 (0%) 1/47 (2%)	0/48 (0%) 0/46 (0%)	2/49 (4%)
Overall Incidence	Total	1/190 (0.53%)	Mean 0.51%	SD 1.02%	Total	3/239 (1.26%)	Mean 1.24%	SD 1.84%
*Prostate: Adenoma		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	0/198 (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: 06/03/2022

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

Length of Study: CHRONIC

			Male				Female	
*Prostate: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/48 (0%) 0/198 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/49 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/246 (0%)	0/48 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Seminal Vesicle: Carcinoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/49 (0%) 0/199 (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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 293

			Male				Female	
#Skeletal Muscle: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma			•••••			•••••		
•		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma							
·	-	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			2/50 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	5/250 (2%)	0/50 (0%) Mean 2%	SD 2%

^{*:} 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: ORAL Vehicle: WATER Page: 294

			Male				Female	
#Skin: Basal Cell Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	Basosquamous	_	0/50 (0%)			0/50 (00/)	0/50 (00/)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Basal Cell Adenoma, Ba	asosquamous To	umor Benign, or Trichoep 0/50 (0%) 0/49 (0%) 0/199 (0%)	ithelioma 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Basar och oarchionia			0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Basar Gen Garemonia		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
	Total	` ,	, ,	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence #Skin:		0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	(,	` '	SD 0%
Overall Incidence #Skin:		0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	(,	` '	SD 0% 0/50 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tur	mor (benign, maligna	nt or				
noo,, or moneopiane.		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep	oithelioma	na,		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%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Fibroma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/49 (2%) 1/199 (0.5%)	0/50 (0%) Mean 0.51%	SD 1.02%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or F 0/50 (0%) 1/49 (2%)	ibrous Histiocytoma 0/50 (0%) 0/50 (0%)			3/50 (6%) 4/50 (8%)	1/50 (2%) 0/50 (0%)	5/50 (10%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	13/250 (5.2%)	Mean 5.2%	SD 4.15%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

^{*:} 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: ORAL Vehicle: WATER

ORAL

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			Male				Female	
#Skin:								
Fibrosarcoma, Sarcoma	, Myxosarcoma	i, or Fibrous Histiocytoma	I					
		0/50 (0%)	0/50 (0%)			3/50 (6%)	1/50 (2%)	5/50 (10%)
		0/49 (0%)	0/50 (0%)			4/50 (8%)	0/50 (0%)	
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	13/250 (5.2%)	Mean 5.2%	SD 4.15%
Skin: Fibrous Histiocytoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	4/50 (8%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	5/250 (2%)	Mean 2%	SD 3.46%
Skin: Keratoacanthoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: 06/03/2022

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

Length of Study: CHRONIC

			Male				Female	
‡Skin: Lipoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
•		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Skin: Melanoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Myxosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Report Date: 06/03/2022

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			Male				Female	
#Skin: Neural Crest Tumor								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/199 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:		" · NOO						
Neurofibrosarcoma or	Schwannoma (n	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	0/00 (0/0)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%
			•••••					•••••
#Skin: Neurofibrosarcoma N	eurofibroma or 9	Schwannoma (benign, ma	lignant or NOS)					
Neuronbrosarcoma, N	euronbronia, or v	ociiwaiiiloilia (beiligii, ilia	ilgilalit of NOS)					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	0/50 (0%)
Overall Incidence	Total	` '	` ,	SD 0%	Total	` '	` ,	0/50 (0%) SD 2.68%
	Total	0/49 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	3/50 (6%)	,
#Skin:	Total	0/49 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	3/50 (6%)	,
	Total	0/49 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	3/50 (6%)	,
#Skin:	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/250 (1.2%)	3/50 (6%) Mean 1.2%	SD 2.68%
#Skin: Osteosarcoma	Total Total	0/49 (0%) 0/199 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0% SD 0%	Total Total	0/50 (0%) 3/250 (1.2%) 0/50 (0%)	3/50 (6%) Mean 1.2% 0/50 (0%)	SD 2.68%
#Skin: Osteosarcoma Overall Incidence #Skin:		0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)			0/50 (0%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%)	3/50 (6%) Mean 1.2% 0/50 (0%) 0/50 (0%)	SD 2.68% 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence		0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)			0/50 (0%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%)	3/50 (6%) Mean 1.2% 0/50 (0%) 0/50 (0%)	SD 2.68% 0/50 (0%)
Overall Incidence #Skin:		0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%			0/50 (0%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	3/50 (6%) Mean 1.2% 0/50 (0%) 0/50 (0%) Mean 0%	SD 2.68% 0/50 (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: ORAL Vehicle: WATER Page: 299

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%
#Skin: Squamous Cell Carcinoma							(22)	0.75
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma or Carcinoma	, Basal Cell C	Carcinoma, Basosquamou	ıs Tumor (malignant o	or NOS),				
Squamous Cell Carcinoma or Carcinoma Overall Incidence	i, Basal Cell (Total	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	or NOS), SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or Carcinoma		0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%)		Total	0/50 (0%) 0/250 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 	,
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma		0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0%		Total Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% SD 0%	Total	0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence #Skin:	Total Total	0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% SD 0%	Total	0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (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: 06/03/2022

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

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Papillor	ma, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma					
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillor	ma, Papilloma, o	r Keratoacanthoma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/47 (0%)	0/50 (0%) 0/48 (0%)			0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: ORAL Vehicle: WATER Page: 301 Report Date: 06/03/2022

			Male				Female	
Spleen: Hemangiosarcoma								
		0/50 (0%)	3/50 (6%)			1/50 (2%)	0/49 (0%)	4/50 (8%)
Overall Incidence	Total	2/47 (4%) 5/195 (2.56%)	0/48 (0%) Mean 2.56%	SD 3.04%	Total	0/50 (0%) 7/248 (2.82%)	2/49 (4%) Mean 2.82%	SD 3.35%
·····	10tai	3/193 (2.30/6)					IVIEATI 2.02/0	
*Spleen: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Insidence	Tatal	0/47 (0%)	0/48 (0%)	CD 00/	Tatal	0/50 (0%)	0/49 (0%)	CD 00/
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Hemangioma								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/250 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillon	na Squamous						
	чроп	1/50 (2%)	1/50 (2%)			2/50 (4%)	1/50 (2%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	, ,
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%

^{*:} 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: ORAL Vehicle: WATER Page: 302

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)			2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/199 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	1/50 (2%) 4/250 (1.6%)	0/50 (0%) Mean 1.6%	SD 1.67%
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '						
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Tatal	0/49 (0%)	0/50 (0%)	CD 00/	Tatal	1/50 (2%)	0/50 (0%)	CD 0.000/
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Tatal	0/49 (0%)	0/50 (0%)	CD 00/	Tatal	1/50 (2%)	0/50 (0%)	CD 0.000/
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Testes: Adenoma								
		3/50 (6%)	0/50 (0%)					
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	SD 3%				
Sveran incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%				

^{*:} 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

Page: 303

Report Date: 06/03/2022

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

			Male		Female	
*Testes: Hemangioma						
		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)	05.00/		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		
*Testes: Hemangiosarcoma						
		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/49 (2%)	0/50 (0%)	CD 1 000/		
	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%		
*Testes: Seratoli Tumor: Benign,	Malignant, NO	s				
		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		
*Testes: Sertoli Cell Tumor Malig	nant					
oon oon ramer mang		0/50 (0%)	0/50 (0%)			
		0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		
*Thymus: Hemangioma						
· ·····g· · ·····		0/46 (0%)	0/37 (0%)		1/49 (2%) 0/46 (0%) 0/49 (09	%)
	-	0/42 (0%)	0/43 (0%)	05.00/	0/44 (0%) 0/48 (0%)	
Overall Incidence	Total	0/168 (0%)	Mean 0%	SD 0%	Total 1/236 (0.42%) Mean 0.41% SD 0.91%)

^{*:} 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: ORAL Vehicle: WATER Page: 304

			Male				Female	
Thymus: Thymoma Benign								
		0/46 (0%) 0/42 (0%)	0/37 (0%) 0/43 (0%)			0/49 (0%) 0/44 (0%)	1/46 (2%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/168 (0%)	Mean 0%	SD 0%	Total	1/236 (0.42%)	Mean 0.43%	SD 0.97%
Thymus: Thymoma Malignant								
		0/46 (0%)	0/37 (0%)			0/49 (0%)	0/46 (0%)	1/49 (2%)
Overall Incidence	Total	0/42 (0%) 0/168 (0%)	0/43 (0%) Mean 0%	SD 0%	Total	0/44 (0%) 1/236 (0.42%)	0/48 (0%) Mean 0.41%	SD 0.91%
·····		` ,				,		
Thymus: Thymoma: Benign, Maligr	nant, NOS							
		0/46 (0%)	0/37 (0%)			0/49 (0%)	1/46 (2%)	1/49 (2%)
	-	0/42 (0%)	0/43 (0%)	00.00/	-	0/44 (0%)	0/48 (0%)	05 4 400/
Overall Incidence	Total	0/168 (0%)	Mean 0%	SD 0%	Total	2/236 (0.85%)	Mean 0.84%	SD 1.16%
Thyroid Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	0/48 (0%)	OD		0/50 (0%)	0/48 (0%)	05.00/
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/48 (0%)	0/48 (0%)	OD 00/		0/50 (0%)	0/48 (0%)	05.00/
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/246 (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: ORAL Vehicle: WATER Page: 305

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)			0/49 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Adenoma	:							
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)			0/49 (0%) 3/50 (6%)	0/49 (0%) 1/48 (2%)	2/50 (4%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	6/246 (2.44%)	Mean 2.42%	SD 2.6%
*Thyroid Gland: Follicular Cell Carcinoma	:							
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)			0/49 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)			0/49 (0%) 3/50 (6%)	0/49 (0%) 1/48 (2%)	2/50 (4%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	6/246 (2.44%)	Mean 2.42%	SD 2.6%
#Tissue NOS: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL Vehicle: WATER Page: 306

			Male			0/50 (0%) 0/50 (0%) otal 0/250 (0%) Mean 0% SD 0% 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)				
#Tissue NOS: Schwannoma Malignant										
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			` ,	` '	0/50 (0%)		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	(,	, ,	SD 0%		
#Tongue: Squamous Cell Carcinoma	a									
		0/50 (0%)	0/50 (0%)			()	` '	0/50 (0%)		
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	, ,	SD 1.1%		
#Tongue: Squamous Cell Carcinoma	a or Papilloma	a Squamous								
#Tongue:		0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/50 (4%) 3/250 (1.2%)	0/50 (0%) 0/50 (0%) Mean 1.2%	0/50 (0%) SD 1.79%		
#Tongue: Squamous Cell Carcinoma Overall Incidence #Tongue:	a or Papilloma Total	0/50 (0%) 0/49 (0%)	0/50 (0%)	SD 0%	Total	2/50 (4%)	0/50 (0%)	(***,		
#Tongue: Squamous Cell Carcinoma Overall Incidence	a or Papilloma Total	0/50 (0%) 0/49 (0%)	0/50 (0%)	SD 0%	Total	2/50 (4%)	0/50 (0%)	(***,		
#Tongue: Squamous Cell Carcinoma Overall Incidence #Tongue:	a or Papilloma Total	0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0% SD 0%	Total Total	2/50 (4%) 3/250 (1.2%) 0/50 (0%)	0/50 (0%) Mean 1.2% 	SD 1.79%		
#Tongue: Squamous Cell Carcinoma Overall Incidence #Tongue: Squamous Cell Papilloma	a or Papilloma Total	0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%			2/50 (4%) 3/250 (1.2%) 0/50 (0%) 1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 1.2% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.79% 0/50 (0%) SD 0.89%		
#Tongue: Squamous Cell Carcinoma Overall Incidence #Tongue: Squamous Cell Papilloma Overall Incidence	a or Papilloma Total	0/50 (0%) 0/49 (0%) 0/199 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)			2/50 (4%) 3/250 (1.2%) 0/50 (0%) 1/50 (2%)	0/50 (0%) Mean 1.2% 0/50 (0%) 0/50 (0%)	SD 1.79% 0/50 (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: ORAL Vehicle: WATER **Page:** 307

			Male				Female	
#Tooth: Sarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
'Urinary Bladder: Hemangiosarcoma		•••••	•••••					
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma			•••••					
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (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/N

Toxicology Data Management System

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/198 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% #Uterus: Adenoma (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Deciduoma Benign 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89%

^{*:} 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

Vehicle: WATER

Page: 309

Report Date: 06/03/2022

Route: ORAL

Length of Study: CHRONIC

Male **Female** #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% #Uterus: Leiomyoma (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Uterus: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (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

Tumor Incidence for Selected Control Animal Groups

Page: 310

Report Date: 06/03/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus:								
Sarcoma Stromal								
						0/50 (0%)	0/50 (0%)	2/50 (4%)
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Sarcoma Stromai or i oryp	Stromai					0/50 (0%)	0/50 (0%)	2/50 (4%)
						1/50 (2%)	1/50 (2%)	2,00 (1,0)
Overall Incidence					Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
·····						` ,		
#Uterus: Schwannoma Malignant								
•						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	` ,
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								•••••
·						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	` '
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
≠Zymbal's Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	` ,
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: ORAL

Report Date: 06/03/2022

Page: 311

Species: MICE Strain: B6C3F1/N

Vehicle: WATER

Length of Study: CHRONIC

			Male			Female 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0%		
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			` ,	` ,	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (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: SKIN Vehicle: ACETONE Page: 312

Report Date: 06/03/2022

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	050510914	09/24/98	726	50(1)	37(710)	53.4	Triethanolamine
					Female		
Battelle Columbus Laboratory	050510914	09/23/98	729	50(1)	35(692)	62.7	Triethanolamine

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: SKIN Vehicle: ACETONE Page: 313

			Male				Female		
#All Organs: Benign Tumors									
		30/50 (60%)				24/50 (48%)			
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	24/50 (48%)	Mean 48%	SD 0%	
#All Organs: Malignant Tumors									
		28/50 (56%)				27/50 (54%)			
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	27/50 (54%)	Mean 54%	SD 0%	
#All Organs: Malignant and Benign Tu	umors	45/50 (90%)				38/50 (76%)			
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%	Total	38/50 (76%)	Mean 76%	SD 0%	
#All Organs: Hemangioma		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Hemangiosarcoma									
		3/50 (6%)				3/50 (6%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma	4/50 (8%)				4/50 (8%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

SKIN .

Page: 314

			Male				Female		
	0/50	(0%)				4/50 (8%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	
istiocytic, Lymp	phocytic, Mixed	, NOS, or	Undifferentiated Ce	II Type					
	0/50	(0%)				8/50 (16%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%	
Malignant, NOS	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
t	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
-		(0%)		05 00/	+	0/50 (0%)		OD 00/	
l otal	0/50 (0%)		Mean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%	
	1/50	(2%)				1/50 (2%)			
Total		(= /0)	Mean 2%	SD 0%	Total	, ,	Mean 2%	SD 0%	
	istiocytic, Lymp Total Malignant, NOS Total t Total	Total 0/50 (0%) istiocytic, Lymphocytic, Mixed 0/50 Total 0/50 (0%) Malignant, NOS Total 0/50 (0%) t 0/50 Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	Total 0/50 (0%) istiocytic, Lymphocytic, Mixed, NOS, or 0/50 (0%) Total 0/50 (0%) Malignant, NOS 0/50 (0%) Total 0/50 (0%) t 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0% istiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Ce 0/50 (0%) Total 0/50 (0%) Mean 0% Malignant, NOS 0/50 (0%) Total 0/50 (0%) Mean 0% t 0/50 (0%) Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0%	O/50 (0%) Mean 0% SD 0%	Total	Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%)	O/50 (0%) Mean 0% SD 0% Total 4/50 (8%) Mean 8%	Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%) Mean 8% SD 0% istiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 8/50 (16%) Mean 16% SD 0% Alalignant, NOS Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% t 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 315

			Male			Female			
#All Organs: Osteosarcoma or Osteoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Cortex: Adenoma	•••••								
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Carcinoma		0/50 (00/				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Sarcoma		0/50 (0%	,)			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benigr									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Malign	ant	0/50 (00/				0/40 /00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (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: SKIN Vehicle: ACETONE **Page:** 316

				Male			Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 1/50 (2%) 1/49 (2%)												
Overall Incidence	Total	1/50 (2%)	,	Mean 2%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%			
*Bone Marrow: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Bone Marrow: Mast Cell Tumor Malignant			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chondroma			(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	. ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Bone: Chondrosarcoma or Chondo												
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Bone: Fibrosarcoma			(0%)									
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

SKIN

Page: 317

			Male			Female			
#Bone: Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Malig		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Page: 318

Report Date: 06/03/2022

Route: SKIN Vehicle: ACETONE

			Male			Female			
*Brain: Oligodendroglioma Benig	n Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma Maligi	nant	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glion		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Sarcoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Adenoma		` ,				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 319

			Male			Female					
*Clitoral/Preputial Gland: Carcinoma or Adenoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
		` '		บ _้		` ,	wiean 0%	0% עכ			
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Coagulating Gland: Adenoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Ear: Neural Crest Tumor, Malign	ant										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Epididymis: Hemangiosarcoma		0/50 (00/)									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%							
Overail incluence	Total	0/50 (0%)	เทษสก บ%	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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 320

			Male			Female				
*Epididymis: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%						
#Eye: Sarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Gallbladder: Adenoma		0/40 (00/)								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%		
*Gallbladder: Sarcoma		0/48 (0%)				0/48 (0%)				
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma										
Overall Incidence	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%		
#Harderian Gland: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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

Tumor Incidence for Selected Control Animal Groups

Page: 321

Report Date: 06/03/2022

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male			Female			
	7/50 (4.40()				7/50 /4.40/\			
Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
	0/50 (00/)				0/50 (00/)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
					0/50 (00/)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (00/)				0/50 /00/			
Total	` '	Moon 0%	SD 00/	Total	` '	Moon 0%	SD 0%	
	Total Total Total	0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) O/50 (0%) O/50 (0%)	7/50 (14%) Total 7/50 (14%) Mean 14% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0%	Total 7/50 (14%) Total 7/50 (14%) Mean 14% SD 0% Total 0/50 (0%) Mean 0% SD 0%	Total 7/50 (14%) Total 7/50 (14%) Mean 14% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 7/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	Total 7/50 (14%) Total 7/50 (14%) Mean 14% SD 0% Total 7/50 (14%) O/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%)	Total 7/50 (14%) Mean 14% SD 0% Total 7/50 (14%) Mean 14%	

^{*:} 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: SKIN Vehicle: ACETONE Page: 322

			Male				Female					
#Intestine Large: Cecum: Leiomyoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Intestine Large: Cecum: Leiomyosarcoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Large: Cecum: Polyp Adenomatous		(00)				0/50 (00)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Large: Colon/Rectu	m:	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Duodenum: Adenoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Duodenum: Carcinoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 323

			Male				Female	
#Intestine Small: Duodenum: Hemangioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Hemangiosarcoma		0/50 (00/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		` '				(,		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	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
Route: SKIN

Page: 324 Report Date: 06/03/2022

Species: MICE Strain: B6C3F1/N

Vehicle: ACETONE

Length of Study: CHRONIC

			Male			Female			
#Intestine Small: Jejunum: Polyp Adenomatous	Tatal	0/50 (0%)	Marca 00/	OD 004	Total	0/50 (0%)	Marca 604	OD 004	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Adenoma	ecified:								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Carcinoma									
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Carcinoma or Adenoma		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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 Inc

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 325

			Male			Female			
#Intestine Small: Site Unspe Polyp Adenomatous	cified:								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma		0/50 (09/				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma		0/50 /00/				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 326

			Male			Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma	Total	0/50 (0%)		CD 00/	Total	1/50 (2%)	M 00/	CD 00/	
Overall Incidence	ı otal	0/50 (0%)	Mean 0%	SD 0%	ı otal	1/50 (2%)	Mean 2%	SD 0%	
*Liver: Hemangiosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatoblastoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 327
Report Date: 06/03/2022

			Male				Female				
*Liver: Hepatocellular Adenoma 19/50 (38%) 9/50 (18%)											
Overall Incidence	Total	19/50 (38%)	Mean 38%	SD 0%	Total	9/50 (18%)	Mean 18%	SD 0%			
*Liver: Hepatocellular Carcinom	na	17/50 (34%)				6/50 (12%)					
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%			
*Liver: Hepatocellular Carcinom		astoma			•••••	6/50 (12%)					
Overall Incidence	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%			
*Liver: Hepatocellular Carcinom		Ilular Adenoma 33/50 (66%)				12/50 (24%)					
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%			
*Liver:		ilar Adenoma, or Hepatob 33/50 (66%)				12/50 (24%)					
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%			
*Liver: Hepatocholangiocarcino	oma	0/50 (00/)				0/50 /09/					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Page: 328 Report Date: 06/03/2022

Species: MICE Strain: B6C3F1/N Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female	
*Liver: Ito Cell Tumor Malignan	ıt	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ad		6/50 (12%)				3/50 (6%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	arcinoma							
Overall Incidence	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Ca		eolar/Bronchiolar Adenor 12/50 (24%)				5/50 (10%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%)	Mean 10%	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: SKIN Vehicle: ACETONE Page: 329

			Male				Female	
*Lung: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma						0/50 /00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma		•••••						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant						0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 330

				Male				Female		
#Lymph Node, Mediastinal: Hemangiosarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangioma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(U70)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	nt	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Sarcoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
O TOTALI III GIGGIIGE	rotai	0/30 (0/0)		Wicaii 070	00 070	iotai	0,00 (0,70)	Wicaii 070	OD 070	

^{*:} 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: SKIN Vehicle: ACETONE Page: 331

		Male				Female			
	0/50 (0%	6)			0/50 (0%)				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	`	,			` '				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	0/50 (0%	2)			0/50 (0%)				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
					0/50 (0%)				
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	Adenoma			•••••					
	,				` '				
	` ,				` '		SD 0%		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
	Total Total or Adenoma Total Carcinoma, or Total	Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) or Adenoma 0/50 (0%) Carcinoma, or Adenoma 0/50 (0%) Total 0/50 (0%) 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% or Adenoma 0/50 (0%) Total 0/50 (0%) Mean 0% Carcinoma, or Adenoma 0/50 (0%) Total 0/50 (0%) Mean 0%	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Carcinoma, or Adenoma 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total or Adenoma 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total Carcinoma, or Adenoma 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Carcinoma, or Adenoma 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Carcinoma, or Adenoma 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 332

			Male				Female	
#Mesentery: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma Overall Incidence		0/50 (0%)			Total	0/50 (0%)	Magn 00/	SD 00/
Overall incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 333

			Male				Female				
*Nose: Hemangioma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Nose: Sarcoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos Papilloma Squamous		ynx, Tooth, Gingiva):				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucos						0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Mucosa:	•••••										
Squamous Cell Carcin	oma	0/50 (0%)				0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

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			Male				Female	
#Oral Mucosa: Squamous Cell Papillom	a							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor Be	enign							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: B	enian. Maliana	ınt. NOS						
Overall Incidence	g,g	,			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Ovary: Luteoma								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Teratoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 336

				Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma												
		0/50	(0%)				8/50 (16%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%			
*Pituitary Gland: Pars Dis Carcinoma		ied Site:										
		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma			(0%)				8/50 (16%)					
Overall Incidence	Total	0/50 (0%)	, ,	Mean 0%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%			
*Pituitary Gland: Pars Int Adenoma			(2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Int Carcinoma or Adenom			(20/)				0/50 (00/)					
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma						•••••						
		0/50	(0%)									
Overall Incidence	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

d Control Animal Groups Report Date: 06/03/2022

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			Male				Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%)		OD 001				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma		2/20 (201)				(00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Seminal Vesicle: Carcinoma		0/50 (0%)						
Overall Incidence	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Report Date: 06/03/2022

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			Male	Female				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)		05.00		0/50 (0%)		00.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)		25 20/		0/50 (0%)	••	05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00/)				4/50 (20/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		` '				, ,		
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (00)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 06/03/2022

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

0/50 (0%)
` '
,
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (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

Route: SKIN

Report Date: 06/03/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: ACETONE

Length of Study: CHRONIC

			Male		Female			
#Skin: Fibroma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma,	, Sarcoma, Myxc	_	brous Histiocytoma			4/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma						1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma, Sarcoma						1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 341

			Male		Female			
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

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керо	rt D	ate:	Ub/(J3/2	202

			Male		Female			
#Skin: Myxosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor	•••••	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	eurofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	alignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Sarcoma		0(50 (05))				0/50 (00/)		
		0/50 (0%)				0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 343

Report Date: 06/03/2022

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male				Female	
#Skin: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (Carcinoma, Basosquamo	ous Tumor (malignan	t or NOS),		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma c	or Papilloma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,		quamous Cell Carcinom		na		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 344

			Male	Female								
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Spleen: Hemangioma		1/49 (2%)				0/50 (0%)						
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Spleen: Hemangiosarcoma												
Overall Incidence	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Spleen: Mast Cell Tumor Malignant		0/40 /09/)				0/50 (0%)						
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 345

				Male		Female			
#Stomach, Forestomach: Hemangioma									
•		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	•	1/50	(2%)		a.		2/50 (4%)		25 200
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		1/50	(2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	,	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Stomach, Glandular: Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma		2/5	(20()				(201)		
Occupati la cidan ca	Tarat	0/50	(0%)	Maran 00/	00.00/	Tatal	0/50 (0%)	M 00/	00.00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ACETONE

Page: 346

			Male			Female				
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)				0/50 (001)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Testes: Adenoma		0/50 (0%)			•••••					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Testes: Hemangioma		0/50 (0%)			•••••					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Testes: Hemangiosarcoma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Testes: Seratoli Tumor: Benign,	Malignant, NOS	6 0/50 (0%)			•••••					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Testes: Sertoli Cell Tumor Malig	nant	0/50 (09/)								
Overall Incidence	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 347 Report Date: 06/03/2022

			Male	Female				
*Thymus: Hemangioma		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/40 (00/)				0/40 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 348

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50	(00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma			(2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Tissue NOS: Sarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(-/-/	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Page: 349

			Male				Female	
#Tongue: Squamous Cell Carcinoma								
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
	ор	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 350

			Male				Female	
*Urinary Bladder: Hemangioma								
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma								
		0/50 (0%)	••	05.00/		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						0/50 (0%)		
Overall Incidence					Total	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/N Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 351

	Male			Female	
#Uterus: Deciduoma Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	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

Tumor Incidence for Selected Control Animal Groups

Page: 352

Report Date: 06/03/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male				Female			
#Uterus: Sarcoma										
						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal										
						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal or Polyp	Stromal									
						1/50 (2%)				
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%		
#Uterus: Schwannoma Malignant										
_						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Squamous Cell Carcinoma										
•						0/50 (0%)				
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%		
#Zymbal's Gland: Adenoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Report Date: 06/03/2022

Page: 353

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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 354

Report Date: 06/03/2022

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		
Southern Research Institute	059302008	05/08/00	729	50(1)	39(710)	52.6	Diisopropylcarbodiimide
					Female		
Southern Research Institute	059302008	05/08/00	732	50(1)	33(674)	65.7	Diisopropylcarbodiimide

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 355

			Male			Female			
#All Organs: Benign Tumors									
J		29/50 (58%)				35/50 (70%)			
Overall Incidence	Total	29/50 (58%)	Mean 58%	SD 0%	Total	35/50 (70%)	Mean 70%	SD 0%	
#All Organs: Malignant Tumors									
_		27/50 (54%)				26/50 (52%)			
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total	26/50 (52%)	Mean 52%	SD 0%	
#All Organs: Malignant and Benign To	umors								
		42/50 (84%)				47/50 (94%)			
Overall Incidence	Total	42/50 (84%)	Mean 84%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%	
#All Organs: Hemangioma									
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#All Organs: Hemangiosarcoma									
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma								
		1/50 (2%)				6/50 (12%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 356

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2	2%)			3/50 (6%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#All Organs: Malignant Lymphoma: I	Histiocytic. Lym			Cell Type			•••••	
g ,	, _ , ,		4%)			10/50 (20%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%
#All Organs: Mesothelioma: Benign, Overall Incidence	Malignant, NOS		0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
·····					·····			
#All Organs: Mesothelioma: Maligna	nt	0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		,	0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 357

		Male			Female			
	0/50 (0%)	Maan 00/		Total	0/50 (0%)	Mann 00/	CD 0%	
ı otal	0/50 (0%)		SD 0%	ı otal	0/50 (0%)	Mean U%	SD 0%	
	5/50 (10%)				0/50 (0%)			
Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	` '	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%	
	, ,				, ,			
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
ınant	0/40 (00/)				0/40 /00/)			
Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
	Total Total Total	0/50 (0%) Total 0/50 (0%) 5/50 (10%) Total 5/50 (10%) 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/49 (0%) Total 0/49 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 5/50 (10%) Total 5/50 (10%) Mean 10% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/49 (0%) Total 0/49 (0%) Mean 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 5/50 (10%) Mean 10% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0%	a	a	a	

^{*:} 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

Page: 358

Report Date: 06/03/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Adrenal Medulla: Pheochromocytoma: Beni	gn, Complex,	, Malignant, NOS						
		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		0/10 / (00/)						
Occupati In al Januari	T-1-1	0/49 (0%)	M 00/	OD 00/	T-1-1	1/49 (2%)	Maria 0.040/	OD 00/
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Bone Marrow: Mast Cell Tumor Malignan	i	0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Bone: Chondroma						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	10tai	0/30 (0 /6)	ivicali 070			0/30 (0 /8)		
#Bone: Chondrosarcoma or Chond	droma							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 359

Report Date: 06/03/2022

Species: MICE

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Bone: Osteoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant		` ,				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maligi		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: SKIN Vehicle: ETHANOL

		Male				Female		
		waie				Female		
*Brain: Oligodendroglioma Benign 0/49 (0%) 0/50 (0%)								
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Malig	ınant	0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glio	ma, or Astrocy	toma 0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Brain: Sarcoma Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma		0/50 (0%)				0/46 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma		0/50 (0%)				0/46 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (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: 06/03/2022

Page: 361

Species: MICE Strain: B6C3F1/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			Female			
*Clitoral/Preputial Gland: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (09/)				0/46 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)				0/46 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%	
#Coagulating Gland: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Ear: Neural Crest Tumor, Maligna		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Epididymis: Hemangiosarcoma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

SKIN

Page: 362

			Male			Female				
*Epididymis: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%						
#Eye: Sarcoma		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Gallbladder: Adenoma		0/45 (0%)				0/42 (0%)				
Overall Incidence	Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/42 (0%)	Mean 0%	SD 0%		
*Gallbladder: Sarcoma Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/42 (0%) 0/42 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma		9/50 (18%)				9/50 (18%)				
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	9/50 (18%)	Mean 18%	SD 0%		
#Harderian Gland: Carcinoma		2/50 (4%)				1/50 (2%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 363 Report Date: 06/03/2022

			Male			Female			
#Harderian Gland: Carcinoma or Adenoma									
		10/50 (20%)				10/50 (20%)			
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%	
*Heart: Hemangiosarcoma									
-		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Heart: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Heart: Schwannoma Malignant									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma or Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 364

				Male			Female			
#Intestine Large: Cecum: Leiomyoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		0/30 (0/8)					0/30 (0 /8)	Weall 076		
#Intestine Large: Cecum: Leiomyosarcoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Polyp Adenomatous		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Colon/Rec Leiomyoma			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum Adenoma										
		1/50	(2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Duodenum Carcinoma	:	0/50	(00/)				0/50 (09/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 365

				Male				Female			
#Intestine Small: Duodenum: Hemangioma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Hemangiosarcoma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Polyp Adenomatous		- /									
Occupation of James	T-1-1		(0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Carcinoma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Adenoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

ute: SKIN

Page: 366

			Male			Female			
#Intestine Small: Jejunum: Polyp Adenomatous									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Maan 00/	SD 0%	
Overall incidence	10tal	0/50 (0%)	wiean 0%		Total	0/50 (0%)	Mean 0%	טט עס U%	
#Intestine Small: Site Unspec Adenoma	ified:								
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Site Unspec Carcinoma	ified:	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Carcinoma or Adenoma	ified:	1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Site Unspec Hemangioma	ified:	0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Hemangiosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

Page: 367

			Male			Female			
#Intestine Small: Site Unspe Polyp Adenomatous	cified:								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma									
		1/49 (2%)				0/50 (0%)			
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma									
	.	0/49 (0%)		00.00/	+	0/50 (0%)		OD 00/	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma									
Overall Insidence	Tatal	1/49 (2%)	Mana 0.040/	CD 00/	Total	0/50 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (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: SKIN Vehicle: ETHANOL Page: 368

			Male			Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma									
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Liver: Cholangiocarcinoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Liver: Hepatoblastoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male			Female				
*Liver: Hepatocellular Adenom	na									
•		18/50 (36%)				21/50 (42%)				
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	21/50 (42%)	Mean 42%	SD 0%		
*Liver: Hepatocellular Carcino	ma	20/50 (40%)				10/50 (20%)				
Overall Incidence	Total	20/50 (40%)	Mean 40%	SD 0%	Total	10/50 (20%)	Mean 20%	SD 0%		
*Liver: Hepatocellular Carcino		astoma				40/50 (000/)				
Overall Incidence	Total	20/50 (40%) 20/50 (40%)	Mean 40%	SD 0%	Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%		
*Liver: Hepatocellular Carcino		Ilular Adenoma 35/50 (70%)				29/50 (58%)				
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%		
*Liver:		ılar Adenoma, or Hepatok 35/50 (70%)				29/50 (58%)				
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%		
*Liver: Hepatocholangiocarcin	oma	0/50 (09/)				0/50 (/09/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N Length of Study: CHRONIC **Toxicology Data Management System**

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Report Date: 06/03/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

			Male			Female			
*Liver: Ito Cell Tumor Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Adenoma	•••••	0(50 (00))				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Ade	enoma	C/EO (420/)				4/50 (8%)			
Overall Incidence	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	
*Lung: Alveolar/Bronchiolar Car	cinoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Car	cinoma or Alve	eolar/Bronchiolar Adenoi 8/50 (16%)	ma			4/50 (8%)			
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	4/50 (8%)	Mean 8%	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

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Report Date: 06/03/2022

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

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			Female			
*Lung: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node: Hemangiosarcoma						0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Bronchial: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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				Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) N	lean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	lean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	lean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	N	lean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	nt								
Overall Incidence	Total	0/50 (0%)	0%) N	lean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Sarcoma			0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	lean 0%	SD 0%	Total	0/50 (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

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Report Date: 06/03/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Adenoma		0/50 (0%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,		Adenoma 1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mesentery: Fibrosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Species: MICE Strain: B6C3F1/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male Female

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			Male				Female	
#Mesentery: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma						0/50 (00/)		
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 06/03/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Nose: Hemangioma								
·		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		, , , ,				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva):						
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma							
-		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 06/03/2022

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			Male				Female	
#Oral Mucosa: Squamous Cell Papillom	a							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
•						1/49 (2%)		
Overall Incidence					Total	1/49 (2.04%)	Mean 2.04%	SD 0%
*Ovary: Granulosa Cell Tumor Be	enign							
Overall Incidence					Total	1/49 (2%)	Mean 2.04%	SD 0%
Overall incidence						1/49 (2.04%)	Viean 2.04%	טט טא U%
*Ovary: Granulosa Cell Tumor: B	Benign, Maligna	int, NOS						
Overall Incidence					Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%
*Ovary: Hemangioma								
						0/49 (0%)		
Overall Incidence					Total	0/49 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma								
						1/49 (2%)		
Overall Incidence					Total	1/49 (2.04%)	Mean 2.04%	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

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

Report Date: 06/03/2022

SD 0%

CD 00/

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Luteoma 0/49 (0%)0/49 (0%) SD 0% **Overall Incidence** Total Mean 0% *Ovary: Teratoma Benign 0/49 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% *Ovary: Thecoma Benign

0/49

0/40

0/49 (0%)

Total

(0%)

(00/)

*Ovary:	
Tubulostromal	Adenoma

		0/49 (070)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%

*Pancreas:

Hemangioma

Overall Incidence

		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

*Pancreas:

Sarcoma

	0/49 (0%)		0/50	(0%)
	()/49 (()%)		0/50	(()%)

Overall incluence	Total	0/49 (0%)	Mean 0%	3D 0%	TOTAL	0/30 (0%)	Wear 0%	3D 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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Dis	stalis or Unspecit	fied Site:						
		0/48 (0%)				4/48 (8%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	4/48 (8.33%)	Mean 8.33%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspecif	fied Site:					•••••	
		0/48 (0%)				1/48 (2%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/48 (2.08%)	Mean 2.08%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspecif							
		0/48 (0%)				5/48 (10%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	5/48 (10.42%)	Mean 10.42%	SD 0%
*Pituitary Gland: Pars Into								
		0/48 (0%)				0/48 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Into								
		0/48 (0%)				0/48 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%)						
Overall Incidence	Total	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 Inc

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 379

			Male				Female		
*Prostate: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
*Prostate: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
*Salivary Glands: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Seminal Vesicle: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%					
#Seminal Vesicle: Carcinoma									
Overall Incidence	Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 380

			Male	Female				
#Skeletal Muscle: Hemangioma								
_		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		4/50 (00)	N			0/50 (00/)		
Overall Incidence	Total	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incidence		1/50 (2%)				0/50 (0%)		
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma							
		1/50 (2%	,			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 06/03/2022

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

0/50 (0%)
` '
` ,
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (0%)
0/50 (0%) Mean 0% SD 0%
0/50 (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/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 382

			Male				Female		
#Skin: Fibroma									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin:									
Fibroma, Fibrosarcoma	, Sarcoma, Myxo		ibrous Histiocytoma			4/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Skin: Fibrosarcoma		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin:									
Fibrosarcoma, Sarcoma	a, Myxosarcoma		na			4/50 (20/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Skin: Fibrous Histiocytoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Hemangioma		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	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: SKIN Vehicle: ETHANOL Page: 383

			Male				Female	
#Skin: Hemangiosarcoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Keratoacanthoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (00/)				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Skin: Myxosarcoma								
		0/50 (0%)		25.00/		0/50 (0%)	••	05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne	urofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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

Tumor Incidence for Selected Control Animal Groups

Page: 385

Report Date: 06/03/2022

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Schwannoma Malignan	nt							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino	oma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquame	ous Tumor (malignar	nt or NOS),		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:	ma, Papilloma, S	quamous Cell Carcinon	na or Keratoacanthor	ma		0/50 /00()		
oquamous och i apmo		0/50 (0%)				0/50 (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: 06/03/2022

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Species: MICE Strain: B6C3F1/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			Female				
#Skin: Squamous Cell Papilloma, I	Papilloma, o	r Keratoacanthoma 0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)				0/50 /00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangioma		0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma		2/42 (221)								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%		
*Spleen: Mast Cell Tumor Malignant		0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 387

				Male				Female	е	
#Stomach, Forestomach: Hemangioma										
_		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma c	•	1/50	(2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma		1/50	(2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	,	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Glandular: Adenoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 388

				Male				Female		
#Stomach, Glandular: Carcinoma or Adenoma										
		,	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma										
		,	0%)							
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%					
*Testes: Hemangioma		0/50	(204)							
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%					
		, ,								
*Testes: Hemangiosarcoma		0/50	(004)							
	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%					
*Testes: Seratoli Tumor: Benign, Maligi										
Occupation and the statement of the stat	T - 1 - 1	,	(0%)	Maran 00/	00.00/					
Overall Incidence	Total ·····	0/50 (0%)		Mean 0%	SD 0%					
*Testes: Sertoli Cell Tumor Malignant		0/50 /	(004)							
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%					
		0/30 (0/0)								

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 389

			Male				Female	Female		
*Thymus: Hemangioma Overall Incidence	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma Benign		0/47 (0%)				0/46 (0%)				
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma Malignant		0/47 (0%)				0/46 (0%)				
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma: Benign, Maligr Overall Incidence	nant, NOS	0/47 (0%)	Mean 0%	SD 00/	Total	0/46 (0%)	Magn 00/	SD 0%		
Overall incidence	Total	0/47 (0%)		SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Adenoma		0/49 (0%)				0/50 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma		0/49 (0%)				0/50 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 390

				Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
Overall Incidence	Total	0/49 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma		0/40	00()						
Overall Incidence	Total	0/49 (0%)	0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		0/49 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/49 ((0%)				3/50 (6%)		
Overall Incidence	Total	0/49 (0%)		Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Tissue NOS: Sarcoma		2/22					2/52 (224)		
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	/	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 391

				Male				Female		
#Tongue: Squamous Cell Carcinoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma		a Squamous								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Sarcoma		0/50	(004)							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Carcinoma or Papilloma							0/50 (09/.)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 392

			Male				Female		
*Urinary Bladder: Hemangioma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Papilloma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Carcinoma									
Overall Incidence					Total	0/50 (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 **Route:** SKIN Report Date: 06/03/2022

Page: 393

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

Vehicle: ETHANOL

	Male			Female	
#Uterus: Deciduoma Benign			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	4/50 (8%) 4/50 (8%)	Mean 8%	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: SKIN Vehicle: ETHANOL Page: 394

		Male			Female			
#Uterus: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp \$						4/50 (8%)		
Overall Incidence					Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%
#Uterus: Schwannoma Malignant						0/50 (0%)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (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/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 395

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

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

^{#:} Denominator is number of animals necropsied