

NTP Historical Controls Report

By Route and Vehicle

MICE

October 2007

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.

Table of Contents

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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: 05/27/2022

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 Battelle Columbus Laboratory	058810504 059902304	05/09/02 04/11/02	728 728	50(1) 50(1)	39(688) 34(692)	56.7 56.2	Isoeugenol beta-Myrcene		
Female									
Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 059902304	05/08/02 04/10/02	727 727	49(5) 50(5)	34(679) 39(705)	65.0 64.1	Isoeugenol beta-Myrcene		

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: 5

			Male				Female	
#All Organs: Benign Tumors								
		33/50 (66%)	33/50 (66%)			20/49 (41%)	21/50 (42%)	
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 0%	Total	41/99 (41.41%)	Mean 41.41%	SD 0.84%
#All Organs: Malignant Tumors								
_		20/50 (40%)	30/50 (60%)			21/49 (43%)	14/50 (28%)	
Overall Incidence	Total	50/100 (50%)	Mean 50%	SD 14.14%	Total	35/99 (35.35%)	Mean 35.43%	SD 10.51%
#All Organs: Malignant and Benign Tu	umors	43/50 (86%)	43/50 (86%)			34/49 (69%)	30/50 (60%)	
Overall Incidence	Total	86/100 (86%)	Mean 86%	SD 0%	Total	64/99 (64.65%)	Mean 64.69%	SD 6.64%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/49 (0%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2%	SD 2.83%
#All Organs: Hemangiosarcoma								
		3/50 (6%)	7/50 (14%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 5.66%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
#All Organs: Hemangiosarcoma or He	emangioma							
		3/50 (6%)	7/50 (14%)			1/49 (2%)	3/50 (6%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 5.66%	Total	4/99 (4.04%)	Mean 4.02%	SD 2.8%

^{*:} 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								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs:					•••••			
Malignant Lymphoma: Hi	istiocytic, Lym	pnocytic, Mixed, NOS, or 0/50 (0%)	1/50 (2%)	Гуре		11/49 (22%)	7/50 (14%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	18/99 (18.18%)	Mean 18.22%	SD 5.97%
#All Organs: Mesothelioma: Benign, N	lalignant, NOS		0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0(50 (00))	0/50 (00.1)			4/40 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%

^{*:} 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: 7

		Male				Female	
na							
	0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
-	` '	, ,	00 4 440/		` '	` '	05 4 440/
l otal	5/100 (5%)	Mean 5%	SD 1.41%	l otal	1/98 (1.02%)	Mean 1%	SD 1.41%
	` '	, ,			` ,	` '	
l otal	0/100 (0%)	Mean 0%	SD 0%	l otal	0/98 (0%)	Mean 0%	SD 0%
ign	0/50 (09/)	0/50 (09/)			0/49 (00/)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
nplex							
	0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
gnant	0/50 /00/\	0/50 (0%)			0/40 (00/)	0/50 (00/)	
Total	` '	` '	SD 0%	Total	()	` ,	SD 0%
	Total Total ign Total nplex Total	0/50 (0%) Total 0/100 (0%) 3/50 (6%) Total 5/100 (5%) 0/50 (0%) Total 0/100 (0%) ign 0/50 (0%) Total 0/100 (0%) nplex 0/50 (0%) Total 0/100 (0%) gnant 0/50 (0%)	10	10	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 3/50 (6%) 2/50 (4%) Total 5/100 (5%) Mean 5% SD 1.41% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total ign 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total nplex 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) 0/50 (0%) SD 0% Total 1/99 (1.01%) 3/50 (6%) 2/50 (4%) O/41% Total 1/99 (1.01%) Total 5/100 (5%) Mean 5% SD 1.41% Total 1/98 (1.02%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/98 (0%) ign 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/98 (0%) iplex 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/98 (0%) iplex 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) iplex 0/50 (0%) Mean 0% SD 0% Total 0/98 (0%) iplex 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) iplex 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%) iplex 0/50 (0%) 0/50 (0%) SD 0% Total 0/98 (0%)	Total 0/50 (0%) 0/50 (0%) SD 0% Total 1/99 (1.01%) Mean 1.02% 3/50 (6%) 2/50 (4%)

^{*:} 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 0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%)												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma			- 15									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (00/)	0/50 (00/)			0/40 /00/	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%				
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/49 (2%)	0/50 (0%) Mean 1.02%	SD 1.44%				

^{*:} 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**: 9

			Male				Female	
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0.50 (00.1)	4/50 (05:)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/47 (0%) 0/96 (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 10

Report Date: 05/27/2022

Length of Study: CHRONIC

Vehicle: CORN OIL

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma								
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/49 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/44 (0%)	0/49 (0%)			0/42 (0%)	0/47 (0%)	
Overall Incidence	Total	0/93 (0%)	Mean 0%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		8/50 (16%)	9/50 (18%)			3/49 (6%)	4/50 (8%)	
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 1.41%	Total	7/99 (7.07%)	Mean 7.06%	SD 1.33%
#Harderian Gland: Carcinoma								
		4/50 (8%)	1/50 (2%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%

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

^{#:} Denominator is number of animals necropsied

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: 11

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%)	9/50 (18%)			4/49 (8%)	4/50 (8%)	
Overall Incidence	Total	21/100 (21%)	Mean 21%	SD 4.24%	Total	8/99 (8.08%)	Mean 8.08%	SD 0.12%
*Heart: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Heart: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma			0/50 /02/			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%)	SD 0%
Overall incidence	Total	0/100 (0%)	Wear 0%	3D 0%	Total	0/99 (0%)	Mean 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: GAVAGE Vehicle: CORN OIL **Page:** 12

			Male				Female		
#Intestine Large: Cecum: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	05.00/		0/49 (0%)	0/50 (0%)	25 -24	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Adenoma									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Carcinoma									
	.	0/50 (0%)	0/50 (0%)	00.00/	-	0/49 (0%)	0/50 (0%)	00.00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Carcinoma		0/50 (00/)	0/50 (00/)			0/40 (00/)	0 (50 (00))		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
Overall incluence	ıvıaı	0/100 (0%)	IVICALI U70	JD 0%	I Ulai	0/33 (070)	IVICALI U70	30 0/6	

^{*:} 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:** 13

			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 /00/)			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
						` '		
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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 Small: Site Unspecified: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%		
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%		
#Intestine Small: Site Unsp Hemangiosarcoma										
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:									
• " "	-	0/50 (0%)	0/50 (0%)	00.00/	T	0/49 (0%)	0/50 (0%)	00.00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unsp Polyp Adenomatous	ecified:									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: Adenoma		0/50 /00/	0/50 (00)			0/47 (00%)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%		
	ı olal	0/100 (0%)	IVICALI U70	JD 0%	TOlai	0/8/ (076)	ivicali 070	3D 0/0		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 15

			Male				Female	
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			0/47 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma	•••••							
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma	•••••	0/50 (00/)	0/50 (00/)			0/47 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangiocarcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} 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:** 16

			Male				Female	
*Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		4/50 (00/)	5/50 /400/			0/40 /00()	0/50 (00/)	
Overall Incidence	Total	1/50 (2%)	5/50 (10%) Mean 6%	SD 5.66%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence		6/100 (6%)	wiean 6%	3D 3.00%	Total	0/99 (0%)	wiean 0%	3D 0%
*Liver: Hepatoblastoma		0/50 (00/)	4/50 (00)			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	3/50 (6%) 7/100 (7%)	4/50 (8%) Mean 7%	SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		24/50 (48%)	26/50 (52%)			11/49 (22%)	6/50 (12%)	
Overall Incidence	Total	50/100 (50%)	Mean 50%	SD 2.83%	Total	17/99 (17.17%)	Mean 17.22%	SD 7.39%
*Liver: Hepatocellular Carcinoma								
• " ' '		8/50 (16%)	14/50 (28%)	00 0 100/	-	3/49 (6%)	1/50 (2%)	00.000/
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 8.49%	Total	4/99 (4.04%)	Mean 4.06%	SD 2.92%

^{*:} 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: 17

			Male				Female	
*Liver: Hepatocellular Carcino	oma or Hepatobl	astoma		,				
•	•	11/50 (22%)	16/50 (32%)			3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	27/100 (27%)	Mean 27%	SD 7.07%	Total	4/99 (4.04%)	Mean 4.06%	SD 2.92%
Liver: Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma						
·	•	28/50 (56%)	33/50 (66%)			13/49 (27%)	7/50 (14%)	
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 7.07%	Total	20/99 (20.2%)	Mean 20.27%	SD 8.86%
Liver:		ular Adenoma, or Hepatob 30/50 (60%)				13/49 (27%)	7/50 (14%)	
Overall Incidence	Total	64/100 (64%)	Mean 64%	SD 5.66%	Total	20/99 (20.2%)	Mean 20.27%	SD 8.86%
Liver: Hepatocholangiocarcir		2/50 (4%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/99 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Maligna			•••••					
		0/50 (0%)	2/50 (4%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/99 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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:** 18

			Male				Female	
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Ade	noma							
		6/50 (12%)	8/50 (16%)			4/48 (8%)	4/50 (8%)	
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 2.83%	Total	8/98 (8.16%)	Mean 8.17%	SD 0.24%
Lung: Alveolar/Bronchiolar Card	cinoma	2/50 (40/)	E/EQ (400/)			0/49 (00/)	2/50 (49/)	
Overall Incidence	Total	2/50 (4%) 7/100 (7%)	5/50 (10%) Mean 7%	SD 4.24%	Total	0/48 (0%) 2/98 (2.04%)	2/50 (4%) Mean 2%	SD 2.83%
*Lung: Alveolar/Bronchiolar Card Overall Incidence	Total	7/50 (14%) 20/100 (20%)	13/50 (26%) Mean 20%	SD 8.49%	Total	4/48 (8%) 10/98 (10.2%)	6/50 (12%) Mean 10.17%	SD 2.59%
Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma		0/50 (00)	0/50 (001)			0140 (00)	0/50 (00/)	
	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/48 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 19

			Male				Female	
Lung: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Lymph Node: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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: 20

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
Occupation of James	Tatal	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma						
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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: 21

			Male				Female	
#Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Mesentery: Hemangiosarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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:** 22

			Male				Female	
*Nose: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Nose: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Nose: Mast Cell Tumor Malign		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phar							
-		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (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: 23

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%)											
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Oral Mucosa: Squamous Cell Carcinor	ma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Ovary: Choriocarcinoma											
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Ovary: Cystadenoma						3/48 (6%)	2/50 (40/)				
Overall Incidence					Total	5/98 (5.1%)	2/50 (4%) Mean 5.12%	SD 1.59%			
*Ovary: Fibrous Histiocytoma											
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor Be	enign										
Overall Incidence					Total	0/48 (0%) 0/98 (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 Vehicle: CORN OIL

Length of Study: CHRONIC

Report Date: 05/27/2022

Page: 24

Male		Female				
*Ovary: Granulosa Cell Tumor Malignant		2442 (221)	2(72 (22))			
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS						
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Hemangioma						
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Hemangiosarcoma						
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Leiomyosarcoma						
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Luteoma						
Overall Incidence	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%		

^{*:} 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:** 25

			Male				Female	
*Ovary: Teratoma Benign						0/40 (00/)	0/50 (00/)	
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	4/47 (9%) 5/97 (5.15%)	1/50 (2%) Mean 5.26%	SD 4.6%
*Pituitary Gland: Pars Distal Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (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: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)(9%)1/50 (2%)0/99 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 5/97 (5.15%) Mean 5.26% SD 4.6% *Pituitary Gland: Pars Intermedia: Adenoma 0/50 (0%)0/49 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/50 (0%)0/49 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% *Prostate: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Prostate: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/99 (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: 27

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		- (a)				2/12	(70)	
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/49 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		2/22 (221)	0.75			2(12 (22))	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence		` '			Total	` '		
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma	ı						
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin:	_							
Basal Cell Adenoma or I	Basosquamous	•	0/50 (00/)			0/40 (00/)	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
		` '				1/99 (1.01/0)	IVICALI I /0	
#Skin:								
Basal Cell Adenoma, Ba	sosquamous T	umor Benign, or Trichoep	oithelioma					
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma				•••••				
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or		s Tumor (malignant or NO				0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin:	Basal Cell Adend	oma, Basosquamous Tur	nor (benign, malignan					
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%)		ıa,		0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%

^{*:} 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:** 29

			Male				Female	
#Skin: Basosquamous Tumor	Benign							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Fibroma								
		0/50 (0%)	0/50 (0%)	25		0/49 (0%)	1/50 (2%)	00 4 4404
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo Total	oma, Myxosarcoma, or Fil 0/50 (0%) 1/100 (1%)	orous Histiocytoma 1/50 (2%) Mean 1%	SD 1.41%	Total	3/49 (6%) 5/99 (5.05%)	2/50 (4%) Mean 5.06%	SD 1.5%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	, ,	CD 4 440/
		, ,				1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin:		, or Fibrous Histiocytoma						
#Skin:		or Fibrous Histiocytoma 0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	3/49 (6%) 5/99 (5.05%)		
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	or Fibrous Histiocytoma 0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%		Total	3/49 (6%) 5/99 (5.05%)	2/50 (4%)	

^{*:} 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:** 30

			Male				Female	
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Hemangiosarcoma								
		1/50 (2%)	1/50 (2%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		2/22 (221)	2/52 (221)			2/12	2/22	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total		` '	SD 0%	Total	` ,	` '	SD 0%
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (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 Re

Report Date: 05/27/2022

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			Male				Female	
#Skin: Neurofibrosarcoma or Sch	wannoma (m	nalignant or NOS) 0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neuro	ofibroma, or §		-		•••••	0/40 /00/	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Osteosarcoma	•••••	0/50 (09/)	0/50 (00/)			0/49 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	1/50 (2%)			3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/99 (4.04%)	Mean 4.06%	SD 2.92%
#Skin: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma	1	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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: 05/27/2022

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell (Carcinoma, Basosquamou	ıs Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	or Papilloma							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, S	Gquamous Cell Carcinoma 0/50 (0%)	or Keratoacanthoma	1		0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, o	or Keratoacanthoma 0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma					•••••			
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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:** 33

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (00)	0/40 /00/			0/40 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
		` '						
*Spleen: Hemangioma								
		0/50 (0%)	0/49 (0%)	05 00/		0/48 (0%)	0/49 (0%)	00.007
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
-		0/50 (0%)	1/49 (2%)			1/48 (2%)	0/49 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/97 (1.03%)	Mean 1.04%	SD 1.47%
#Stomach, Forestomach: Mast Cell Tumor Malignant		2/20	(0.5)					
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-!	0/49 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (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:** 34

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
•	•	0/50 (0%)	0/50 (0%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
#Stomach, Forestomach: Squamous Cell Papilloma	•••••	0/50 (0%)	0/50 (0%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
#Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	0/50 /00/\			4/40 /20/	0/50 (09/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 00/	Total	1/49 (2%)	0/50 (0%)	SD 1.440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%

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

^{#:} Denominator is number of animals necropsied

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:** 35

		Male				Female	
Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%				
	0/50 (0%)						
Total	0/100 (0%)	Mean 0%	SD 0%				
	;						
Total	0/100 (0%)	Mean 0%	SD 0%				
ant							
Total	0/100 (0%)	Mean 0%	SD 0%				
Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
nant, NOS	0/40 /050	0.47 (00)			0/47 (00/)	0/40 /00/	
Total	0/48 (0%) 0/95 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
	Total Malignant, NOS Total ant Total Total	Total 2/100 (2%) 0/50 (0%) Total 0/100 (0%) Malignant, NOS	2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Malignant, NOS 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% ant 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/48 (0%) 0/47 (0%) Total 0/95 (0%) Mean 0%	2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Malignant, NOS 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% ant 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/48 (0%) 0/47 (0%) Total 0/95 (0%) Mean 0% SD 0%	Total 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% O/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Alignant, NOS	2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% O/50 (0%) 0/50 (0%) Mean 0% SD 0% Aalignant, NOS	2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Aalignant, NOS 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% ant 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ant 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ant 0/47 (0%) 0/49 (0%) Total 0/95 (0%) Mean 0% SD 0% Total 0/96 (0%) Mean 0% O/48 (0%) 0/47 (0%) O/47 (0%) 0/48 (0%) 0/47 (0%) 0/49 (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:** 36

1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (0%)	SD 0% SD 0% SD 0%	Total Total	0/48 (0%) 0/98 (0%) 0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
/50 (0%) /lean 0% //50 (0%) //50 (0%) //50 (0%)	SD 0%	Total	0/98 (0%) 0/48 (0%) 0/98 (0%) 0/48 (0%)	Mean 0% 0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
1/50 (0%) Ilean 0% 1/50 (0%) Ilean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%) 0/48 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
lean 0% 0/50 (0%) lean 0%			0/98 (0%)	Mean 0% 0% 0/50 (0%)	
lean 0% 0/50 (0%) lean 0%			0/98 (0%)	Mean 0% 0% 0/50 (0%)	
lean 0%	SD 0%	Total	` '	` '	
lean 0%	SD 0%	Total	` '	` '	
		iotai	0/98 (0%)	Mean 0%	SD 0%
	SD 0%	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%
/50 (2%)			0/48 (0%)	0/50 (0%)	
lean 2%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
/50 (00/)			0/40 /00/	4/50 (00()	
/50 (2%)	CD 00/	Total	` ,	` ,	SD 1.41%
1	/50 (2%) flean 2% /50 (2%)	/50 (2%) Mean 2% SD 0% /50 (2%)	/50 (2%) 1ean 2% SD 0% Total /50 (2%)	/50 (2%)	/50 (2%) 0/48 (0%) 0/50 (0%) flean 2% SD 0% Total 0/98 (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: CORN OIL **Page**: 37

			Male				Female	
#Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (00)	0/50 (00/)			0/40 (00/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)	00.00/		0/49 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (00)	4/50 (00/)			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%)	SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	` '	Mean 1%			0/99 (0%)	wean 0%	
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous						
		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} 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: 38

			Male				Female	
#Tooth: Odontoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0(40 (00))	0/50 (004)			0/47 (00/)	0/50 (00)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/49 (0%)	0/50 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Deciduoma Benign						0(10 (00))	0/50 (00)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma			0/49 (0%)	0/50 (0%)	
Overall Incidence		Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina:								
Squamous Cell Papilloma Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} 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: 05/27/2022

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			26/50 (52%) 26/50 (52%) Mean 52% SD 09 39/50 (78%) 39/50 (78%) Mean 78% SD 09 1/50 (2%) 1/50 (2%) Mean 2% SD 09 3/50 (6%) 3/50 (6%) Mean 6% SD 09			
#All Organs: Benign Tumors									
•		37/50 (74%)				25/50 (50%)			
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	, ,		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%)				20/50 /78%\			
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	` ,	Mean 78%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				` '			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,		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

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	
#All Organs: Histiocytic Sarcoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
Overall incidence	rotai	0/50 (0%)		wean 0%	SD 0%	ı otal	2/50 (4%)	wean 4%	SD 0%
#All Organs: Malignant Lymphoma: Histi	ocytic, Lymp			Undifferentiated Ce	ell Type		0/50 (400/)		
Overall Incidence	Total	2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#All Organs: Mesothelioma: Benign, Mali		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%)	(0,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		- 1							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(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

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: Sarcoma								
		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 Medulla: Pheochromocytoma Benign								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comple								
		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 Medulla: Pheochromocytoma Maligna	ant					(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%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0%												
Overall Incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Bone Marrow: Hemangiosarcoma		1/50	(2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	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: 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												
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 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%			

^{*:} 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: 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: 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%
*Clitoral/Preputial Gland: Adenoma		2/22 (221)				(200)		
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/48 (0%)	Mana 00/	CD 00/
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: 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%
*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%

^{*:} 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	
*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%
*Epididymis: Sarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma		0.000				(201)		
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		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								
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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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		Male				Female	
Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%
	0/50 (0%)		05.00/		0/50 (0%)		25
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (0%)				0/50 (0%)		
Total	` '		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (00/)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	1/50 (2%)				0/50 (0%)		
Total	` '	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
					0/50 (00/)		
Total	,	Mean 2%	SD 0%	Total	` '	Mean 0%	SD 0%
	Total Total Total	Total 11/50 (22%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) 1/50 (2%)	11/50 (22%) Total 11/50 (22%) Mean 22% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% 1/50 (2%) Total 1/50 (2%) 1/50 (2%)	Total 11/50 (22%) Total 11/50 (22%) Mean 22% SD 0% O/50 (0%)	Total 11/50 (22%) Total 11/50 (22%) Mean 22% 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 1/50 (2%) Mean 2% SD 0% Total	Total 11/50 (22%) Mean 22% SD 0% Total 4/50 (8%) Total	Total 11/50 (22%) Mean 22% SD 0% Total 4/50 (8%) Mean 8% O/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

	Male							Female	
#Intestine Large: Cecum: Leiomyosarcoma		2/20	(224)				(201)		
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50	(00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,				10lai			JD 0%
fintestine Small: Duodenum: Adenoma									
	-	,	(0%)		00.007	.	0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Carcinoma		0/50 ((0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(3,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma									

SD 0%

Total

0/50 (0%)

Total

0/50 (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: METHYLCELLULOSE

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			Male				Female	
#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		•••••		•••••		•••••		
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: 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%
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: Polyp Adenomatous								
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 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: METHYLCELLULOSE

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				Male				Female				
#Intestine Small: Site Unspecified: Carcinoma												
Overall Incidence	Total	0/50 (0%)	0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Intestine Small: Site Unsp Carcinoma or Adenoma												
Overall Incidence	Total	1/50 (2%)	2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:		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 Unsp Leiomyosarcoma			0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Intestine Small: Site Unsp Polyp Adenomatous				•••••			•••••		•••••			
Overall Incidence	Total	0/50 (0/50 (0%)	0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Islets, Pancreatic: Adenoma		0/50					4/40 (00/)					
Overall Incidence	Total	0/50 (0/50 (0%)	0%)	Mean 0%	SD 0%	Total	1/46 (2%) 1/46 (2.17%)	Mean 2.17%	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	
*Islets, Pancreatic: 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%
*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								
		0/49 (0%)				0/48 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	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%
		, ,						
*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%
*Liver: Cholangiocarcinoma		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%
Overall incidence	างเลเ	0/50 (0%)	IVIEAN U%	SD 0%	างเลเ	0/50 (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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Liver: 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%
*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%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	28/50 (56%) 28/50 (56%)	Mean 56%	SD 0%	Total	15/50 (30%) 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%

^{*:} 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						
*Liver: Hepatocellular Carcinoma or Hepatoblastoma												
.,		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:		Under Ademand		•••••								
Hepatocellular Carcino	ma or Hepatoce	37/50 (74%)				19/50 (38%)						
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%				
*Liver: Hepatocellular Carcino Overall Incidence	ma, Hepatocellu Total	38/50 (76%) 38/50 (76%)	olastoma Mean 76%	SD 0%	Total	19/50 (38%) 19/50 (38%)	Mean 38%	SD 0%				
Liver: Hepatocholangiocarcin		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: Ito Cell Tumor Maligna	nt	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%				
*Liver:												
Sarcoma		0/50 (00/)				0/50 (0%)						
Sarcoma		0/50 (0%)				0/00 (0/0)						

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: MICE

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

Vehicle: METHYLCELLULOSE

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			Male				Female	
*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 Ade								
		11/50 (22%)				1/50 (2%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Lung: Alveolar/Bronchiolar Card	cinoma	4/50 (00)				E/F0 (400)		
O	T-1-1	1/50 (2%)	M 00/	OD 00/	T-1-1	5/50 (10%)	M 400/	OD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Lung: Alveolar/Bronchiolar Card						6/50 (12%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
*Lung: 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%
*Lung: 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%

^{*:} 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%	
#Lymph Node: 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%	
#Lymph Node: 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: 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: Fibrous Histiocytoma		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

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	
#Lymph Node, Mediastinal: Hemangiosarcoma									
			(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		- /							
Overell Incidence	Total	0/50 0/50 (0%)	(0%)	Maan Oo/	SD 0%	Total	0/50 (0%) 0/50 (0%)	Maan 00/	SD 0%
Overall Incidence	notai	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	2D 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		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%
#Mamman, Cland									
#Mammary Gland: Carcinoma									
		0/50	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Carcinoma or Adenoma									
		0/50	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or		(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	(0/0)	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

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			
#Mesentery: Fibrosarcoma										
		,	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Fibrous Histiocytoma		0/50 //	00()				0/50 (004)			
O	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%	
#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%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Sarcoma										
		,	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				
*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%		
*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: Mast 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%		
*Nose: 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%		
#Oral Cavity (Oral Mucosa, Papilloma Squamous or	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 Carcinon	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%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1/N Length of Study: CHRONIC

Route: GAVAGE Vehicle: METHYLCELLULOSE **Page:** 60

			Male				Female					
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)												
#Oral Mucosa: Squamous Cell Carcinom	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: Choriocarcinoma						0/47 (00/)						
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%				
*Ovary: Cystadenoma						2/47 (4%)						
Overall Incidence					Total	2/47 (4.26%)	Mean 4.26%	SD 0%				
*Ovary: Fibrous Histiocytoma												
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%				
*Ovary: Granulosa Cell Tumor Be	nign					0/47 /00/						
Overall Incidence					Total	0/47 (0%) 0/47 (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					
*Ovary: Granulosa Cell Tumor Malignant							
Overall Incidence	То		0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
Overall Incidence	То		0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Hemangioma			0/47 (00/)				
Overall Incidence	То		0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Hemangiosarcoma							
Overall Incidence	То	tal 1/4	` '	Mean 2.13%	SD 0%		
*Ovary: Leiomyosarcoma							
Overall Incidence	То		0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Luteoma					•••••		
Overall Incidence	То		0/47 (0%) 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

Contract/Lab. All Laboratories

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			
*Ovary: Teratoma Benign										
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenoma										
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%		
*Pancreas: Carcinoma										
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: Carcinoma or Adenoma		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 Distali Adenoma										
	-	0/50 (0%)		OD .00/	+	1/46 (2%)		OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%		
*Pituitary Gland: Pars Distali Carcinoma	s or Unspeci	ied 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%		

^{*:} 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					
Pituitary Gland: Pars Distalis or Unspecified Site: 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%				
*Pituitary Gland: Pars Inter 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 Inter 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%				
*Prostate: Adenoma		0/49 (0%)										
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma												
		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%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
Overall illulation	IUIAI	U/3U (U70)	IVIEATI U70	OD 0%	ı Ulal	0/30 (0%)	IVICALI U%	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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female		
*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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Skeletal Muscle: 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%	
#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 I									
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: Sarcoma		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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous [°]	•				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: Basal Cell Adenoma, Ba	asosquamous Tu Total	umor Benign, or Tricho 0/50 (0%) 0/50 (0%)	pepithelioma Mean 0%	SD 0%	Total	0/50 (0%) 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: Basal Cell Carcinoma of	r Basosquamous Total	s Tumor (malignant or 0/50 (0%) 0/50 (0%)	NOS) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelic		ma, Basosquamous T	umor (benign, maligna	ant or		1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, Sc				ma,		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

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							
#Skin: 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: 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 Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or F 1/50 (2%) 1/50 (2%)	brous Histiocytoma Mean 2%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%					
#Skin: Fibrosarcoma		0/50 (0%)				3/50 (6%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%					
#Skin:	a, Myxosarcoma,	or Fibrous Histiocytom	a			3/50 (6%)							
#Skin:	a, Myxosarcoma , Total	, or Fibrous Histiocytom	a Mean 2%	SD 0%	Total		Mean 6%	SD 0%					
#Skin: Fibrosarcoma, Sarcom		or Fibrous Histiocytom				3/50 (6%)							

^{*:} 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			
#Skin: Hemangioma								
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: 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: Liposarcoma		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%
#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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		1 (5-1)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: R6C3E1/N

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					
#Skin: Neurofibrosarcoma or Schwannoma (malignant 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, Neur	ofibroma, or S	chwannoma (benign, ma	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%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: 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%				
#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 Carcinom	na	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

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or 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% **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 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, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #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 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 70

			Male		Female			
#Skin: Sebaceous 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%
#Spinal Cord: 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%
*Spleen: Fibrous Histiocytoma		0/49 (0%)				0/47 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/49 (0%)				0/47 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		2/49 (4%)				0/47 (0%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Mast Cell Tumor Malignan	t	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: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 71

		Male						Female					
#Stomach, Forestomach: 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%				
#Stomach, Forestomach:	o or Donillom	Caucamous											
Squamous Cell Carcinom	a or Papilloma	o/50	(0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Stomach, Forestomach: 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%				
#Stomach, Glandular: Adenoma		0/50	(0%)				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%				
#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%				
#Stomach, Glandular: Carcinoma or Adenoma		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%				

^{*:} 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

Page: 72

				Male				Female	
*Testes: Adenoma									
		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, Mali									
Overell Insidence	Tatal	0/50	(0%)	Mann 00/	CD 00/				
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%				
*Thymus: Thymoma Malignant		0/20	(00()				0/42 /00/		
Overall Incidence	Total	0/38 0/38 (0%)	(0%)	Mean 0%	SD 0%	Total	0/43 (0%) 0/43 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malignar	it, NOS								
		0/38	(0%)				0/43 (0%)		
Overall Incidence	Total	0/38 (0%)		Mean 0%	SD 0%	Total	0/43 (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: 73

				Male				Female	
*Thyroid Gland: Adenoma									
Overell hasidenes	Tatal		(0%)	Mana 00/	CD 00/	Tatal	0/46 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma									
			(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 or Adenoma		0/50	(0%)				0/46 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Adenoma									
			(6%)				1/46 (2%)		
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	1/46 (2.17%)	Mean 2.17%	SD 0%
*Thyroid Gland: Follicular Cel 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%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma			(60/)				4/46 (20/.)		
Overall Incidence	Total		(0%)	Mean 6%	SD 0%	Total	` ,	Mean 2 17%	SD 0%
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	1/46 (2%) 1/46 (2.17%)	Mean 2.17%	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

Page: 74

				Male				Female	
#Tissue NOS: Carcinoma									
		0/50 (0	%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		n 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma									
		0/50 (0	%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear	า 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0	.07.)				0/50 (00/)		
Overall Incidence	Total	0/50 (0 0/50 (0%)	l%) Mear	n 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
·····		, ,							
#Tongue: Squamous Cell Carcinoma		0/50 /0					0/50 (00/)		
Overall Incidence	Total	0/50 (0 0/50 (0%)	,	า 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,							
#Tongue: Squamous Cell Carcinoma of	or Papilloma	•					2/22 (221)		
	-	•	(%)	001	00.00/		0/50 (0%)		OD 00/
Overall Incidence	Total	0/50 (0%)	Mear	n 0% 	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma									
		,	1%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mear		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

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male			Female			
#Tooth: Odontoma 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: Hemangioma		0/49 (00/)				0/45 (00/)			
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma		1/48 (2%)				0/45 (0%)			
Overall Incidence	Total	1/48 (2.08%)	Mean 2.08%	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									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Deciduoma Benign						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:** 76

ep	or	t L	ate:	05/	21	//2	022

Male				
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
Total	0/50 (0%) 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%	
	Total Total Total	Total 0/50 (0%) 1/50 (2%) Total 1/50 (2%) 1/50 (2%) Total 1/50 (2%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	Total 0/50 (0%) Mean 0% 1/50 (2%) Total 1/50 (2%) Mean 2% 1/50 (2%) Total 1/50 (2%) Mean 2% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (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: METHYLCELLULOSE

Page: 77

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma						4/50 (001)		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Squamous Cell Papilloma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: 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%
#Zymbal's Gland: 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: WATER **Page:** 78

Report Date: 05/27/2022

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 Battelle Columbus Laboratory	058812307 059501106	10/04/01 08/09/01	728 728	50(1) 50(1)	39(698) 40(702)	52.9 52.3	Formamide 5-(Hydroxymethyl)-2-furfural
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 059501106	10/03/01 08/08/01	727 727	50(5) 50(5)	38(692) 39(694)	64.7 64.4	Formamide 5-(Hydroxymethyl)-2-furfural

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:** 79

			Male				Female	
#All Organs: Benign Tumors		04/50 (000)	40/50 /0.40/			47/50 (046)	00/50 /500/	
Overall Incidence	Total	31/50 (62%) 73/100 (73%)	42/50 (84%) Mean 73%	SD 15.56%	Total	17/50 (34%) 43/100 (43%)	26/50 (52%) Mean 43%	SD 12.73%
#All Organs: Malignant Tumors								
Overall Incidence	Total	28/50 (56%) 54/100 (54%)	26/50 (52%) Mean 54%	SD 2.83%	Total	26/50 (52%) 42/100 (42%)	16/50 (32%) Mean 42%	SD 14.14%
#All Organs: Malignant and Benign T								
Overall Incidence	Total	41/50 (82%) 90/100 (90%)	49/50 (98%) Mean 90%	SD 11.31%	Total	36/50 (72%) 70/100 (70%)	34/50 (68%) Mean 70%	SD 2.83%
#All Organs: Hemangioma		2/50 (4%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	2/50 (4%) 7/100 (7%)	5/50 (10%) Mean 7%	SD 4.24%
#All Organs: Hemangiosarcoma or H	lemangioma							
Overall Incidence	Total	5/50 (10%) 7/100 (7%)	2/50 (4%) Mean 7%	SD 4.24%	Total	2/50 (4%) 9/100 (9%)	7/50 (14%) Mean 9%	SD 7.07%

^{*:} 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: 80

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cell	Туре				
		2/50 (4%)	2/50 (4%)			10/50 (20%)	8/50 (16%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	18/100 (18%)	Mean 18%	SD 2.83%
#All Organs: Mesothelioma: Benign, Ma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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:** 81

			Male				Female	
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		2/50 (4%)	5/49 (10%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	7/99 (7.07%)	Mean 7.1%	SD 4.39%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma								
		0/50 (0%)	0/49 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comple								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maligna	ant							
		1/50 (2%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (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: 82

			Male				Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 1/50 (2%) 0/49 (0%) 0/50 (0%) 0/50 (0%)												
Occupation delicated and a	Taral	1/50 (2%)	0/49 (0%)	00 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/40 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/49 (0%) Mean 0%	SD 0%				
		0/100 (0%)			Total	0/99 (0%)	iviedii 0%	0%				
#Bone: Osteoma		0/50 (00)	0(50 (00))			0/50 (001)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
		` '				` '						
#Bone: Osteosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma or Osteoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

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: 83

			Male				Female	
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		-4						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Tatal	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '			Total	(,		ט עא ט עא
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	25
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
	.	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	00.004
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 84

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/47 (0%) 0/50 (0%) Total 0/97 (0%) Mean 0% SD 4/50 (8%) 7/50 (14%)			
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	, ,	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Eye: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
*Gallbladder: Adenoma		0/45 (0%)	0/49 (0%)					
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	` '	` ,	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	6/50 (12%) 17/100 (17%)	11/50 (22%) Mean 17%	SD 7.07%	Total	, ,	, ,	SD 4.24%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%

^{*:} 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: 85

			Male Female				8/50 (16%) 7/50 (14%) % Total 15/100 (15%) Mean 15% SD 0/50 (0%) 0/50 (0%) % Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) O/50 (0%) 0/50 (0%)		
#Harderian Gland: Carcinoma or Adenoma									
		7/50 (14%)	13/50 (26%)			8/50 (16%)	7/50 (14%)		
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 8.49%		` ,		SD 1.41%	
*Heart: Hemangioma									
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
Heart: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			` '	` '		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		' '		SD 0%	
Heart: Sarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` ,		SD 0%	
fintestine Large: Cecum: Carcinoma									
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

^{*:} 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: 86

			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	Taral	0/50 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (09/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (00/)	0/50 (00)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	Total	` '			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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 87

			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		- (aa)					(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						0/100 (0 %)		
#Intestine Small: Jejunum: Hemangiosarcoma		2/22 (221)	0.750 (001)			2(22)	0.750 (001)	
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma								
		0/50 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	05.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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

			Male				Female	
#Intestine Small: Site Unspe Carcinoma	ecified:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Hemangiosarcoma	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma	ecified:	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspe Polyp Adenomatous								•••••
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
	-	0/50 (0%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 89

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD		
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			` '	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	1/50 (2%)			` '	` '	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		- (ac.)					(00)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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:** 90

			Male Female					
*Liver: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatoblastoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	24/50 (48%) 57/100 (57%)	33/50 (66%) Mean 57%	SD 12.73%	Total	6/50 (12%) 20/100 (20%)	14/50 (28%) Mean 20%	SD 11.31%
*Liver: Hepatocellular Carcinoma		4E/E0 (2004)	44/50 (222/)			A/EO (00/)	2/50 /40/	
Overall Incidence	Total	15/50 (30%) 26/100 (26%)	11/50 (22%) Mean 26%	SD 5.66%	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page**: 91

			Male			Female		
*Liver: Hepatocellular Carcino	ma or Hepatobla	astoma						
	-	16/50 (32%)	12/50 (24%)			4/50 (8%)	3/50 (6%)	
Overall Incidence	Total	28/100 (28%)	Mean 28%	SD 5.66%	Total	7/100 (7%)	Mean 7%	SD 1.41%
*Liver: Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma						
·	•	33/50 (66%)	39/50 (78%)			9/50 (18%)	14/50 (28%)	
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	23/100 (23%)	Mean 23%	SD 7.07%
•	•	ular Adenoma, or Hepatob 34/50 (68%)	39/50 (78%)	00 7.07%		9/50 (18%)	15/50 (30%)	OD 0.4004
Overall Incidence	Total	73/100 (73%)	Mean 73%	SD 7.07%	Total	24/100 (24%)	Mean 24%	SD 8.49%
*Liver: Hepatocholangiocarcin	noma	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignar								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
• " " " "	-	0/50 (0%)	0/50 (0%)	OD 00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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	Male Female				
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ac	lenoma							
O	Taral	10/50 (20%)	10/50 (20%)	OD 00/	T-1-1	4/50 (8%)	2/50 (4%)	00.000/
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%
*Lung: Alveolar/Bronchiolar Ca	ırcinoma	6/50 (12%)	7/50 (14%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca Overall Incidence		reolar/Bronchiolar Adenor 16/50 (32%) 32/100 (32%)		SD 0%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%
Overall incidence		32/100 (32%)	Wean 32%	งบ 0% 	ı olal	6/100 (6%)		SD 2.03%
*Lung: Fibrosarcoma								
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 93

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%				
*Lung: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%	
				05 070					
#Lymph Node: Fibrous Histiocytoma									
•		0/50 (0%)	0/50 (0%)			` ,	` '		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Lymph Node: Hemangiosarcoma									
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	` '	CD 00/	
Overali incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ıotaı	0/100 (0%)	wean 0%	SD 0%	
#Lymph Node: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	` '	SD 0%	
#Lymph Node, Bronchial: Hemangiosarcoma									
-		0/50 (0%)	0/50 (0%)			` ,	` ,		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Fibrous Histiocytoma									
	.	0/50 (0%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	00.00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

^{*:} 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				0/50 (0%) 0/50 (0%) 7 Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0% 7 Total 0/100 (0%) Mean 0% 7 Total 1/100 (1%) Mean 1% 2/50 (4%) 1/50 (2%) 7 Total 3/100 (3%) Mean 3% 2/50 (4%) 1/50 (2%) Mean 3%		
#Lymph Node, Mediastinal: Hemangiosarcoma									
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Fibrous Histiocytoma		- (a)	(201)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
#Lymph Node, Mesenteric: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Mammary Gland: Carcinoma		0/50 (001)	0/50 (00/)			0(50 (40))	4/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	()	SD 1.41%	
#Mammary Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
#Mammary Gland: Fibroma, Fibroadenoma, Ca									
,	.,	0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%	

^{*:} 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		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE			Female		
#Mesentery: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)			` ,	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Mesentery: Fibrous Histiocytoma										
		0/50 (0%)	0/50 (0%)			` ,	` '			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Mesentery: Hemangioma		0/50 (00/)	0/50 (00)			0(50 (00))	0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	` '	` ,	CD 00/		
		0/100 (0%)	Mean 0%	SD 0%		, ,		SD 0%		
#Mesentery: Hemangiosarcoma		0/50 (00/)	0/50 (00()			0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%		
#Mesentery: Leiomyosarcoma										
		0/50 (0%)	0/50 (0%)			, ,	` ,			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Mesentery: Sarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

^{*:} 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	
*Nose: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Nose: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Nose: Mast Cell Tumor Maligr	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	0/49 (0 <i>%)</i> Mean 0%	SD 0%
*Nose: Sarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phary							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phary	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: WATER **Page:** 97

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41%											
#Oral Mucosa:											
Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Ovary: Choriocarcinoma						•••••					
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Ovary:						•••••					
Cystadenoma						1/50 (2%)	3/50 (6%)				
Overall Incidence					Total	4/100 (4%)	Mean 4%	SD 2.83%			
*Ovary: Fibrous Histiocytoma											
						0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor Benig	gn										
Occupation of the second					Takal	0/50 (0%)	0/50 (0%)	OD 00/			
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 98

м	ale		Female	
*Ovary: Granulosa Cell Tumor Malignant				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangioma		0/00 (00)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangiosarcoma		0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Luteoma				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 99

			Male				Female	
*Ovary: Teratoma Benign						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma								
Overall Incidence	Total	1/50 (2%) 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%	Total	3/50 (6%) 5/99 (5.05%)	2/49 (4%) Mean 5.04%	SD 1.36%
*Pituitary Gland: Pars Distali Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 100

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		2/50 (4%)	0/48 (0%)			3/50 (6%)	2/49 (4%)					
Overall Incidence	Total	2/98 (2.04%)	Mean 2%	SD 2.83%	Total	5/99 (5.05%)	Mean 5.04%	SD 1.36%				
*Pituitary Gland: Pars Int Adenoma	ermedia:											
		0/50 (0%)	0/48 (0%)			1/50 (2%)	2/49 (4%)					
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%				
*Pituitary Gland: Pars Int Carcinoma or Adenom		2(52 (22()	0/40 /00/			4/50 (001)	0/40 /40/					
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 3/99 (3.03%)	2/49 (4%) Mean 3.04%	SD 1.47%				
		` '	······································									
*Prostate: Adenoma		0/50 (00)	0(50 (00))									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%								
		, ,										
*Prostate: Carcinoma or Adenom	a											
		0/50 (0%)	0/50 (0%)	25 22/								
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%								
*Salivary Glands: Carcinoma												
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

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	
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	1/50 (2%)	0/50 (0%)	OD 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 102 Report Date: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benian						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba	asosquamous T	umor Benign, or Trichoep				0/50 (00)	0 (50 (00))	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` '		
#Skin: Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '						
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignant or No	OS) 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:	Basal Cell Adend	oma, Basosquamous Tun	nor (benign, malignan					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carcin	oma, Carcinom	a, Basosq. Tumor (M or B ratoacanthoma, Trichoep 0/50 (0%)), Basal Cell Adenom			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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	
#Skin: Basosquamous Tumor B	Benign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myx	oma, Myxosarcoma, or Fib	rous Histiocytoma 0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:								
Fibrosarcoma, Sarcoma,	wyxosarcoma	, or Fibrous Histiocytoma 0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Fibrous Histiocytoma					•••••			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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	
#Skin: Hemangioma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total		0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 105

			Male				Female				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin:		Schwannoma (benign, ma									
Neuronbrosarcoma, Neu	ironbronia, or s	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Osteosarcoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Sarcoma											
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Schwannoma Malignant											
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinor	na										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 106

			Male				Female	
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma	2(52 (52))	2/52 (221)			2/22 (221)	(201)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 0%
Overall incidence	Total	0/100 (0%)		SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma or Papilloma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma	1		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma, Papilloma, o	r Keratoacanthoma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (051)	0/50 (00)			0/50 (00)	0/50 (00/)	
Owner Haller and America	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)			0/50 /00/\	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		- (a)	(201)			2/52 (221)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Spleen: Hemangioma						0/50 /00/\	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	1/50 (2%) 5/99 (5.05%)	4/49 (8%) Mean 5.08%	SD 4.36%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 108

		Male				Female			
#Stomach, Forestomach: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma	a or Papillom	a Squamous							
•	•	0/50 (0%)	2/50 (4%)			1/50 (2%)	2/50 (4%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	2/50 (4%)			1/50 (2%)	2/50 (4%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%	
#Stomach, Glandular: Adenoma		2.72				2(20)	(201)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/30 (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: WATER **Page:** 109

			Male				Female	
*Testes: Adenoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign, Ma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Maligna		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Malignant		24-	(201)			(201)		
Overall Incidence	Total	0/47 (0%) 0/90 (0%)	0/43 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malign:	ant, NOS							
, a a a g ,g	,	0/47 (0%)	0/43 (0%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/96 (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	
*Thyroid Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (09/)	0/50 (00/)			0/40 (00/)	0/49 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
·····		` '						
*Thyroid Gland: Follicular Cell: Adenoma	!							
		0/50 (0%)	2/50 (4%)			2/49 (4%)	1/48 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/97 (3.09%)	Mean 3.08%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%)	2/50 (4%)			2/49 (4%)	1/48 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	3/97 (3.09%)	Mean 3.08%	SD 1.41%

^{*:} 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	
#Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illicidence					10(a)	0/100 (0 /8)		
#Tissue NOS: Schwannoma Malignant		0/50 (00)	0/50 (00/)			0(50 (00))	0/50 (00/)	
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall incidence	Total	0/100 (0%)		SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Tongue: Squamous Cell Carcinoma								
•	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tongue: Squamous Cell Papilloma		0/50 (00/)	0/50 (00/)			0/50 (00%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%
Overall incidence	Total	0/100 (0%)	Mean 0%	3D 0%	างเลเ	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 112

			Male				Female	
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (00)	- ()			2/-2 (221)	(201)	
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma	•••••							
O					T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign						(0)	(00)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence						, ,	ivicali 0%	30 0/0

^{*:} 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: WATER

Length of Study: CHRONIC

Report Date: 05/27/2022

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	Male			Female	
#Uterus: Hemangioma			2(22)	2/22 (121)	
Overall Incidence		Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyoma			0.50		
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 114

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal					0/50 (00/)	4/50 (20()	
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma			0/50 (00/)			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} 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: 05/27/2022

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 Northwest	059601106	06/11/01	729	50(5)	38(709)	53.9	Cumene
Battelle Northwest	058800406	09/27/99	729	50(5)	41(702)	52.2	Divinylbenzene
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	059700806	09/17/01	729	50(5)	37(694)	53.5	Propargyl alcohol
Battelle Northwest	059600106	12/21/98	729	50(5)	34(690)	53.2	Stoddard solvent (type IIC)
					Female		
Battelle Northwest	059601106	06/11/01	731	50(5)	37(685)	60.7	Cumene
Battelle Northwest	058800406	09/27/99	731	50(5)	33(681)	63.0	Divinylbenzene
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	059700806	09/17/01	731	50(5)	39(699)	58.3	Propargyl alcohol
Battelle Northwest	059600106	12/21/98	731	50(5)	36(702)	54.6	Stoddard solvent (type IIC)

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

Page: 116

			Male				Female	
#All Organs: Benign Tumors								
		43/50 (86%)	35/50 (70%)	27/50 (54%)		34/50 (68%)	28/50 (56%)	29/50 (58%)
		35/50 (70%)	28/50 (56%)	32/50 (64%)		26/50 (52%)	26/50 (52%)	27/50 (54%)
Overall Incidence	Total	200/300 (66.67%)	Mean 66.67%	SD 11.64%	Total	170/300 (56.67%)	Mean 56.67%	SD 6.02%
#All Organs: Malignant Tumors								
		27/50 (54%)	26/50 (52%)	29/50 (58%)		26/50 (52%)	22/50 (44%)	30/50 (60%)
		19/50 (38%)	22/50 (44%)	23/50 (46%)		29/50 (58%)	23/50 (46%)	19/50 (38%)
Overall Incidence	Total	146/300 (48.67%)	Mean 48.67%	SD 7.34%	Total	149/300 (49.67%)	Mean 49.67%	SD 8.52%
#All Organs: Malignant and Benign T	umors							
		48/50 (96%)	43/50 (86%)	45/50 (90%)		42/50 (84%)	40/50 (80%)	42/50 (84%)
		43/50 (86%)	38/50 (76%)	42/50 (84%)		40/50 (80%)	37/50 (74%)	39/50 (78%)
Overall Incidence	Total	259/300 (86.33%)	Mean 86.33%	SD 6.62%	Total	240/300 (80%)	Mean 80%	SD 3.79%
#All Organs: Hemangioma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#All Organs: Hemangiosarcoma								
		0/50 (0%)	6/50 (12%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	3/50 (6%)
		4/50 (8%)	2/50 (4%)	1/50 (2%)		4/50 (8%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	16/300 (5.33%)	Mean 5.33%	SD 4.32%	Total	12/300 (4%)	Mean 4%	SD 2.53%

^{*:} 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 Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 1/50 (2%)6/50 (12%)4/50 (8%)1/50 (2%)2/50 (4%)3/50 (6%)4/50 (8%)2/50 (4%)2/50 (4%)5/50 (10%)2/50 (4%)2/50 (4%)**Overall Incidence** Total 19/300 (6.33%) Mean 6.33% SD 3.67% Total 15/300 (5%) Mean 5% SD 2.76% #All Organs: **Histiocytic Sarcoma** (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 1/50 (2%)3/50 (6%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 8/300 (2.67%) Mean 2.67% SD 2.07% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 2/50 (4%)1/50 (2%)1/50 (2%)7/50 (14%)11/50 (22%)13/50 (26%)(0%)3/50 0/50 1/50 (2%)(6%)15/50 (30%)13/50 (26%)5/50 (10%)**Overall Incidence** Total 8/300 (2.67%) Mean 2.67% SD 2.07% 64/300 (21.33%) Mean 21.33% SD 7.76% Total **#All Organs:** Mesothelioma: Benign, Malignant, NOS 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

0/300 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Osteosarcoma or Osteoma								
		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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
'Adrenal Cortex: Adenoma								
		1/50 (2%)	3/49 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	4/49 (8%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	11/297 (3.7%)	Mean 3.72%	SD 3.01%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Adrenal Cortex:								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (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: 05/27/2022

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	nign							
		0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	2/50 (4%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		2/50 (4%)	1/48 (2%)	1/49 (2%)
Overall Incidence	Total	2/294 (0.68%)	Mean 0.68%	SD 1.67%	Total	6/296 (2.03%)	Mean 2.02%	SD 1.79%
Adrenal Medulla: Pheochromocytoma Co	mplex							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma	lignant							
		0/50 (0%)	0/49 (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%)	0/48 (0%)	1/49 (2%)
Overall Incidence	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/296 (0.34%)	Mean 0.34%	SD 0.83%
*Adrenal Medulla: Pheochromocytoma: Be	enign, Complex	x, Malignant, NOS						
		0/50 (0%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	2/50 (4%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		2/50 (4%)	1/48 (2%)	2/49 (4%)
Overall Incidence	Total	3/294 (1.02%)	Mean 1.01%	SD 1.7%	Total	7/296 (2.36%)	Mean 2.36%	SD 1.98%
*Bone Marrow: Hemangiosarcoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.63%	Total	2/297 (0.67%)	Mean 0.67%	SD 1.63%

^{*:} 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	
*Bone Marrow: Mast Cell Tumor Malignant								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/49 (0%) SD 0.82%	Total	0/50 (0%) 0/297 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
	10tai	1/299 (0.33%)			ı otal	0/297 (0%)	iviean 0%	3D 0%
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Tarat	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Bone: Osteosarcoma or Osteoma								
		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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Bone: 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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (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: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
-		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (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	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/43 (2%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/258 (0.39%)	Mean 0.39%	SD 0.95%
Epididymis: Sarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
∉Eye: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Gallbladder: Adenoma								
		0/43 (0%)	1/42 (2%)	0/43 (0%)		0/38 (0%)	0/45 (0%)	0/42 (0%)
		0/42 (0%)	0/40 (0%)	0/39 (0%)		0/47 (0%)	0/41 (0%)	0/40 (0%)
overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.97%	Total	0/253 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		8/50 (16%)	5/50 (10%)	5/50 (10%)		8/50 (16%)	4/50 (8%)	6/50 (12%)
		10/50 (20%)	3/50 (6%)	7/50 (14%)		3/50 (6%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	38/300 (12.67%)	Mean 12.67%	SD 5.01%	Total	29/300 (9.67%)	Mean 9.67%	SD 3.67%

^{*:} 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	
#Harderian Gland: Carcinoma								
		4/50 (8%)	1/50 (2%)	2/50 (4%)		5/50 (10%)	2/50 (4%)	1/50 (2%)
		1/50 (2%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	11/300 (3.67%)	Mean 3.67%	SD 2.94%	Total	10/300 (3.33%)	Mean 3.33%	SD 3.5%
#Harderian Gland: Carcinoma or Adenoma								
		11/50 (22%)	6/50 (12%)	7/50 (14%)		12/50 (24%)	6/50 (12%)	7/50 (14%)
		11/50 (22%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	4/50 (8%)	5/50 (10%)
Overall Incidence	Total	48/300 (16%)	Mean 16%	SD 4.73%	Total	38/300 (12.67%)	Mean 12.67%	SD 6.02%
Heart: Hemangioma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma				•••••				
•		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: INHALATION

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Report Date: 05/27/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
fintestine Large: Cecum: Polyp Adenomatous								
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

ct2007 Toxicology Data Manageme

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: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	3/50 (6%)	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	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	0/300 (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 Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Adenoma	cified:							
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Unspe Carcinoma	cified:							
		1/50 (2%)	3/50 (6%)	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	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	0/300 (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 Small: Site Uns Carcinoma or Adenoma	•							
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 6/300 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2.19%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#Intestine Small: Site Uns Hemangiosarcoma								
U		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Adenoma								
		0/50 (0%)	1/49 (2%)	1/49 (2%)		1/49 (2%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	3/295 (1.02%)	Mean 1.02%	SD 1.12%	Total	2/295 (0.68%)	Mean 0.68%	SD 1.05%

^{*:} 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	
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	1/48 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/295 (0.34%)	0/49 (0%) Mean 0.33%	0/48 (0%) SD 0.82%	Total	0/49 (0%) 2/295 (0.68%)	1/50 (2%) Mean 0.68%	0/49 (0%) SD 1.05%
						2/200 (0.0070)		
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%)	1/49 (2%)		1/49 (2%)	1/48 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 4/295 (1.36%)	1/49 (2%) Mean 1.35%	0/48 (0%) SD 1.05%	Total	0/49 (0%) 4/295 (1.36%)	1/50 (2%) Mean 1.36%	1/49 (2%) SD 1.05%
		` ,				,		
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
	.	0/50 (0%)	0/49 (0%)	0/50 (0%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (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%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
_		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hemangiosarcoma								
		0/50 (0%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		4/50 (8%)	1/49 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/299 (3.34%)	Mean 3.34%	SD 3.26%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Liver: Hepatoblastoma								
•		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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 Adenoma								
		34/50 (68%)	22/50 (44%)	17/50 (34%)		18/50 (36%)	17/49 (35%)	13/50 (26%)
Overall Incidence	Total	24/50 (48%)	21/49 (43%) Mean 47.14%	23/50 (46%) SD 11.3%	Total	10/50 (20%) 82/299 (27.42%)	15/50 (30%) Mean 27.45%	9/50 (18%) SD 7.47%
Overali incluence		141/299 (47.16%)	47.14%	אני וו קפ	Total	02/299 (27.42%)	Wiean 27.45%	3D 7.47%
Liver: Hepatocellular Carcinom	a							
		13/50 (26%)	13/50 (26%)	12/50 (24%)		10/50 (20%)	5/49 (10%)	6/50 (12%)
		10/50 (20%)	10/49 (20%)	16/50 (32%)		3/50 (6%)	4/50 (8%)	6/50 (12%)
Overall Incidence	Total	74/299 (24.75%)	Mean 24.73%	SD 4.42%	Total	34/299 (11.37%)	Mean 11.37%	SD 4.83%
*Liver: Hepatocellular Carcinom Overall Incidence	a or Hepatob Total	14/50 (28%) 10/50 (20%) 75/299 (25.08%)	13/50 (26%) 10/49 (20%) Mean 25.07%	12/50 (24%) 16/50 (32%) SD 4.61%	Total	10/50 (20%) 3/50 (6%) 34/299 (11.37%)	5/49 (10%) 4/50 (8%) Mean 11.37%	6/50 (12%) 6/50 (12%) SD 4.83%
Liver: Hepatocellular Carcinom	a or Hepatoc	ellular Adenoma						
•	•	40/50 (80%)	30/50 (60%)	27/50 (54%)		25/50 (50%)	19/49 (39%)	17/50 (34%)
		28/50 (56%)	26/49 (53%)	34/50 (68%)		13/50 (26%)	17/50 (34%)	13/50 (26%)
Overall Incidence	Total	185/299 (61.87%)	Mean 61.84%	SD 10.43%	Total	104/299 (34.78%)	Mean 34.8%	SD 8.98%
Liver: Hepatocellular Carcinom	a, Hepatocell	ular Adenoma, or Hepato	blastoma					
		41/50 (82%)	30/50 (60%)	27/50 (54%)		25/50 (50%)	19/49 (39%)	17/50 (34%)
		28/50 (56%)	26/49 (53%)	34/50 (68%)		13/50 (26%)	17/50 (34%)	13/50 (26%)
Overall Incidence	Total	186/299 (62.21%)	Mean 62.18%	SD 11.13%	Total	104/299 (34.78%)	Mean 34.8%	SD 8.98%

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

^{#:} Denominator is number of animals necropsied

*Liver:

*Liver:

*Liver: Sarcoma

*Lung: Adenoma

*Lung:

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** Hepatocholangiocarcinoma 0/50 (0%)1/50 (2%)5/50 (10%)0/50 (0%)1/49 (2%)1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/299 (0.67%) Total 6/299 (2.01%) Mean 2% SD 4% Total Mean 0.67% SD 1.04% **Ito Cell Tumor Malignant** (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/299 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/299 (0%) Mean 0% SD 0% 0/299 (0%) Mean 0% SD 0% Total 0/50 0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0%

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Report Date: 05/27/2022

Total

13/50

8/50

58/299 (19.4%)

(26%)

(16%)

.....

12/49

10/50

Mean 19.41%

(24%)

(20%)

9/50

6/50

SD 5.26%

(18%)

(12%)

1/50

1/50

15/300 (5%)

Total

(2%)

4/50

3/50

(8%)

(6%)

Mean 5%

4/50

2/50

SD 2.76%

(8%)

(4%)

Alveolar/Bronchiolar Adenoma

^{*:} 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: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Ca	ırcinoma							
		9/50 (18%)	5/49 (10%)	5/50 (10%)		3/50 (6%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	5/50 (10%) 38/299 (12.71%)	7/50 (14%) Mean 12.7%	7/50 (14%) SD 3.23%	Total	1/50 (2%) 8/300 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.42%
Lung:								
Alveolar/Bronchiolar Ca	ircinoma or Al	veolar/Bronchiolar Adeno 19/50 (38%)	oma 16/49 (33%)	14/50 (28%)		4/50 (8%)	6/50 (12%)	4/50 (8%)
		13/50 (26%)	17/50 (34%)	13/50 (26%)		2/50 (4%)	5/50 (10%)	2/50 (4%)
Overall Incidence	Total	92/299 (30.77%)	Mean 30.78%	SD 4.89%	Total	23/300 (7.67%)	Mean 7.67%	SD 3.2%
Lung: 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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: 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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (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	
#Lymph Node: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
£Lymph Node, Bronchial: 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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
#Lymph Node, Mediastinal: 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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%

^{*:} 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: INHALATION

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Report Date: 05/27/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	· Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 3/300 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.1%
		0/300 (0%)				(,		
Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
*Nose: Hemangioma								
		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%
*Nose: Mast Cell Tumor Malignant								
· ·		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%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (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: Sarcoma								
		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%)		0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
Oral Cavity (Oral Mucos Papilloma Squamous	sa, Tongue, Pha							
		0/50 (0%)	0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67%	0/50 (0%) 0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%
Oral Cavity (Oral Mucos Squamous Cell Carcin	. •	rynx, Tooth, Gingiva): Squamous, or Papilloma						
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Oral Mucosa: Squamous Cell Carcin	oma							
		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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%		1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 05/27/2022

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** *Ovary: Choriocarcinoma 0/48 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% *Ovary: Cystadenoma (10%)5/48 3/48 (6%)0/49 (0%)2/48 (4%)6/49 (12%)1/49 (2%)**Overall Incidence** Total 17/291 (5.84%) Mean 5.85% SD 4.76% *Ovary: **Fibrous Histiocytoma** 0/48 0/48 (0%)0/49 (0%)(0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/48 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Malignant** 0/48 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/49 (0%)

Total

0/291 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Version: Oct2007 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: 05/27/2022

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Ma	le		Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/48 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/291 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma				
•		0/48 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
*Ovary: Hemangiosarcoma				
•		0/48 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/291 (0%)	Mean 0%	SD 0%
*Ovary: Leiomyosarcoma				
• • • • • • • • • • • • • • • • • • • •		0/48 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
*Ovary: Luteoma			•••••	
		0/48 (0%)	1/48 (2%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/291 (0.34%)	Mean 0.35%	SD 0.85%

^{*:} 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	
Ovary: Teratoma Benign					,				
							1/48 (2%)	0/48 (0%)	0/49 (0%)
Overall Incidence						Total	0/48 (0%) 2/291 (0.69%)	0/49 (0%) Mean 0.69%	1/49 (2%) SD 1.06%
*Ovary: Tubulostromal Adenoma									
							0/48 (0%)	0/48 (0%)	0/49 (0%)
							0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence						Total	0/291 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma									
		0/50 (0%)	0/49 (0%)	0/49	(0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49	(0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%		Total	0/295 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma									
		0/50 (0%)	0/49 (0%)	0/49	(0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49	(0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%		Total	0/295 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma									
		1/48 (2%)	0/48 (0%)	0/50	(0%)		8/50 (16%)	8/47 (17%)	7/50 (14%)
		0/48 (0%)	0/47 (0%)	0/49	(0%)		4/50 (8%)	4/50 (8%)	10/47 (21%)
Overall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	·	Total	41/294 (13.95%)	Mean 14.05%	SD 5.25%

^{*:} 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: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dis Carcinoma	stalis or Unspec	ified Site:						
		0/48 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/48 (0%)	0/47 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/47 (0%)
verall Incidence	Total	0/290 (0%)	Mean 0%	SD 0%	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•	ified Site:						
		1/48 (2%)	0/48 (0%)	0/50 (0%)		8/50 (16%)	8/47 (17%)	7/50 (14%)
		0/48 (0%)	0/47 (0%)	0/49 (0%)		4/50 (8%)	5/50 (10%)	10/47 (21%)
verall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	42/294 (14.29%)	Mean 14.38%	SD 4.84%
Pituitary Gland: Pars Into Adenoma				•••••				
		0/48 (0%)	0/48 (0%)	0/50 (0%)		2/50 (4%)	1/47 (2%)	0/50 (0%)
		1/48 (2%)	0/47 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	3/294 (1.02%)	Mean 1.02%	SD 1.69%
Pituitary Gland: Pars Into Carcinoma or Adenoma								
		0/48 (0%)	0/48 (0%)	0/50 (0%)		2/50 (4%)	1/47 (2%)	0/50 (0%)
		1/48 (2%)	0/47 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	3/294 (1.02%)	Mean 1.02%	SD 1.69%
Prostate: Adenoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/46 (0%)				
Overall Incidence	Total	0/294 (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	
Prostate: Carcinoma or Adenoma									
		0/50 (0%)	0/48 (0%)	,	(0%)				
		0/50 (0%)	0/50 (0%)	0/46 ((0%)				
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%					
Salivary Glands: Carcinoma									
		0/49 (0%)	0/50 (0%)	,	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	,	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Carcinoma or Adenoma									
		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%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Seminal Vesicle: Adenoma									
		0/50 (0%)	0/50 (0%)	,	(0%)				
		0/50 (0%)	0/50 (0%)	,	(0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%					
#Skeletal Muscle: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	,	(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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%		Total	0/300 (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%)	0/50 (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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma o	r Rhabdomyoma							
·	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
tSkin: Basal Cell Adenoma οι	r Basosquamous	Tumor Benign						
	·	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
≮Skin: Basal Cell Adenoma, B	Basosquamous Tı	ımor Benign, or Trichoep	oithelioma					
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Call Carcinoma	or Basosauamou	ıs Tumor (malignant or I	NOS)					
Dasai Celi Calcillollia (or basosquamou	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tu	, , ,			0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma,		oma, Basosquamous Tu 0/50 (0%) 0/50 (0%) 0/300 (0%)	mor (benign, malignar 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%) 1/50 (2%)	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% sa, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total Total	0/50 (0%) 0/300 (0%) 1/50 (2%)	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% sa, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithelicoverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, September 1988	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% sa, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithelicoverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, September 1988	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0% sa, 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%) Mean 1%	0/50 (0%) SD 0% 0/50 (0%) 1/50 (2%) 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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:								
Fibroma, Fibrosarcoma,	Sarcoma, Myx	oma, Myxosarcoma, or F	ibrous Histiocytoma					
		2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		6/50 (12%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	14/300 (4.67%)	Mean 4.67%	SD 4.5%
#Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	Myxosarcoma	a or Fibrous Histiocytom	ıa					
r ibrodurooma, ourooma	, myxoodroom	2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		6/50 (12%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%	Total	14/300 (4.67%)	Mean 4.67%	SD 4.5%
#Skin: Fibrous Histiocytoma								
•		1/50 (2%)	2/50 (4%)	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%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

^{*:} 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: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#Skin: Liposarcoma								
		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Mast Cell Tumor Malignant								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
5		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (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

Page: 147 Tumor Incidence for Selected Control Animal Groups Report Date: 05/27/2022 Route: INHALATION Vehicle: AIR

			Male				Female	
Skin: Neural Crest Tumor								
		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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Neurofibrosarcoma or	Schwannoma (m	nalignant or NOS)						
recuronorosarooma or	Conwamionia (iii	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	Tarat	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/000 (00/)	Maan 000	OD 00/	T-1-1	0/200 (00()	Mann 000	00,000
	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Overall Incidence #Skin: Osteosarcoma	Total	0/300 (0%)	Mean 0%	SD 0%	ı otal	0/300 (0%)	Mean 0%	SD 0%
Skin:	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	i otai	0/50 (0%)	0/50 (0%)	0/50 (0%)
Skin: Osteosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Skin: Osteosarcoma	Total Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Skin: Osteosarcoma Overall Incidence		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence #Skin:		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence #Skin:		0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/300 (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

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: INHALATION Vehicle: AIR

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				Male						F	emale		
#Skin: Schwannoma Malignant													
		0/50 (0%)	,	(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	0/300 (0%)	Mean	0%	SD 0%		Total	0/300 (0	0%)	Mea	n 0%	SD	0%
#Skin: Squamous Cell Carcinom	ıa												
·		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	0/300 (0%)	Mean	0%	SD 0%		Total	1/300 (0.3	33%)	Mean	0.33%	SD 0	.82%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell C	•	`		•	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Squamous Cell Carcinom	na, Basal Cell C	0/50 (0%) 0/50 (0%) 0/300 (0%)) 0/50	(0%) (0%)	or NOS), 0/50 0/50 SD 0%	(0%) (0%)	Total	1/50 0/50 1/300 (0.3	(2%) (0%) 33%)	0/50 0/50 Mean	(0%) (0%) 0.33%	0/50 0/50 SD 0	(0%) (0%) .82%
Squamous Cell Carcinom or Carcinoma	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)) 0/50) 0/50 Mean	(0%) (0%) 0%	0/50 0/50 SD 0%	(0%)	Total	0/50 1/300 (0.:	(0%) 33%) 	0/50 Mean	(0%) 0.33%	0/50 SD 0	(0%) .82%
Squamous Cell Carcinom or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)) 0/50) 0/50 Mean) 0/50	(0%) (0%) 0% (0%)	0/50 0/50 SD 0%	(0%)	Total	0/50 1/300 (0.: 0/50	(0%) 33%) 	0/50 Mean 1/50	(0%) 0.33% (2%)	0/50 SD 0	(0%) .82% (0%)
Squamous Cell Carcinom or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)) 0/50) 0/50 Mean) 0/50	(0%) (0%) 0% (0%) (0%)	0/50 0/50 SD 0%	(0%)	Total Total	0/50 1/300 (0.:	(0%) 33%) (0%) (0%)	0/50 Mean 1/50 0/50	(0%) 0.33%	0/50 SD 0	(0%) .82% (0%) (2%)
Squamous Cell Carcinom or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma	Total Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%)) 0/50) 0/50 Mean) 0/50) 0/50	(0%) (0%) 0% (0%) (0%)	0/50 0/50 SD 0% 0/50 0/50	(0%)		0/50 1/300 (0.3 0/50 0/50	(0%) 33%) (0%) (0%)	0/50 Mean 1/50 0/50	(0%) 0.33% (2%) (0%)	0/50 SD 0 0/50 1/50	(0%) .82% (0%) (2%)
Squamous Cell Carcinom or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%)) 0/50) 0/50 Mean) 0/50) 0/50 Mean	(0%) (0%) 0% (0%) (0%)	0/50 0/50 SD 0% 0/50 0/50	(0%)		0/50 1/300 (0.3 0/50 0/50	(0%) 33%) (0%) (0%)	0/50 Mean 1/50 0/50	(0%) 0.33% (2%) (0%)	0/50 SD 0 0/50 1/50	(0%) .82% (0%) (2%)
Squamous Cell Carcinom or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)) 0/50) 0/50 Mean) 0/50) 0/50 Mean	(0%) (0%) 0% (0%) (0%) (0%)	0/50 0/50 SD 0% 0/50 0/50 SD 0%	(0%) (0%) (0%)		0/50 1/300 (0.: 0/50 0/50 2/300 (0.	(0%) 33%) (0%) (0%) 67%)	0/50 Mean 1/50 0/50 Mean	(0%) 0.33% (2%) (0%) 0.67%	0/50 SD 0 0/50 1/50 SD 1	(0%) .82% (0%) (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Vehicle: AIR

			Male				Female	
#Skin:		,				,		
Squamous Cell Papillo	ma, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Skin:								
Squamous Cell Papillo	ma, Papilloma, o							
		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin: Sebaceous Gland: Adenoma	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Sebaceous Gland:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Spinal Cord: Meningioma Malignant	t							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
*Spleen: Fibrous Histiocytoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	1/50 (2%)
		1/50 (2%)	1/49 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	4/297 (1.35%)	Mean 1.35%	SD 1.04%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		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	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: Squamous Cell Carcinoma	or Papillom	na Squamous						
	-	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%
#Stomach, Forestomach: Squamous Cell Papilloma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 1.03%	Total	1/50 (2%) 3/300 (1%)	1/50 (2%) Mean 1%	0/50 (0%) SD 1.1%
		2/300 (0.67%)	Mean 0.67%			3/300 (1%)		
#Stomach, Glandular: Adenoma								
		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%

^{*:} 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: Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%				
*Testes: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign	, Malignant, NO	s						
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Mali	gnant							
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Malignant								
· •		0/45 (0%)	0/44 (0%)	1/42 (2%)		0/49 (0%)	0/49 (0%) 0/4	19 (0%)
		0/41 (0%)	0/47 (0%)	0/41 (0%)		0/50 (0%)	0/49 (0%) 0/4	3 (0%)
Overall Incidence	Total	1/260 (0.38%)	Mean 0.4%	SD 0.97%	Total	0/289 (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: 05/27/2022

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

			Male				Female	
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/45 (0%) 0/41 (0%)	0/44 (0%) 0/47 (0%)	1/42 (2%) 0/41 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/43 (0%)
Overall Incidence	Total	1/260 (0.38%)	Mean 0.4%	SD 0.97%	Total	0/289 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/297 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	10lal	0/29/ (0%)			10tai	0/299 (0%)	iviean 0%	3D 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
Overell Incidence	Total	0/50 (0%)	0/49 (0%)	0/49 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0.82%
Overall Incidence	Total	0/297 (0%)	Mean 0%	3D 0%	Total	1/299 (0.33%)	Mean 0.33%	3D 0.82%
Thyroid Gland: Follicular Ce Adenoma	ell:							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
	-	3/50 (6%)	0/49 (0%)	1/49 (2%)	-	3/50 (6%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	4/297 (1.35%)	Mean 1.34%	SD 2.42%	Total	8/299 (2.68%)	Mean 2.67%	SD 2.42%

^{*:} 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 Cell: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	0/49 (0%)	1/50 (2%)
		3/50 (6%)	0/49 (0%)	1/49 (2%)		3/50 (6%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	4/297 (1.35%)	Mean 1.34%	SD 2.42%	Total	10/299 (3.34%)	Mean 3.33%	SD 2.07%
#Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Tissue NOS: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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	
#Tongue: Squamous Cell Carcinor	ma							
		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinor	ma or Papillom	a Squamous						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Tongue: Squamous Cell Papillom						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Hemangioma								
-		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/296 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/294 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/48 (0%)0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/49 (0%)0/49 (0%)(0%)0/48 (0%)**Overall Incidence** Total 0/296 (0%) Mean 0% SD 0% Total 0/294 (0%) Mean 0% SD 0% #Uterus: Adenoma (0%) 0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Carcinoma 3/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 4/300 (1.33%) Mean 1.33% SD 2.42% #Uterus: Deciduoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)

Total

0/300 (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: INHALATION Vehicle: AIR

Page: 157

	Male			Female	
Uterus: Hemangiosarcoma					
			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	ר	Γotal	1/50 (2%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%
Uterus: Leiomyoma					•••••
Loromyonia			0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	٦	Γotal	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Leiomyosarcoma					
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	٦	Γotal	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Uterus: Polyp Stromal					
. 71			3/50 (6%)	1/50 (2%)	3/50 (6%)
			3/50 (6%)	2/50 (4%)	2/50 (4%)
Overall Incidence	٦	Γotal	14/300 (4.67%)	Mean 4.67%	SD 1.63%
Uterus: Sarcoma Stromal					
			0/50 (0%)	0/50 (0%)	1/50 (2%)
	_		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence		Γotal	2/300 (0.67%)	Mean 0.67%	SD 1.03%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

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Report Date: 05/27/2022

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal 3/50 (6%)1/50 (2%)4/50 (8%)3/50 (6%)2/50 (4%)3/50 (6%)Mean 5.33% **Overall Incidence** Total 16/300 (5.33%) SD 2.07% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (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

Page: 159

	Male						Female	
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 160

Report Date: 05/27/2022

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	058813804	09/14/99	730	50(1)	44(717)	46.0	Benzophenone
Southern Research Institute	059902704	07/29/02	729	50(1)	46(715)	50.0	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517406	N/A	N/A	0(0)	0(0)	N/A	Cresols
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
					Female		
Battelle Columbus Laboratory	058813804	09/13/99	729	50(5)	40(706)	46.2	Benzophenone
Southern Research Institute	059902704	07/29/02	732	50(5)	45(698)	50.3	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517406	08/20/02	728	50(5)	41(696)	51.8	Cresols
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

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

			Male				Female	
#All Organs: Benign Tumors								
		27/50 (54%) 23/50 (46%)	28/50 (56%) 26/50 (52%)			15/50 (30%) 13/50 (26%)	16/50 (32%) 18/50 (36%)	16/50 (32%)
Overall Incidence	Total	104/200 (52%)	Mean 52%	SD 4.32%	Total	78/250 (31.2%)	Mean 31.2%	SD 3.63%
#All Organs: Malignant Tumors								
		17/50 (34%)	24/50 (48%)			16/50 (32%)	22/50 (44%)	20/50 (40%)
Overall Incidence	Total	20/50 (40%) 76/200 (38%)	15/50 (30%) Mean 38%	SD 7.83%	Total	12/50 (24%) 90/250 (36%)	20/50 (40%) Mean 36%	SD 8%
All Organs: Malignant and Benign T	umors							
g		38/50 (76%)	40/50 (80%)			25/50 (50%)	31/50 (62%)	29/50 (58%)
		32/50 (64%)	34/50 (68%)			23/50 (46%)	29/50 (58%)	
Overall Incidence	Total	144/200 (72%)	Mean 72%	SD 7.3%	Total	137/250 (54.8%)	Mean 54.8%	SD 6.57%
All Organs: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Verall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence	ı olal	0/200 (0%)	Mean 0%			` ,		3D 0%
‡All Organs: Hemangiosarcoma								
		3/50 (6%)	2/50 (4%)			1/50 (2%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	2/50 (4%) 8/200 (4%)	1/50 (2%) Mean 4%	SD 1.63%	Total	2/50 (4%) 10/250 (4%)	3/50 (6%) Mean 4%	SD 2%
		3/200 (4/6)				` '		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/27/2022

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

			Male				Female	
#All Organs: Hemangiosarcoma or	Hemangioma							
		3/50 (6%) 2/50 (4%)	2/50 (4%) 1/50 (2%)			1/50 (2%) 2/50 (4%)	3/50 (6%) 3/50 (6%)	1/50 (2%)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	10/250 (4%)	Mean 4%	SD 2%
All Organs: Histiocytic Sarcoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
Overall Incidence	Total	phocytic, Mixed, NOS, or 2/50 (4%) 2/50 (4%) 9/200 (4.5%)	2/50 (4%) 3/50 (6%) Mean 4.5%	SD 1%	Total	8/50 (16%) 6/50 (12%) 33/250 (13.2%)	5/50 (10%) 7/50 (14%) Mean 13.2%	7/50 (14%) SD 2.28%
All Organs:								
Mesothelioma: Benign	, Malignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
				00, 00/	T	0/050 (00()	M 00/	OD 00/
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
		0/200 (0%)	Mean 0%	SD 0%	I otal	0/250 (0%)	Mean 0%	SD 0%
Poverall Incidence #All Organs: Mesothelioma: Maligna		0/200 (0%) 	0/50 (0%)	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)

^{*:} 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: 163

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	0/50 (0%)	OD 00/	T	1/50 (2%)	0/50 (0%)	00 4 40/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#All Organs: Osteosarcoma or Osteom	na							
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	4/50 (8%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 4%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
Adrenal Cortex: 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%)	
Overall Incidence	Total	0/200 (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

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: ORAL Vehicle: FEED Page: 164

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	nign							
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Adrenal Medulla: Pheochromocytoma Co								
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma		0/50 (0%)	0/49 (0%)			0/50 (0%)	1/49 (2%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	., (=,0)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.11%
Adrenal Medulla: Pheochromocytoma: Be	enign, Complex	, Malignant, NOS						
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	1/49 (2%) 1/50 (2%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/248 (1.61%)	Mean 1.62%	SD 0.9%
Bone Marrow: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/199 (1.01%)	1/50 (2%) Mean 1%	SD 1.15%	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: FEED **Page:** 165

			Male				Female	
*Bone Marrow: Mast Cell Tumor Malignant								
		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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		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	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Bone: Osteosarcoma or Osteoma								
		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	0/200 (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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (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: FEED Page: 166

			Male				Female	
Brain: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		•••••	•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/243 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Carcinoma or Adenoma		•••••	•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/243 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/243 (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: FEED Page: 167

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma		0/50 (00()	0/50 (00/)					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma				•••••				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma								
		0/45 (0%)	0/46 (0%)			0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall In aldeman	Tatal	0/46 (0%)	0/44 (0%)	CD 00/	Tatal	0/49 (0%)	0/47 (0%)	CD 00/
Overall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		6/50 (12%)	5/50 (10%)			1/50 (2%)	7/50 (14%)	6/50 (12%)
Overall Incidence	Total	9/50 (18%) 24/200 (12%)	4/50 (8%) Mean 12%	SD 4.32%	Total	3/50 (6%) 23/250 (9.2%)	6/50 (12%) Mean 9.2%	SD 5.02%
Jveran incluence	ıvıaı	24/200 (12/0)	IVICALI IZ/0	JD 4.32/0	ı Ulal	23/230 (3.2/0)	IVICALI 3.2/0	3D 3.02 /6

^{*:} 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: ORAL Vehicle: FEED Page: 168

			Male				Female	
#Harderian Gland: Carcinoma								
		1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)			0/50 (0%) 1/50 (2%)	2/50 (4%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 0%	Total	5/250 (2%)	Mean 2%	SD 1.41%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%) 10/50 (20%)	5/50 (10%) 5/50 (10%)			1/50 (2%) 4/50 (8%)	9/50 (18%) 7/50 (14%)	7/50 (14%)
Overall Incidence	Total	27/200 (13.5%)	Mean 13.5%	SD 4.73%	Total	28/250 (11.2%)	Mean 11.2%	SD 6.26%
Heart: Hemangioma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
-		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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (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: FEED Page: 169

			Male				Female	
#Intestine Large: Cecum: 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous								•••••
		0/50 (0%) 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		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	1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	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

Report Date: 05/27/2022

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

			Male				Female	
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Small: Jejunum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/200 (1%)	0/50 (0%) Mean 1%	SD 1.15%	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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

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

			Male				Female				
#Intestine Small: Jejunum: 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
#Intestine Small: Jejunum: Leiomyosarcoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/50 (0%) 0/200 (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%			
						, ,					
#Intestine Small: Jejunum: Polyp Adenomatous											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (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 Unspe Adenoma	cified:										
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
		, ,					·····				
#Intestine Small: Site Unspe Carcinoma	cified:										
		0/50 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	1/50 (2%) 3/200 (1.5%)	0/50 (0%) Mean 1.5%	SD 1.91%	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

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: 05/27/2022

Route: ORAL

			Male				Female	
Intestine Small: Site Unstancinoma or Adenoma	•							
		0/50 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Site Uns Hemangiosarcoma	specified:							
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Site Uns Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Islets, Pancreatic: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/249 (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

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED **Page:** 173

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%
'Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	2/50 (4%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/249 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/249 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	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: FEED Page: 174 Report Date: 05/27/2022

			Male				Female	
*Liver: Cholangiocarcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%) 0/250 (0%)	0/50 (0%)	CD 00/
	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
•		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma								
•		0/50 (0%)	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	0/200 (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: 05/27/2022

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

			Male				Female				
*Liver: Hepatocellular Adenoma											
		11/50 (22%) 7/50 (14%)	21/50 (42%) 17/50 (34%)			5/50 (10%) 3/50 (6%)	1/50 (2%) 4/50 (8%)	4/50 (8%)			
Overall Incidence	Total	56/200 (28%)	Mean 28%	SD 12.44%	Total	17/250 (6.8%)	Mean 6.8%	SD 3.03%			
Liver: Hepatocellular Carcinor											
		8/50 (16%) 4/50 (8%)	15/50 (30%) 10/50 (20%)			0/50 (0%) 2/50 (4%)	3/50 (6%) 1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	37/200 (18.5%)	Mean 18.5%	SD 9.15%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%			
*Liver: Hepatocellular Carcinor Overall Incidence	ma or Hepatobl	8/50 (16%) 4/50 (8%) 37/200 (18.5%)	15/50 (30%) 10/50 (20%) Mean 18.5%	SD 9.15%	Total	0/50 (0%) 2/50 (4%) 7/250 (2.8%)	3/50 (6%) 1/50 (2%) Mean 2.8%	1/50 (2%) SD 2.28%			
Liver: Hepatocellular Carcinor	ma or Henatoce	allular Adenoma									
ricpatoccilular Garcinoi	na or riepatoce	18/50 (36%)	32/50 (64%) 23/50 (46%)			5/50 (10%) 4/50 (8%)	4/50 (8%) 5/50 (10%)	4/50 (8%)			
		10/50 (20%)	23/30 (40/0)			` ,					
Overall Incidence	Total	10/50 (20%) 83/200 (41.5%)	Mean 41.5%	SD 18.43%	Total	22/250 (8.8%)	Mean 8.8%	SD 1.1%			
Overall Incidence ' 'Liver: Hepatocellular Carcinor		` ,	Mean 41.5%	SD 18.43%	Total	, ,	Mean 8.8% 4/50 (8%) 5/50 (10%)	SD 1.1% 4/50 (8%)			

^{*:} 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:** 176

			Male				Female				
*Liver: Hepatocholangiocarcinoma											
		0/50 (0%) 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
Liver: Ito Cell Tumor Malignant	t										
		0/50 (0%) 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
Liver:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
Lung: Adenoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
Lung: Alveolar/Bronchiolar Add	enoma										
		14/50 (28%) 11/50 (22%)	13/50 (26%) 8/50 (16%)			0/50 (0%) 4/50 (8%)	1/50 (2%) 0/50 (0%)	5/50 (10%)			
Overall Incidence	Total	46/200 (23%)	Mean 23%	SD 5.29%	Total	10/250 (4%)	Mean 4%	SD 4.69%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 177

Report Date: 05/27/2022

Strain: B6C3F1/N

Vehicle: FEED Length of Study: CHRONIC

			Male				Female	
*Lung: Alveolar/Bronchiolar Car	cinoma							
		2/50 (4%)	3/50 (6%)			1/50 (2%)	1/50 (2%)	2/50 (4%)
		6/50 (12%)	2/50 (4%)	05 0		0/50 (0%)	3/50 (6%)	05 - 000/
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 3.79%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
Lung: Alveolar/Bronchiolar Car	cinoma or Alv	veolar/Bronchiolar Adeno	ma					
		16/50 (32%)	16/50 (32%)			1/50 (2%)	2/50 (4%)	5/50 (10%)
		14/50 (28%)	9/50 (18%)			4/50 (8%)	3/50 (6%)	
Overall Incidence	Total	55/200 (27.5%)	Mean 27.5%	SD 6.61%	Total	15/250 (6%)	Mean 6%	SD 3.16%
*Lung: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma								
·		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
		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	1/200 (0.5%)	Mean 0.5%	SD 1%	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

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Report Date: 05/27/2022

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

			Male				Female	
Lymph Node: Fibrous Histiocytoma								
		0/50 (0%) 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	0/200 (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%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
£Lymph Node: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Bronchial: 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (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: FEED **Page:** 179

			Male				Female	
Lymph Node, Mediastinal: 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%) 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma						•••••		
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
					·····			
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 4/250 (1.6%)	1/50 (2%) Mean 1.6%	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

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Report Date: 05/27/2022

mor incidence for Selected Control Anir Route: ORAL

Vehicle: FEED

			Male				Female	
#Mammary Gland:		,						
Fibroma, Fibroadenoma	a, Carcinoma, or	r Adenoma						
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%
Mesentery: Fibrosarcoma								
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma								
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: Hemangioma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mesentery: 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	0/200 (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: FEED Page: 181

			Male				Female	
#Mesentery: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
'Nose: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Nose: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Nose: Mast Cell Tumor Malignan	t							
•		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	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: FEED Page: 182

			Male				Female	
*Nose: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o		ynx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Occupation and the second	Total	0/50 (0%) 0/50 (0%) 0/200 (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%
Overali incidence	I Otal	0/200 (0/0)				0,200 (0,0)		
Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma	0/50 (00()					
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva):	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	` ,	SD 0%	Total	0/50 (0%)	0/50 (0%)	
#Oral Cavity (Oral Mucos Squamous Cell Carcin Overall Incidence	sa, Tongue, Phar oma, Papilloma S Total	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin Overall Incidence #Oral Mucosa:	sa, Tongue, Phar oma, Papilloma S Total	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%) 0/50 (0%)	0/50 (0%)	SD 0%		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)

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

^{#:} 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: 05/27/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
*Ovary: Choriocarcinoma				
		0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/245 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Cystadenoma				
Oystadenoma .		1/49 (2%)	0/48 (0%)	1/50 (2%)
		0/50 (0%)	2/48 (4%)	
Overall Incidence	Total	4/245 (1.63%)	Mean 1.64%	SD 1.74%
*Ovary: Fibrous Histiocytoma				
•		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign				
· ·		0/49 (0%)	2/48 (4%)	0/50 (0%)
		0/50 (0%)	2/48 (4%)	05 0000
Overall Incidence	Total	4/245 (1.63%)	Mean 1.67%	SD 2.28%
*Ovary: Granulosa Cell Tumor Malignant				
		0/49 (0%) 0/50 (0%)	1/48 (2%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.42%	SD 0.93%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)3/48 (6%)0/50 (0%)0/50 (0%)2/48 (4%)**Overall Incidence** Total 5/245 (2.04%) Mean 2.08% SD 2.95% *Ovary: Hemangioma (0%) 0/49(0%)0/48 0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% *Ovary: Hemangiosarcoma 0/49 0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% *Ovary: Leiomyosarcoma 0/49 0/50 (0%)0/48 (0%)(0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% *Ovary: Luteoma 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/245 (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: 05/27/2022

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Species: MICE Strain: B6C3F1/N

Vehicle: FEED

			Male				Female	
*Ovary: Teratoma Benign								
						0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/245 (0%)	0/48 (0%) Mean 0%	SD 0%
Ovary: Tubulostromal Adenoma								
rabarost omar y asiroma						1/49 (2%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence					Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
Pancreas: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/249 (0%)	0/49 (0%) Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
ouromonia or Adenonia		0/50 (0%) 0/50 (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	0/199 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distali Adenoma								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%)			2/50 (4%) 1/50 (2%)	1/47 (2%) 5/49 (10%)	2/50 (4%)
Overall Incidence	Total	0/194 (0%)	Mean 0%	SD 0%	Total	11/246 (4.47%)	Mean 4.47%	SD 3.35%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 05/27/2022

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			Male				Female	
*Pituitary Gland: Pars Di Carcinoma	stalis or Unspeci	ified Site:						
		0/48 (0%)	0/48 (0%)			0/50 (0%)	0/47 (0%)	0/50 (0%)
Occupation of the second	T-1-1	0/49 (0%)	0/49 (0%)	OD 00/	T-1-1	0/50 (0%)	0/49 (0%)	OD 00/
Overall Incidence	Total	0/194 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Di Carcinoma or Adenom		ified Site:						
		0/48 (0%)	0/48 (0%)			2/50 (4%)	1/47 (2%)	2/50 (4%)
		0/49 (0%)	0/49 (0%)			1/50 (2%)	5/49 (10%)	
Overall Incidence	Total	0/194 (0%)	Mean 0%	SD 0%	Total	11/246 (4.47%)	Mean 4.47%	SD 3.35%
*Pituitary Gland: Pars Int Adenoma	ermedia:							
		0/48 (0%)	0/48 (0%)			0/50 (0%)	1/47 (2%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/194 (0%)	Mean 0%	SD 0%	Total	1/246 (0.41%)	Mean 0.43%	SD 0.95%
*Pituitary Gland: Pars Int Carcinoma or Adenom								
		0/48 (0%)	0/48 (0%)			0/50 (0%)	1/47 (2%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/194 (0%)	Mean 0%	SD 0%	Total	1/246 (0.41%)	Mean 0.43%	SD 0.95%
*Prostate: Adenoma		2(20)						
		0/50 (0%)	1/50 (2%)					
Overell Incidence	Total	0/49 (0%)	0/50 (0%)	CD 40/				
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: ORAL Vehicle: FEED Page: 187

			Male				Female	
Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)					
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%				
Salivary Glands: 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma			•••••					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma								
-		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/200 (1%)	1/50 (2%) Mean 1%	SD 1.15%	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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date: 05/27/2022

Vehicle: FEED

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma o	r Rhabdomyoma							
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma or	· Basosquamous	Tumor Benign						
	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, B	asosquamous T	umor Benign, or Trichoer	oithelioma					
		0/50 (0%)	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	0/200 (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

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 189 Report Date: 05/27/2022

			Male				Female	
Skin:								
Basal Cell Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
····· ∤Skin:								
Basal Cell Carcinoma	or Basosquamou	is Tumor (malignant or NO	OS)					
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
		oma, Basosquamous Tum		t or				
		oma, Basosquamous Tum 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	sd or	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci	Totalinoma, Carcinoma	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	,
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci	Totalinoma, Carcinoma	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%)	,
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci	Totalinoma, Carcinoma	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% , Basal Cell Adenom	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence *Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Totalinoma, Carcinoma	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B rratoacanthoma, Trichoepi 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%), Basal Cell Adenomithelioma 0/50 (0%)	SD 0%	Total Total	0/50 (0%) 0/250 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci	Total Total inoma, Carcinoma Sq Papilloma, Kei	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%)	SD 0%		0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	Total Total inoma, Carcinoma Sq Papilloma, Kei	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepithel Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	Total Total inoma, Carcinoma Sq Papilloma, Kei	0/50 (0%) 0/50 (0%) 0/200 (0%) a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%		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%) 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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** #Skin: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)5/50 (10%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%) **Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% Total 10/250 (4%) Mean 4% SD 3.74% #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 7/250 (2.8%) Mean 2.8% SD 3.03% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)5/50 (10%) 1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% Total 10/250 (4%) Mean 4% SD 3.74% #Skin: **Fibrous Histiocytoma** 0/50 (0%)1/50 (2%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 1%

Total

1/250 (0.4%)

Mean 0.4%

SD 0.89%

Total

1/200 (0.5%)

Mean 0.5%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 191

			Male				Female	
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	1/50 (2%) 3/250 (1.2%)	2/50 (4%) Mean 1.2%	SD 1.79%
·····		1/200 (0.576)				3/230 (1.276)		
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Ossanall Inglidanaa	Tatal	0/50 (0%)	0/50 (0%)	SD 0%	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/200 (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

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

			Male				Female	
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Skin: Neurofibrosarcoma, N	eurofibroma, or	Schwannoma (benign, ma	alignant or NOS)					
Neurofibrosarcoma, No	Total	Schwannoma (benign, ma 1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) 0/50 (0%) Mean 0.5%	SD 1%	Total	1/50 (2%) 0/50 (0%) 2/250 (0.8%)	1/50 (2%) 0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.1%
Neurofibrosarcoma, No	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) 0/50 (0%) Mean 0.5%	,,		0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%
Neurofibrosarcoma, No Overall Incidence #Skin: Osteosarcoma	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0.5%			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%
Neurofibrosarcoma, No Overall Incidence #Skin: Osteosarcoma	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0.5%	,,		0/50 (0%) 2/250 (0.8%) 1/50 (2%)	0/50 (0%) Mean 0.8% 0/50 (0%)	SD 1.1%
Neurofibrosarcoma, No Overall Incidence #Skin:	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0.5% 0/50 (0%) 0/50 (0%) Mean 0%			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1% 0/50 (0%) SD 0.89%
Neurofibrosarcoma, No Overall Incidence #Skin: Osteosarcoma Overall Incidence	Total	1/50 (2%) 0/50 (0%) 1/200 (0.5%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0.5% 0/50 (0%) 0/50 (0%)			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%

^{*:} 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

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

			Male				Female	
≮Skin: Schwannoma Malignant	t							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Skin: Squamous Cell Carcino	ma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
	ma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
Squamous Cell Carcino or Carcinoma	ma, Basal Cell (Total	0/50 (0%) 0/50 (0%) 0/50 (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%
Squamous Cell Carcino or Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%		Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Squamous Cell Carcino or Carcinoma Overall Incidence Skin: Squamous Cell Papillon	Total na	0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)
Squamous Cell Carcino or Carcinoma Overall Incidence Skin: Squamous Cell Papillon	Total	0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%		Total Total	0/50 (0%) 0/250 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
Squamous Cell Carcino or Carcinoma Overall Incidence Skin: Squamous Cell Papillon Overall Incidence	Total na Total	0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%) SD 0%
Squamous Cell Carcino or Carcinoma Overall Incidence #Skin: Squamous Cell Papillon Overall Incidence	Total na Total	0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	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

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 Papillo	ma, Papilloma, S	Squamous Cell Carcinom	a or Keratoacanthoma	1				
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papillo	ma, Papilloma, o	or Keratoacanthoma						
		0/50 (0%)	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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Skin: Sebaceous Gland:								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Spinal Cord: Meningioma Malignant								
		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	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (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: ORAL Vehicle: FEED Page: 195

			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
•		1/50 (2%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	1/48 (2%)
Overall Incidence	Total	1/50 (2%) 2/199 (1.01%)	0/49 (0%) Mean 1%	SD 1.15%	Total	0/50 (0%) 5/247 (2.02%)	2/49 (4%) Mean 2.03%	SD 2.02%
		2/199 (1.01/0)					Weatt 2.0570	
#Stomach, Forestomach: Mast Cell Tumor Malignant								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Overall incluence		,				,		

^{*:} 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

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Report Date: 05/27/2022

Species: MICE

Route: ORAL Vehicle: FEED

			Male				Female				
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous											
·		1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%)			2/50 (4%) 2/50 (4%)	0/50 (0%) 2/50 (4%)	0/50 (0%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%			
#Stomach, Forestomach: Squamous Cell Papilloma						4/50 (00)	0/50 (00/)	0/50 (00/)			
		1/50 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%)			1/50 (2%) 2/50 (4%)	0/50 (0%) 2/50 (4%)	0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	5/250 (2%)	Mean 2%	SD 2%			
#Stomach, Glandular: Adenoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
Overall incluence	ı Olai	0/200 (0%)				0/250 (0%)	iviean 0%	30 0%			
Stomach, Glandular: 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	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
Stomach, Glandular: Carcinoma or Adenoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
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

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 05/27/2022

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			Male				Female	
*Testes: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Testes: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign,	Malignant, NO	s					•••••	
3 ,	,	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Testes: Sertoli Cell Tumor Malig							•••••	
_		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Thymus: Thymoma Malignant								
		0/46 (0%) 0/47 (0%)	0/41 (0%) 0/48 (0%)			0/46 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/47 (0%)	0/46 (0%) Mean 0%	SD 0%	Total	0/30 (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: ORAL Vehicle: FEED Page: 198

			Male				Female	
Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/46 (0%) 0/47 (0%)	0/41 (0%) 0/48 (0%)			0/46 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/182 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
'Thyroid Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%
Thyroid Gland: C-Cell: 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%)	0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or 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%)	0/48 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Ce Adenoma	ell:					•••••		
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)			0/50 (0%) 1/49 (2%)	1/50 (2%) 0/50 (0%)	0/48 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%

^{*:} 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	
Thyroid Gland: Follicular Cell Carcinoma	:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/50 (0%) Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/48 (0%)
Normall In aideman	Tatal	0/50 (0%)	1/50 (2%)	CD 4.450/	Tatal	1/49 (2%)	0/50 (0%)	CD 4.440/
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%
Tissue NOS: 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%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Tissue NOS: Schwannoma Malignant								
5 44 4		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	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

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Report Date: 05/27/2022

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

			Male				Female	
#Tongue: Squamous Cell Carcinoma	1							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Tongue:								
Squamous Cell Carcinoma	a or Papillom	a Squamous 0/50 (0%) 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	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell 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%)	0/50 (0%)	0/30 (0/0)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		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%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
J		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	0/200 (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

Strain: B6C3F1/N

Toxicology Data Management System

Vehicle: FEED

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: ORAL

Length of Study: CHRONIC

Page: 201

			Male				Female	
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						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: Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
Uterus: Deciduoma Benign								
						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: Hemangioma								
•						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

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: ORAL Vehicle: FEED Page: 202

Male	Female	
fUterus:		
Hemangiosarcoma	0/50 (0%) 0/50 (0%)	0/50 (0%)
	1/50 (2%) 0/50 (0%)	0/30 (0%)
Overall Incidence	Total 1/250 (0.4%) Mean 0.4%	SD 0.89%
Uterus: Leiomyoma		
	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:		
Leiomyosarcoma	0/50 (0%) 2/50 (4%)	0/50 (0%)
	0/50 (0%) 2/50 (4%)	0/30 (0 /0)
Overall Incidence	Total 2/250 (0.8%) Mean 0.8%	SD 1.79%
tUterus: Polyp Stromal		
	4/50 (8%) 2/50 (4%)	0/50 (0%)
	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total 6/250 (2.4%) Mean 2.4%	SD 3.58%
Uterus: Sarcoma Stromal		
	1/50 (2%) 0/50 (0%)	0/50 (0%)
	1/50 (2%) 0/50 (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

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus:	.h 01							
Sarcoma Stromal or Po	olyp Stromai					5/50 (10%)	2/50 (4%)	0/50 (0%)
						1/50 (10%)	0/50 (0%)	0/30 (0 /8)
Overall Incidence					Total	8/250 (3.2%)	Mean 3.2%	SD 4.15%
#Uterus: Schwannoma Malignan	A							
Scriwariiloma Manghan	ıı					0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	1/50 (2%)	(676)
Overall Incidence					Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Vagina: Squamous Cell Carcino								
1						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 Papillo								
						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: 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%)	1/50 (2%)	
Overall Incidence	Total	0/200 (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

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 204

Report Date: 05/27/2022

Length of Study: CHRONIC

Vehicle: FEED

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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Page: 205

Report Date: 05/27/2022

Route: ORAL Vehicle: WATER

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	052011406	09/04/02	729	50(1)	33(700)	55.6	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	729	50(1)	38(696)	54.1	Water disinfection byproducts (Bromochloroacetic acid)
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	059601506	08/22/01	729	50(1)	40(697)	54.0	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601004	09/30/98	729	50(1)	38(694)	54.1	Water disinfection byproducts (Sodium chlorate)
					Female		
Southern Research Institute	052011406	09/04/02	735	50(5)	35(701)	64.3	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	734	50(5)	36(693)	63.0	Water disinfection byproducts (Bromochloroacetic acid)
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	059601506	08/22/01	731	50(5)	35(705)	60.9	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601004	09/30/98	735	50(5)	36(691)	66.5	Water disinfection byproducts (Sodium chlorate)

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: ORAL Vehicle: WATER Page: 206

			Male				Female	
#All Organs: Benign Tumors								
		42/50 (84%)	41/50 (82%)			27/50 (54%)	32/50 (64%)	34/50 (68%)
O	T-1-1	25/49 (51%)	32/50 (64%)	34/50 (68%)	T-1-1	29/50 (58%)	29/50 (58%)	38/50 (76%)
Overall Incidence	Total	174/249 (69.88%)	Mean 69.8%	SD 13.6%	Total	189/300 (63%)	Mean 63%	SD 8.07%
#All Organs: Malignant Tumors								
		31/50 (62%)	36/50 (72%)			22/50 (44%)	38/50 (76%)	43/50 (86%)
		23/49 (47%)	29/50 (58%)	29/50 (58%)	-	36/50 (72%)	31/50 (62%)	33/50 (66%)
Overall Incidence	Total	148/249 (59.44%)	Mean 59.39%	SD 9.01%	Total	203/300 (67.67%)	Mean 67.67%	SD 14.28%
#All Organs: Malignant and Benign T	umors	40/50 (000/)	47/50 (040/)			26/50 (720/)	42/F0 (969/)	46/50 (000/)
		49/50 (98%) 37/49 (76%)	47/50 (94%) 41/50 (82%)	45/50 (90%)		36/50 (72%) 42/50 (84%)	43/50 (86%) 44/50 (88%)	46/50 (92%) 47/50 (94%)
Overall Incidence	Total	219/249 (87.95%)	Mean 87.9%	SD 9.11%	Total	258/300 (86%)	Mean 86%	SD 7.8%
#All Organs: Hemangioma								
-		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	9/300 (3%)	Mean 3%	SD 2.1%
#All Organs: Hemangiosarcoma								
-		4/50 (8%)	3/50 (6%)			2/50 (4%)	1/50 (2%)	8/50 (16%)
		4/49 (8%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	13/249 (5.22%)	Mean 5.23%	SD 3.07%	Total	18/300 (6%)	Mean 6%	SD 5.22%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 05/27/2022

Page: 207

Species: MICE Strain: B6C3F1/N

Vehicle: WATER

			Male				Female					
#All Organs: Hemangiosarcoma or Hemangioma												
-	_	4/50 (8%) 4/49 (8%)	4/50 (8%) 2/50 (4%)	1/50 (2%)		3/50 (6%) 4/50 (8%)	3/50 (6%) 3/50 (6%)	8/50 (16%) 5/50 (10%)				
Overall Incidence	Total	15/249 (6.02%)	Mean 6.03%	SD 2.86%	Total	26/300 (8.67%)	Mean 8.67%	SD 3.93%				
#All Organs: Histiocytic Sarcoma												
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (20/)		2/50 (4%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	Total	0/50 (0%) 7/300 (2.33%)	4/50 (8%) Mean 2.33%	0/50 (0%) SD 3.2%				
	• • • • • • • • • • • • • • • • • • • •		•••••	•••••								
#All Organs: Malignant Lymphoma: H	istiocytic Lym	nphocytic, Mixed, NOS, or	r Undifferentiated Cell	I Tyne								
manghant Lymphoma. 11	ishocyho, Lyn	2/50 (4%)	2/50 (4%)	Турс		7/50 (14%)	18/50 (36%)	29/50 (58%)				
		0/49 (0%)	0/50 (0%)	3/50 (6%)		27/50 (54%)	9/50 (18%)	23/50 (46%)				
Overall Incidence	Total	7/249 (2.81%)	Mean 2.8%	SD 2.68%	Total	113/300 (37.67%)	Mean 37.67%	SD 18.44%				
#All Organs: Mesothelioma: Benign, M	//alignant, NOS	S										
		2/50 (4%)	0/50 (0%)	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%)	0/50 (0%)				
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/300 (0%)	Mean 0%	SD 0%				
‡All Organs: Mesothelioma: Malignan	t											
_		2/50 (4%)	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%)				
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/300 (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: ORAL Vehicle: WATER Page: 208

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%
#All Organs: Osteosarcoma			-4					
		1/50 (2%) 0/49 (0%)	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		••••••				·····		
#All Organs: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	1/50 (2%)
	-	0/49 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Adrenal Cortex: Adenoma								
		7/49 (14%)	9/50 (18%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
		3/49 (6%)	6/50 (12%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	28/248 (11.29%)	Mean 11.28%	SD 5.22%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Adrenal Cortex: Sarcoma								
		0/49 (0%)	0/50 (0%)			0/49 (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%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: ORAL Vehicle: WATER Page: 209

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	nign							
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	1/49 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	3/299 (1%)	Mean 1%	SD 1.1%
Adrenal Medulla: Pheochromocytoma Co	mplex							
		0/49 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Adrenal Medulla: Pheochromocytoma Ma		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/49 (0%)	Total	0/49 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	3/299 (1%)	Mean 1%	SD 1.67%
Adrenal Medulla: Pheochromocytoma: Be	enign, Complex	·	2/52 (221)			242 (224)	2/22 (424)	(00)
		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/49 (2%)	0/49 (0%)		0/49 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	1/50 (2%) 3/50 (6%)
Overall Incidence	Total	2/246 (0.81%)	Mean 0.82%	SD 1.12%	Total	7/299 (2.34%)	Mean 2.33%	SD 2.34%
		2/240 (0.0170)						OD 2.5470
Bone Marrow: Hemangiosarcoma								
		1/49 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/47 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%	Total	3/300 (1%)	Mean 1%	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: 210

			Male				Female	
*Bone Marrow: Mast Cell Tumor Malignant								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	- / / / / / / / / / /		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Bone: Osteosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 211

			Male				Female	
Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/48 (0%)	- ()		0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/285 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/285 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/285 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/43 (0%)	0/48 (0%)
• " " "	.	0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/285 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: ORAL

Species: MICE Strain: B6C3F1/N

Vehicle: WATER

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinom	a							
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/285 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)					
		0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%				
#Eye: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma								
		0/47 (0%)	0/45 (0%)			0/44 (0%)	0/42 (0%)	0/46 (0%)
		0/39 (0%)	0/47 (0%)	0/44 (0%)		0/47 (0%)	0/46 (0%)	0/40 (0%)
Overall Incidence	Total	0/222 (0%)	Mean 0%	SD 0%	Total	0/265 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		6/50 (12%)	5/50 (10%)			4/50 (8%)	1/50 (2%)	3/50 (6%)
		3/49 (6%)	5/50 (10%)	6/50 (12%)		9/50 (18%)	6/50 (12%)	11/50 (22%)
Overall Incidence	Total	25/249 (10.04%)	Mean 10.02%	SD 2.4%	Total	34/300 (11.33%)	Mean 11.33%	SD 7.55%

^{*:} 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: ORAL Vehicle: WATER Page: 213

			Male				Female	
Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	2/50 (4%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	8/300 (2.67%)	Mean 2.67%	SD 1.03%
Harderian Gland: Carcinoma or Adenoma								
		6/50 (12%)	5/50 (10%)			5/50 (10%)	3/50 (6%)	4/50 (8%)
		3/49 (6%)	5/50 (10%)	6/50 (12%)		10/50 (20%)	8/50 (16%)	12/50 (24%)
Overall Incidence	Total	25/249 (10.04%)	Mean 10.02%	SD 2.4%	Total	42/300 (14%)	Mean 14%	SD 7.16%
Heart: 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%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
_		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%)	0/49 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Heart: Sarcoma								
		0/50 (0%)	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%)	0/49 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/299 (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: 214

			Male				Female	
#Intestine Large: Cecum: Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	-	0/49 (0%)	0/50 (0%)	0/50 (0%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		1/50 (2%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/249 (2.41%)	Mean 2.4%	SD 2.19%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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:** 215

			Male				Female		
#Intestine Small: Duodenum: Carcinoma									
		0/50 (0%)	1/50 (2%)	2/22 (221)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		' '				` '			
Intestine Small: Duodenum: Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
	T	0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Carcinoma									
		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%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
#Intestine Small: Jejunum: 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%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma									
		0/50 (0%)	1/50 (2%)			1/50 (2%)	1/50 (2%)	0/50 (0%)	
		0/49 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6%	SD 1.67%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	

^{*:} 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: ORAL Vehicle: WATER Page: 216

			Male				Female	
#Intestine Small: Jejunum: Hemangiosarcoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	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%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Adenoma	ecified:							
		1/50 (2%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/249 (2.41%)	Mean 2.4%	SD 2.19%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Unspe Carcinoma	ecified:							
		0/50 (0%)	2/50 (4%)			1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2%	SD 2%	Total	3/300 (1%)	Mean 1%	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

Control Animal Groups Report Date: 05/27/2022 RAL

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			Male				Female	
#Intestine Small: Site Uns Carcinoma or Adenoma								
		1/50 (2%)	5/50 (10%)			1/50 (2%)	2/50 (4%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/249 (4.02%)	Mean 4%	SD 4%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%
#Intestine Small: Site Uns Hemangiosarcoma								
-		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous								
		0/50 (0%)	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%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/300 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Adenoma								
		3/49 (6%)	1/50 (2%)			1/49 (2%)	1/49 (2%)	3/49 (6%)
		0/46 (0%)	1/50 (2%)	1/48 (2%)		1/49 (2%)	1/49 (2%)	0/46 (0%)
Overall Incidence	Total	6/243 (2.47%)	Mean 2.44%	SD 2.24%	Total	7/291 (2.41%)	Mean 2.38%	SD 2.01%

^{*:} 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

Length of Study: CHRONIC

Route: ORAL
Vehicle: WATER

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			Male				Female	
'Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/46 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	0/291 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		3/49 (6%)	1/50 (2%)			1/49 (2%)	1/49 (2%)	3/49 (6%)
		0/46 (0%)	1/50 (2%)	1/48 (2%)		1/49 (2%)	1/49 (2%)	0/46 (0%)
Overall Incidence	Total	6/243 (2.47%)	Mean 2.44%	SD 2.24%	Total	7/291 (2.41%)	Mean 2.38%	SD 2.01%
'Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	4/50 (8%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/248 (2.02%)	Mean 2.01%	SD 3.46%	Total	0/299 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	4/50 (8%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/248 (2.02%)	Mean 2.01%	SD 3.46%	Total	0/299 (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: 05/27/2022

Length of Study: CHRONIC

Vehicle: WATER

			Male				Female	
Liver: Cholangiocarcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/247 (0.4%)	0/50 (0%) Mean 0.42%	1/48 (2%) SD 0.93%	Total	0/49 (0%) 0/297 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
·····		1/247 (0.470)			10tai	0/297 (0 /6)		30 0%
Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	2/12 (22/)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	0/49 (0%)	0/50 (0%)	0/48 (0%)	T-1-1	0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	0/48 (0%)		1/49 (2%)	0/50 (0%)	2/49 (4%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	4/297 (1.35%)	Mean 1.36%	SD 1.67%
_iver: Hemangiosarcoma								
-		1/50 (2%)	2/50 (4%)			1/49 (2%)	0/50 (0%)	2/50 (4%)
		1/49 (2%)	0/50 (0%)	1/48 (2%)		1/49 (2%)	2/50 (4%)	1/49 (2%)
verall Incidence	Total	5/247 (2.02%)	Mean 2.02%	SD 1.41%	Total	7/297 (2.36%)	Mean 2.35%	SD 1.5%
Liver: Hepatoblastoma								
•		17/50 (34%)	4/50 (8%)			0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	6/48 (13%)		1/49 (2%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	28/247 (11.34%)	Mean 11.3%	SD 13.62%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.11%

^{*:} 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: 05/27/2022

Route: ORAL

Vehicle: WATER

			Male				Female	
*Liver: Hepatocellular Adenom	ıa							
		36/50 (72%)	27/50 (54%)			14/49 (29%)	27/50 (54%)	24/50 (48%)
		18/49 (37%)	29/50 (58%)	30/48 (63%)		19/49 (39%)	19/50 (38%)	30/49 (61%)
Overall Incidence	Total	140/247 (56.68%)	Mean 56.65%	SD 12.99%	Total	133/297 (44.78%)	Mean 44.76%	SD 11.92%
Liver: Hepatocellular Carcinor	ma							
		14/50 (28%)	19/50 (38%)			8/49 (16%)	14/50 (28%)	13/50 (26%)
		14/49 (29%)	24/50 (48%)	20/48 (42%)		3/49 (6%)	10/50 (20%)	3/49 (6%)
Overall Incidence	Total	91/247 (36.84%)	Mean 36.85%	SD 8.6%	Total	51/297 (17.17%)	Mean 17.1%	SD 9.47%
*Liver: Hepatocellular Carcinor Overall Incidence	ma or Hepatob	25/50 (50%) 14/49 (29%) 107/247 (43.32%)	21/50 (42%) 24/50 (48%) Mean 43.3%	23/48 (48%) SD 8.76%	Total	8/49 (16%) 4/49 (8%) 54/297 (18.18%)	14/50 (28%) 10/50 (20%) Mean 18.11%	14/50 (28%) 4/49 (8%) SD 8.95%
Liver: Hepatocellular Carcinor	ma or Henatoc	ellular Adenoma						
	ma or riepatoo	42/50 (84%)	34/50 (68%)			17/49 (35%)	31/50 (62%)	30/50 (60%)
			(, - ,			()	` ,	` ,
		28/49 (57%)	37/50 (74%)	41/48 (85%)		22/49 (45%)	27/50 (54%)	31/49 (63%)
Overall Incidence	Total	28/49 (57%) 182/247 (73.68%)	37/50 (74%) Mean 73.71%	41/48 (85%) SD 11.73%	Total	22/49 (45%) 158/297 (53.2%)	27/50 (54%) Mean 53.14%	SD 11.29%
Overall Incidence 'Liver:		182/247 (73.68%)	Mean 73.71%	()	Total	, ,	` ,	, ,
Overall Incidence 'Liver:		, ,	Mean 73.71% Mean blastoma	()	Total	, ,	Mean 53.14%	SD 11.29%
Overall Incidence 'Liver:		182/247 (73.68%)	Mean 73.71% Ó	()	Total	158/297 (53.2%)	` ,	, ,

^{*:} 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: 05/27/2022

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

			Male				Female	
Liver: Hepatocholangiocarcino	ma							
		0/50 (0%)	0/50 (0%)	2/12 (22/)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	0/49 (0%)	0/50 (0%)	0/48 (0%) SD 0%	Total	0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	บ บ‰	Total	0/297 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	2/50 (4%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/247 (0.81%)	Mean 0.8%	SD 1.79%	Total	0/297 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/48 (0%)		1/49 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	1/297 (0.34%)	Mean 0.34%	SD 0.83%
Lung: Adenoma								
		0/50 (0%)	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%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Ade	enoma							
		15/50 (30%)	4/50 (8%)			1/50 (2%)	2/50 (4%)	6/50 (12%)
		7/49 (14%)	6/50 (12%)	6/50 (12%)		1/50 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	38/249 (15.26%)	Mean 15.26%	SD 8.55%	Total	16/300 (5.33%)	Mean 5.33%	SD 3.72%

^{*:} 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: 05/27/2022

Species: MICE Strain: B6C3F1/N

Route: ORAL Vehicle: WATER

			Male				Female	
*Lung: Alveolar/Bronchiolar Car	cinoma							
		3/50 (6%)	12/50 (24%)			2/50 (4%)	6/50 (12%)	1/50 (2%)
Occupation of desires	T-1-1	5/49 (10%)	4/50 (8%)	4/50 (8%)	T-1-1	1/50 (2%)	6/50 (12%)	1/50 (2%)
Overall Incidence	Total	28/249 (11.24%)	Mean 11.24%	SD 7.29%	Total	17/300 (5.67%)	Mean 5.67%	SD 4.97%
*Lung:								
Alveolar/Bronchiolar Car	cinoma or Al	veolar/Bronchiolar Adeno 16/50 (32%)	ma 15/50 (30%)			2/50 (4%)	8/50 (16%)	6/50 (12%)
		12/49 (24%)	10/50 (30%)	10/50 (20%)		2/50 (4%)	9/50 (18%)	4/50 (8%)
Overall Incidence	Total	63/249 (25.3%)	Mean 25.3%	SD 5.56%	Total	31/300 (10.33%)	Mean 10.33%	SD 5.99%
		, ,						
*Lung: Fibrosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma								
•		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
. .		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 223

			Male				Female	
#Lymph Node: Fibrous Histiocytoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Lymph Node, Bronchial: Hemangiosarcoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma								
-		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 224

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		0/249 (0%)	Mean 0%	 	Total	0/300 (0%)	wiean 0%	טט טא U%
#Lymph Node, Mesenteric: Hemangiosarcoma								
-		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: WATER

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	. Carcinoma or	Adenoma						
Fibroilla, Fibroadellollia	a, Carcinonia, Oi	0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Mesentery: Fibrosarcoma			•••••					
		0/50 (0%)	0/50 (0%)			3/50 (6%)	0/50 (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	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 2.45%
#Mesentery: Fibrous Histiocytoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Mesentery: 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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Mesentery: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: 226

			Male					Female	
#Mesentery: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	`	(2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%		Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	,	(0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%		Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Nose: Carcinoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 ((0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
'Nose: Hemangioma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	`	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%		Total	0/300 (0%)	Mean 0%	SD 0%
'Nose: Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	,	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%		Total	0/300 (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: 227

			Male				Female	
*Nose: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos) Papilloma Squamous		ynx, Tooth, Gingiva):						
	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/50 (2%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		Squamous, or Papilloma						
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/49 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	3/300 (1%)	0/50 (0%) Mean 1%	SD 1.67%
	I Ulai	0/249 (070)	IVIEAII U%		10lal	3/300 (170)	IVIEAN 170	3D 1.07%
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%

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

	Male			Female	
*Ovary: Choriocarcinoma					
			0/50 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 1/291 (0.34%)	1/50 (2%) Mean 0.33%	0/45 (0%) SD 0.82%
*Ovary:				•••••	
Cystadenoma			1/50 (2%)	2/47 (4%)	4/50 (8%)
			0/49 (0%)	1/50 (2%)	1/45 (2%)
Overall Incidence		Total	9/291 (3.09%)	Mean 3.08%	SD 2.76%
*Ovary: Fibrous Histiocytoma				•••••	•••••
			0/50 (0%)	0/47 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence		Total	0/291 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign					
Cramarou con ramo. Zomg.			0/50 (0%)	0/47 (0%)	1/50 (2%)
			0/49 (0%)	1/50 (2%)	1/45 (2%)
Overall Incidence		Total	3/291 (1.03%)	Mean 1.04%	SD 1.14%
*Ovary: Granulosa Cell Tumor Malignant					
			0/50 (0%)	0/47 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence		Total	0/291 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/47 (0%)1/50 (2%)0/49 (0%)1/50 (2%)1/45 (2%)**Overall Incidence** Total 3/291 (1.03%) Mean 1.04% SD 1.14% *Ovary: Hemangioma (0%) 0/50 (0%)0/47 0/50 (0%)0/49 (0%)0/50 (0%)0/45 (0%)**Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% *Ovary: Hemangiosarcoma 0/50 0/47 2/50 (4%)0/49 (0%)0/50 (0%)0/45 (0%)**Overall Incidence** Total 2/291 (0.69%) Mean 0.67% SD 1.63% *Ovary: Leiomyosarcoma 0/50 0/50 (0%)0/47 (0%)(0%)0/49 (0%)0/50 (0%)0/45 (0%)**Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% *Ovary: Luteoma 0/50 (0%)0/47 (0%)0/50 (0%)0/49 (0%)0/50 (0%)3/45 (7%)**Overall Incidence** Total 3/291 (1.03%) Mean 1.11% SD 2.72%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

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Report Date: 05/27/2022

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

Route: ORAL Vehicle: WATER

			Male				Female	
Ovary: Teratoma Benign								
						0/50 (0%)	0/47 (0%)	0/50 (0%)
						0/49 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence					Total	0/291 (0%)	Mean 0%	SD 0%
Ovary: Tubulostromal Adenoma								
						0/50 (0%)	0/47 (0%)	0/50 (0%)
						0/49 (0%)	1/50 (2%)	0/45 (0%)
Overall Incidence					Total	1/291 (0.34%)	Mean 0.33%	SD 0.82%
Pancreas: Carcinoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	1/49 (2%)	0/50 (0%)
		0/46 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
Pancreas: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	1/49 (2%)	0/50 (0%)
		0/46 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
Pituitary Gland: Pars Distali Adenoma								
		0/49 (0%)	1/50 (2%)			3/48 (6%)	4/48 (8%)	3/49 (6%)
		0/45 (0%)	0/49 (0%)	0/47 (0%)		2/47 (4%)	2/48 (4%)	3/46 (7%)
Overall Incidence	Total	1/240 (0.42%)	Mean 0.4%	SD 0.89%	Total	17/286 (5.94%)	Mean 5.94%	SD 1.56%

^{*:} 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

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Report Date: 05/27/2022

Route: ORAL

		Male				Female	
alis or Unspec	ified Site:						
	0/49 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	0/49 (0%)
	` '	` '	` ,		` '	` ,	0/46 (0%)
	` '		SD 0%	Total	0/286 (0%)	Mean 0%	SD 0%
alis or Unspec	ified Site:						
	0/49 (0%)	1/50 (2%)			3/48 (6%)	4/48 (8%)	3/49 (6%)
	` '	0/49 (0%)	0/47 (0%)		, ,	2/48 (4%)	3/46 (7%)
Total	, ,	Mean 0.4%	SD 0.89%	Total	17/286 (5.94%)	Mean 5.94%	SD 1.56%
	0/49 (0%) 0/45 (0%)	1/50 (2%) 0/49 (0%)	0/47 (0%)	Tatal	0/48 (0%) 1/47 (2%)	0/48 (0%) 0/48 (0%)	2/49 (4%) 0/46 (0%)
	, ,		SD 0.89%	ı otai	3/286 (1.05%)	Mean 1.03%	SD 1.72%
media:	0/40 (00/)	1/50 (20/)			0/49 (00/)	0/49 (09/)	2/40 (40/)
	()	` '	0/47 (0%)		()	\ /	2/49 (4%) 0/46 (0%)
Total	` '	, ,	` '	Total	` '	Mean 1.03%	SD 1.72%
	` ,				,		
	0/50 (0%)	0/50 (0%)					
	,	` ,	0/50 (0%)				
Total	` '	` '	` ,				
	Total Total Total Total Total Total Total	O/45 (0%) Total O/240 (0%) alis or Unspecified Site: O/49 (0%) 0/45 (0%) Total 1/240 (0.42%) media: O/49 (0%) 0/45 (0%) Total 1/240 (0.42%) media: O/49 (0%) 0/45 (0%) Total 1/240 (0.42%) Total 1/240 (0.42%)	O/49 (0%)	Alis or Unspecified Site: 0/49	Alis or Unspecified Site:	Alis or Unspecified Site: 0/49 (0%)	Alis or Unspecified Site: 0/49

^{*:} 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: ORAL Vehicle: WATER Page: 232

			Male				Female	
Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)					
		0/48 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
		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%)	0/48 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/298 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		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%)	0/48 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/298 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
		0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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 pups Report Date: 05/27/2022

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			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma o	r Rhabdomyoma							
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
Skin: Basal Cell Adenoma or	· Basosquamous	Tumor Benign						
	•	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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, B	asosquamous Ti	umor Benign, or Trichoep	ithelioma					
,	•	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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: ORAL Vehicle: WATER Page: 234

			Male				Female	
#Skin:								
Basal Cell Carcinoma		1/50 (2%)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		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%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:					•••••			
Basal Cell Carcinoma o	r Basosquamou	ıs Tumor (malignant or N	OS)					
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
		oma, Basosquamous Tur	, , ,	nt or				
		oma, Basosquamous Tur 1/50 (2%) 0/49 (0%) 1/249 (0.4%)	nor (benign, malignar 0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence #Skin: Basal or Sq. Cell Carcir	Total	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or E	0/50 (0%) 0/50 (0%) Mean 0.4% 3), Basal Cell Adenom	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence #Skin: Basal or Sq. Cell Carcir	Total	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	0/50 (0%) 0/50 (0%) Mean 0.4% 3), Basal Cell Adenom bithelioma 1/50 (2%)	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 0/50 (0%)
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom q Papilloma, Ke	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0.4% B), Basal Cell Adenomithelioma 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0.89% na,		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence #Skin: Basal or Sq. Cell Carcir	Total	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 1/50 (2%)	0/50 (0%) 0/50 (0%) Mean 0.4% 3), Basal Cell Adenom bithelioma 1/50 (2%)	0/50 (0%) SD 0.89%	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 0/50 (0%)
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence #Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S Overall Incidence	Total Total noma, Carcinom q Papilloma, Ke	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0.4% B), Basal Cell Adenomithelioma 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0.89% na,		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence *Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom q Papilloma, Ke	1/50 (2%) 0/49 (0%) 1/249 (0.4%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0.4% B), Basal Cell Adenomithelioma 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0.89% na,		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Basal Cell Carcinoma, I NOS), or Trichoepithelic Overall Incidence *Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S Overall Incidence	Total Total noma, Carcinom q Papilloma, Ke	1/50 (2%) 0/49 (0%) 1/249 (0.4%) a, Basosq. Tumor (M or Estatoacanthoma, Trichoep 1/50 (2%) 0/49 (0%) 2/249 (0.8%)	0/50 (0%) 0/50 (0%) Mean 0.4% B), Basal Cell Adenomithelioma 1/50 (2%) 0/50 (0%) Mean 0.8%	0/50 (0%) SD 0.89% na,		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibroma** 0/50 (0%)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%)0/300 (0%) **Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% Total Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)1/50 (2%)2/50 (4%)2/50 (4%)5/50 (10%)1/49 (2%)0/50 (0%)4/50 (8%)4/50 (8%)0/50 (0%)0/50 17/300 (5.67%) Mean 5.67% **Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% Total SD 3.67% #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)(8%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% 7/300 (2.33%) Mean 2.33% SD 2.94% Total #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (0%)0/50 (0%)2/50 (4%)2/50 (4%)5/50 (10%)0/49 (0%)0/50 (0%)0/50 (0%)4/50 (8%)4/50 (8%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 17/300 (5.67%) Mean 5.67% SD 3.67% #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 4/300 (1.33%) Mean 1.33% SD 2.42%

^{*:} 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

Vehicle: WATER

Report Date: 05/27/2022 Route: ORAL Female

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			Male				Female	
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	4/50 (8%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	5/300 (1.67%)	Mean 1.67%	SD 3.2%
#Skin: Liposarcoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Melanoma 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 237

			Male				Female	
#Skin: Neural Crest Tumor								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:	Cabusana ama (m	adiamant an NOS)						
Neurofibrosarcoma or	Schwannoma (m	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%)	3/50 (6%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 2.45%
rediction osarcoma, re	curonbroma, or c	Schwannoma (benign, ma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 1%	3/50 (6%) SD 2.45%
Overall Incidence #Skin: Osteosarcoma	Total	` ,	` '	` '	Total	` '	` '	3/50 (6%)
Skin:	Total	0/249 (0%)	Mean 0% 0/50 (0%)	SD 0%	Total	3/300 (1%) 0/50 (0%)	Mean 1% O/50 (0%)	3/50 (6%) SD 2.45% 0/50 (0%)
#Skin: Osteosarcoma		0/249 (0%) 0/50 (0%) 0/49 (0%)	Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		3/300 (1%) 0/50 (0%) 0/50 (0%)	Mean 1% 0/50 (0%) 0/50 (0%)	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%)
#Skin: Osteosarcoma	Total Total	0/249 (0%)	Mean 0% 0/50 (0%)	SD 0%	Total Total	3/300 (1%) 0/50 (0%)	Mean 1% O/50 (0%)	3/50 (6%) SD 2.45% 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence		0/249 (0%) 0/50 (0%) 0/49 (0%)	Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		3/300 (1%) 0/50 (0%) 0/50 (0%)	Mean 1% 0/50 (0%) 0/50 (0%)	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence #Skin:		0/249 (0%) 0/50 (0%) 0/49 (0%)	Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%		3/300 (1%) 0/50 (0%) 0/50 (0%)	Mean 1% 0/50 (0%) 0/50 (0%)	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%)
#Skin: Osteosarcoma Overall Incidence #Skin:		0/249 (0%) 0/50 (0%) 0/49 (0%) 0/249 (0%)	Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%		3/300 (1%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	Mean 1% 0/50 (0%) 0/50 (0%) Mean 0%	3/50 (6%) SD 2.45% 0/50 (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

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Report Date: 05/27/2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** #Skin: Schwannoma 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%)0/50 (0%)3/50 (6%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 3/300 (1%) Mean 1% SD 2.45% #Skin: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma (2%)0/50 0/50 0/50 0/50 (0%)1/50 (0%)(0%)(0%)(0%) 0/49 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/249 (0.4%) Mean 0.4% SD 0.89% Total 0/300 (0%) Mean 0% SD 0% #Skin: **Squamous Cell Papilloma** 0/50 (0%)(2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (0%)(0%)0/49 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 1/249 (0.4%) Mean 0.4% SD 0.89% Total 0/300 (0%) Mean 0% #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.89%

Total

0/300 (0%)

Mean 0%

SD 0%

Total

1/249 (0.4%)

Mean 0.4%

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

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Report Date: 05/27/2022

Contract/Lab: All Laboratories Tumor Incidence for Selected

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin:								
Squamous Cell Papillo	ma, Papilloma, S	Squamous Cell Carcinoma	a or Keratoacanthom	a				
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:								
Squamous Cell Papillo	ma, Papilloma, c	or Keratoacanthoma						
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous 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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Sebaceous Gland: Carcinoma or 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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Spinal Cord: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: ORAL Vehicle: WATER Page: 240

			Male				Female	
*Spleen: Fibrous Histiocytoma								
		0/49 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	0/48 (0%)		0/48 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/244 (0%)	Mean 0%	SD 0%	Total	0/294 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/49 (0%) 0/47 (0%)	1/50 (2%) 0/50 (0%)	0/48 (0%)		0/48 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	1/244 (0.41%)	Mean 0.4%	SD 0.89%	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%
*Spleen: Hemangiosarcoma								
•		2/49 (4%)	1/50 (2%)			1/48 (2%)	1/49 (2%)	4/50 (8%)
Overall Incidence	Total	2/47 (4%) 6/244 (2.46%)	1/50 (2%) Mean 2.47%	0/48 (0%) SD 1.76%	Total	0/50 (0%) 8/294 (2.72%)	0/48 (0%) Mean 2.7%	2/49 (4%) SD 3.01%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		0,210 (0,0)						
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	1/50 (20/)			0/50 /09/	0/50 (09/)	0/50 (09/)
		0/50 (0%) 1/49 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/300 (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

ncidence for Selected Control Animal Gro **Route:** ORAL Page: 241

Report Date: 05/27/2022

Vehicle: WATER

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papillom	a Squamous						
		0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21%	SD 1.79%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#Stomach, Forestomach: Squamous Cell Papilloma	1							
		0/50 (0%)	2/50 (4%)	0/50 (00/)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 2/249 (0.8%)	0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.79%	Total	1/50 (2%) 3/300 (1%)	1/50 (2%) Mean 1%	0/50 (0%) SD 1.1%
#Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)	(00)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Glandular:								
		0/50 (0%)	0/50 (0%)	0.750 (004)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		3/243 (0/0)						
#Stomach, Glandular: Carcinoma or Adenoma								
		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%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/300 (2%)	Mean 0.33%	SD 0.82%

^{*:} 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: 05/27/2022

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

			Male		Female
*Testes: Adenoma					
		0/50 (0%)	1/50 (2%)		
		0/49 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	
*Testes: Hemangiosarcoma					
		0/50 (0%)	0/50 (0%)		
		1/49 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	
*Testes: Seratoli Tumor: Benign	ı, Malignant, NO	S			
		0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	
*Testes: Sertoli Cell Tumor Mali	gnant				
·	•	0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant					
		0/49 (0%)	0/46 (0%)		0/46 (0%) 0/49 (0%) 1/49 (2%)
		0/42 (0%)	0/44 (0%)	0/43 (0%)	0/44 (0%) 0/46 (0%) 0/48 (0%)
Overall Incidence	Total	0/224 (0%)	Mean 0%	SD 0%	Total 1/282 (0.35%) Mean 0.34% SD 0.83%

^{*:} 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: 243 Report Date: 05/27/2022

			Male					Female	
*Thymus: Thymoma: Benign, Maligr	nant, NOS								
		0/49 (0%)	0/46 (0%)				0/46 (0%)	0/49 (0%)	1/49 (2%)
		0/42 (0%)	0/44 (0%)		(0%)		0/44 (0%)	0/46 (0%)	0/48 (0%)
Overall Incidence	Total	0/224 (0%)	Mean 0%	SD 0%		Total	1/282 (0.35%)	Mean 0.34%	SD 0.83%
*Thyroid Gland: Adenoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/48	(0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%		Total	0/297 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/48	(0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%		Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)				0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/48	(0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%		Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: Follicular C Adenoma	ell:								
		1/50 (2%)	3/50 (6%)				1/50 (2%)	3/50 (6%)	2/50 (4%)
		0/48 (0%)	3/50 (6%)	0/48	(0%)		3/50 (6%)	1/49 (2%)	1/48 (2%)
Overall Incidence	Total	7/246 (2.85%)	Mean 2.8%	SD 3.03%		Total	11/297 (3.7%)	Mean 3.69%	SD 1.95%

^{*:} 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: ORAL Vehicle: WATER

Control Animal Groups

Report Date: 05/27/2022

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			Male				Female	
Thyroid Gland: Follicular C Carcinoma	Cell:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:							
		1/50 (2%)	3/50 (6%)			1/50 (2%)	3/50 (6%)	2/50 (4%)
		0/48 (0%)	3/50 (6%)	0/48 (0%)		3/50 (6%)	1/49 (2%)	1/48 (2%)
Overall Incidence	Total	7/246 (2.85%)	Mean 2.8%	SD 3.03%	Total	11/297 (3.7%)	Mean 3.69%	SD 1.95%
#Tissue NOS: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma								
		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%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 05/27/2022

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

			Male				Female	
#Tongue: Squamous Cell Carcinoma	a							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Tongue:		_						
Squamous Cell Carcinoma	a or Papillom	a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Tooth: Odontoma								
		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%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
- J		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/299 (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: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ORAL

Report Date: 05/27/2022

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			Male				Female	
*Urinary Bladder: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
tUterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
Uterus: Deciduoma Benign								
-						0/50 (0%)	0/50 (0%)	1/50 (2%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Hemangioma								
-						0/50 (0%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: ORAL Vehicle: WATER Page: 247

	Male			Female	
#Uterus: Hemangiosarcoma					
			0/50 (0%)	0/50 (0%)	2/50 (4%)
Occupation of the second	-		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		otal 	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#Uterus: Leiomyoma					
•			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	To	otal	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma				•••••	•••••
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		otal	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal		•••••		•••••	
. Styp Stromat			1/50 (2%)	2/50 (4%)	0/50 (0%)
			1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	To	otal	6/300 (2%)	Mean 2%	SD 1.26%
#Uterus: Sarcoma Stromal				•••••	
			0/50 (0%)	0/50 (0%)	2/50 (4%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	To	otal	2/300 (0.67%)	Mean 0.67%	SD 1.63%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal 1/50 (2%)2/50 (4%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 8/300 (2.67%) Mean 2.67% SD 1.03% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: **Squamous Cell Papilloma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Zymbal's Gland: 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%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/300 (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: 05/27/2022

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

			Male			Female				
#Zymbal's Gland: Carcinoma or 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%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 250

Report Date: 05/27/2022

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 Female									
Battelle Columbus Laboratory	050510914	09/23/98	729	50(1)	35(692)	62.7	Triethanolamine		

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: 251

			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 To	umors	45/50 (000/)				20/50 /760/\		
Overall Incidence	Total	45/50 (90%) 45/50 (90%)	Mean 90%	SD 0%	Total	38/50 (76%) 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

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: 252

0/50 (0%) 0/50 (0%) cytic, Mixed, NOS, or U 0/50 (0%) 0/50 (0%)	ndifferentiated Cel	I Type SD 0%	Total Total	4/50 (8%) 4/50 (8%) 8/50 (16%) 8/50 (16%)	Mean 8% Mean 16%	SD 0% SD 0%
0/50 (0%) cytic, Mixed, NOS, or U 0/50 (0%) 0/50 (0%)	ndifferentiated Cel	I Type SD 0%		4/50 (8%)		
cytic, Mixed, NOS, or U 0/50 (0%) 0/50 (0%)	ndifferentiated Cel	I Type SD 0%		8/50 (16%)		
cytic, Mixed, NOS, or U 0/50 (0%) 0/50 (0%)	ndifferentiated Cel	I Type SD 0%	Total	` '	Mean 16%	SD 0%
0/50 (0%)			Total	` '	Mean 16%	SD 0%
` '			Total	8/50 (16%)	Mean 16%	SD 00/
						30 0/0
0/50 (0%)				0/50 (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%)				0/50 (0%)		
0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
1/50 (2%)				1/50 (2%)		
` '	Mean 2%	SD 0%	Total	` '	Mean 2%	SD 0%
	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%	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%) 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% Total 0/50 (0%) 1/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 1/50 (2%)	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% 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% 1/50 (2%)

^{*:} 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: 253

Report Date: 05/27/2022

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female				
#All Organs: Osteosarcoma or Osteoma	1	1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Cortex: 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%		
*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 Benig	n	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%		
*Adrenal Medulla: Pheochromocytoma Comp	lex	0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Maligi	nant									
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

Page: 254

Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ACETONE

			Male				Female		
*Adrenal Medulla: Pheochromocytoma: Benig	n, Complex,	, Malignant, NOS 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	
*Bone Marrow:									
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%	
*Bone Marrow: 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%	
·····									
#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		4/50 (00/)				0(50 (00))			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
·····	10tai	1/30 (2/0)	IVICALI Z/0			0/30 (0/0)		OD 070	

^{*:} 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: 255

			Male			Female			
#Bone: 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%	
*Brain: Schwannoma 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%	
*Clitoral/Preputial 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%	
*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%	
*Clitoral/Preputial Gland: 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%	
*Clitoral/Preputial Gland: Hemangiosarcoma		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

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: 256

			Male			Female			
*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%	
*Epididymis: Sarcoma									
		0/50 (0%)		00.007					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
#Eye: Sarcoma									
		0/50 (0%)		00.007		0/50 (0%)		25 22/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
'Gallbladder: Adenoma		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									
		7/50 (14%)				5/50 (10%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
#Harderian Gland: Carcinoma									
		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: ACETONE nal Groups Report Date: 05/27/2022

Page: 257

			Male				Female	
#Harderian Gland: Carcinoma or 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%
*Heart: 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%
*Heart: Hemangiosarcoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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%
#Intestine Large: Cecum: 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%
#Intestine Large: Cecum: Carcinoma or Adenoma	•••••	(A-1)				(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: ACETONE Report Date: 05/27/2022

Page: 258

			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma		0/50 /05	0()			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%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (09				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		0/50 /05	0/ \			0/50 (09/)		
Overall Incidence	Total	0/50 (09 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (09				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								
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (09	0/ ₁)			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: 259

				Male			Female			
#Intestine Small: Jejunum: Adenoma										
	-	,	0%)		05 , 00/	+	0/50 (0%)		OD .00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma										
		,	6%)	••	05.00/		0/50 (0%)		00.00	
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Hemangiosarcoma		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%	
		, ,								
#Intestine Small: Jejunum: 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%	
#Intestine Small: Jejunum: Polyp Adenomatous										
		,	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 Adenoma	cified:	0/20								
Overall Institutes	Tatal	,	0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 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

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: 260

			Male				Female	
#Intestine Small: Site Unsp	pecified:							
Overall Incidence	Total	3/50 (6%)	%) Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp	pecified:							
Overall Incidence	Total	3/50 (6%)	%) Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma			0(1)			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 Unsp Leiomyosarcoma		0/50 (0 ⁴				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp					•••••			
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		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%

^{*:} 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: 261

			Male				Female			
*Islets, Pancreatic: 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%		
*Islets, Pancreatic: Carcinoma or Adenoma										
Occupation of the second	T-1-1	0/50 (0%)	Mara 2007	00.00/	T-1-1	0/50 (0%)	Maran 00/	OD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Adenoma		1/50 (00)				2(22)				
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 (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%		
*Kidney: Renal Tubule: Carcinoma or Adenoma										
Overall Incidence	Total	1/50 (2%)	Moon 20/	CD 00/	Total	0/50 (0%)	Maan OO/	CD 00/		
Overali incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Cholangiocarcinoma		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%		
Overali ilicidelice	ı ulaı	` '				0/50 (0%)		טט U%		

^{*:} 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: 262

			Male			Female			
*Liver: 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%	
*Liver: Hemangioma									
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: Hemangiosarcoma		1/50 (2%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 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%	
*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 Carcinoma		17/50 (34%)				6/50 (12%)			
Overall Incidence	Total	17/50 (34%)	Mean 34%	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

Page: 263

Report Date: 05/27/2022

Route: SKIN

Vehicle: ACETONE

			Male			Female			
*Liver: Hepatocellular Carcinoma o	or Hepatobla	astoma 18/50 (36%)				6/50 (12%)			
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%	
*Liver: Hepatocellular Carcinoma o	or Hepatocel								
Overall Incidence	Total	33/50 (66%) 33/50 (66%)	Mean 66%	SD 0%	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	
*Liver: Hepatocellular Carcinoma,						12/50 (24%)			
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	12/50 (24%)	Mean 24%	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%	
*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%	

^{*:} 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: 264

			Male			Female			
*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 Ade	enoma								
		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 Car	cinoma								
		7/50 (14%)				2/50 (4%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Lung: Alveolar/Bronchiolar Car						5/50 (10%)			
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
*Lung: 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%	
*Lung: Fibrous Histiocytoma		0/50 (00/)				0/50 (00/)			
Overall Institutes	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 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 Report Date: 05/27/2022

Page: 265

			Male			Female			
*Lung: Hemangiosarcoma									
Occupation and desires	T-1-1	0/50 (0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	Marana 00/	00.00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node: Fibrous Histiocytoma									
Occupation of desired	T-1-1	0/50 (0%)	Maran 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%	
#Lymph Node: Hemangiosarcoma		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%	
·······································		` '							
#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									
_		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, Mandibular: Fibrous Histiocytoma									
		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

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 266

			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%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: 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%
Overall incluence		0/50 (0%)	iviean 0%		ı Olai		Wearr 0%	3D 0%
#Mammary Gland: 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%
#Mammary 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%
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, or					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: ACETONE Page: 267

			Male				Female	
#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%
#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:	Total	0/50 (0%)	Weari 0%	SD 0%	Total	0/50 (0%)	iviean 0%	SD 0%
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%

^{*:} 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: 268

			Male				Female	
*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%
*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: Mast Cell Tumor Malign	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%
*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 o		nx, 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 Mucosa Squamous Cell Carcino		nx, Tooth, Gingiva):				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 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: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male			Female					
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%) Overall Incidence Total O(50 (0%) Near 0% SD 0% Total O(50 (0%) Near 0% SD 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										
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: Choriocarcinoma						0/50 (00/)					
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Cystadenoma						4/50 (20/)					
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Ovary: Fibrous Histiocytoma	•••••										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor B	enign					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

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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	Male		Female				
*Ovary: Granulosa Cell Tumor Malignant							
<u>-</u>			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
Overall Incidence		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%		
*Ovary: Leiomyosarcoma			0/50 (00/)				
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Luteoma							
			1/50 (2%)				
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%		
* Denominator is number of animals with tissues examined microscopically							

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

^{#:} Denominator is number of animals necropsied

*Ovary:

*Ovary:

*Pancreas: Carcinoma

*Pancreas:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Teratoma Benign

Tubulostromal Adenoma

.....

Carcinoma or Adenoma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Male

Route: SKIN Vehicle: ACETONE

Page: 271

Mean 0%

Mean 0%

0/50

0/50

0/50

0/50

0/50 (0%)

0/50 (0%)

0/50 (0%)

0/50 (0%)

Total

Total

Total

Total

(0%)

(0%)

(0%)

(0%)

Report Date: 05/27/2022

Female)	
Mean 0%	SD 0%	
Mean 0%	SD 0%	

SD 0%

SD 0%

*Pituitary Gland: Pars Distalis or Unspecified Site:
Adenoma

Total

Total

		0/50 (0%)				8/50 (16%)
Overall Incidence	Total	0/50 (0%)	Moon 0%	SD 0%	Total	9/50 (169/)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(0%)

Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%

*Pituitary Gland: Pars Distalis or Unspecified Site:

Carcinoma

0/50 (0%)

0/50 (0%)

0/50 (0%)

0/50 (0%)

0/50 (0%)

0/50 (0%)

Mean 0%

Mean 0%

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

SD 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: 05/27/2022 SKIN

Page: 272

			Male				Female		
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	is or Unspecif	ied Site:							
		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 Interm Adenoma	nedia:								
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma									
Overell Incidence	Tatal	1/50 (2%)	Mann 20/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Prostate: Carcinoma or Adenoma									
		0/50 (0%)							
Overall Incidence	Total	0/50 (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%	
		0/30 (0/8)				, ,			

^{*:} 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: 273

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%						
*Salivary Glands: Carcinoma or Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	(,	Mean 0%	SD 0%			
#Seminal Vesicle: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%							
#Skeletal Muscle: Hemangiosarcoma		0/50 (00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)									
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		1/50 (2%)		SD 0%			
#Skeletal Muscle: Rhabdomyosarcoma or											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	(,	Mean 2%	SD 0%			
#Skeletal Muscle: Sarcoma		0/50 (653)				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

Tumor Incidence for Selected Control Animal Groups

Report Date: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female		
#Skin:	_							,	
Basal Cell Adenoma of	r Basosquamous	•				0(50 (00()			
Occupation of the second	T-1-1	0/50 (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%	
#Skin:									
Basal Cell Adenoma, E	Basosquamous Tu	umor Benign, or Tricho	epithelioma						
·	•	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%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		0/30 (0 /6)			10tai	0/30 (0 /6)		30 0/0	
#Skin:									
Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant 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:	DI O-II A I	D							
NOS), or Trichoepithel	ioma	ma, Basosquamous Tu	ımor (benign, maiigna	ant or					
,		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#01-2									
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S		a, Basosq. Tumor (M or		ma,					
· ····································		0/50 (0%)	.1			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

SKIN

Page: 275

			Male			Female		
#Skin: Basosquamous Tumor E	3enign	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: Fibroma								
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: Fibroma, Fibrosarcoma,						1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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		•				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: 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%

^{*:} 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

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Report Date: 05/27/2022

Route: SKIN Vehicle: ACETONE

			Male				Female	
#Skin: 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%
		0/50 (0%)			10lai	0/50 (0%)		
#Skin: Hemangiosarcoma		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: Liposarcoma								
	-	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%
#Skin: 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%
#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%
#Skin: Neural Crest Tumor		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

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: 277

			Male				Female				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 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	chwannoma (benign, ma	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 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Schwannoma 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%			
#Skin: Squamous Cell Carcino	oma										
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: 278

Report Date: 05/27/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male				Female	
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (Carcinoma, Basosquamo	us Tumor (malignan	t 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: 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 Overall Incidence	or Papilloma Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 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,						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%)		05.00/		1/50 (2%)	••	05 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

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: 279

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% S 0/50 (0%) Total 0/50 (0%) Mean 0% S 0/50 (0%) Total 0/50 (0%) Mean 0% S			
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Spleen: Hemangioma		1/49 (2%)				0/50 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	` '	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		2/49 (4%)				` '		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: 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%

^{*:} 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: 280

				Male		2/50 (4%) Total 2/50 (4%) Mean 4% 2/50 (4%) Total 2/50 (4%) Mean 4% 0/50 (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												
1		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, Forestomach: Squamous Cell Papilloma		1/50	(2%)				2/50 (4%)					
Overall Incidence	Total	1/50 (2%)	(= / - /	Mean 2%	SD 0%	Total	` '	Mean 4%	SD 0%			
#Stomach, Glandular: Adenoma		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	` '	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%			
#Stomach, Glandular: Carcinoma or Adenoma		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%			

^{*:} 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

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Report Date: 05/27/2022

Route: SKIN

Vehicle: ACETONE

			Male				Female	
*Testes: Adenoma								
Overall Incidence	Total	0/50 (0%) 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,		3						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Malig		0/50 (0%)						
Overall Incidence	Total	0/50 (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	ınant, NOS	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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Manag

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

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Mean 2%

SD 0%

Report Date: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male Female *Thyroid 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% *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% *Thyroid Gland: C-Cell: 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% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total Mean 0% SD 0% 0/50 (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 1/50 (2%)1/50 (2%)

SD 0%

Total

1/50 (2%)

Total

1/50 (2%)

Mean 2%

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: SKIN Vehicle: ACETONE Page: 283

		M	ale		Total 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%) Mean 0% SD 0%			
	,	,			` ,			
Total	0/50 (0%)	Mean 09	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	`	,			` ,		00.00	
Total	0/50 (0%)	Mean 09	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (0)	0/ \			0/50 (0%)			
Total	,	,	6 SD 0%	Total	` '	Mean 0%	SD 0%	
	, ,					·····		
	0/50 (0	%)			0/50 (0%)			
Total	0/50 (0%)	Mean 09	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	s Squamous				0/50 /00/)			
Total	0/50 (0%)	,	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 /0	961			0/50 (0%)			
Total	`	,	% SD 0%	Total	` '	Mean 0%	SD 0%	
	Total or Papilloma	Total 0/50 (0%) 0/50 (0) Total 0/50 (0%) 0/50 (0) Total 0/50 (0%) Total 0/50 (0%) or Papilloma Squamous 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% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% or Papilloma Squamous 0/50 (0%) Total 0/50 (0%) Mean 0%	Total 0/50 (0%) Mean 0% SD 0% O/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total Total	O/50 (0%) Mean 0% SD 0% Total O/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%) Or Papilloma Squamous 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% 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

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for S

Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ACETONE

Length of Study: CHRONIC

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			Male			0/50 (0%) tal 0/50 (0%) Mean 0% SD 0% 0/50 (0%) tal 0/50 (0%) Mean 0% SD 0% 0/50 (0%) tal 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	` ,	Mean 0%	SD 0%
Jrinary Bladder: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%
Jrinary Bladder: Hemangiosarcoma		0/50 (0%)						
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
lterus: Adenoma verall Incidence					Total	` ,	Mean 0%	SD 0%
Jterus: Carcinoma								
verall Incidence					Total	0/50 (0%)		SD 0%
Uterus: Deciduoma Benign								
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: 285

	Male			Female	
#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			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
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%

^{*:} 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: 286

			Male	Female				
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Schwannoma Malignant		•••••						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma	1					(201)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: 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%
#Zymbal's 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%

^{*:} 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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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	059700308	06/25/02	730	50(1)	34(702)	54.2	1,2-Dibromo-2,4-dicyanobutane		
Southern Research Institute	059302008	05/08/00	729	50(1)	39(710)	52.6	Diisopropylcarbodiimide		
Female									
Battelle Columbus Laboratory	059700308	06/24/02	729	50(1)	33(693)	60.9	1,2-Dibromo-2,4-dicyanobutane		
Southern Research Institute	059302008	05/08/00	732	50(1)	33(674)	65.7	Diisopropylcarbodiimide		

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 05/27/2022

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

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors Overall Incidence	Total	40/50 (80%) 69/100 (69%)	29/50 (58%) Mean 69%	SD 15.56%	Total	39/50 (78%) 74/100 (74%)	35/50 (70%) Mean 74%	SD 5.66%
#All Organs: Malignant Tumors Overall Incidence	Total	27/50 (54%) 54/100 (54%)	27/50 (54%) Mean 54%	SD 0%	Total	31/50 (62%) 57/100 (57%)	26/50 (52%) Mean 57%	SD 7.07%
#All Organs: Malignant and Benign To	umors Total	45/50 (90%) 87/100 (87%)	42/50 (84%) Mean 87%	SD 4.24%	Total	46/50 (92%) 93/100 (93%)	47/50 (94%) Mean 93%	SD 1.41%
#All Organs: Hemangioma Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#All Organs: Hemangiosarcoma Overall Incidence	Total	6/50 (12%) 6/100 (6%)	0/50 (0%) Mean 6%	SD 8.49%	Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%
#All Organs: Hemangiosarcoma or He	emangioma Total	6/50 (12%) 7/100 (7%)	1/50 (2%) Mean 7%	SD 7.07%	Total	1/50 (2%) 7/100 (7%)	6/50 (12%) Mean 7%	SD 7.07%

^{*:} 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: 289 Report Date: 05/27/2022

	Male					14/50 (28%) 10/50 (20%) Total 24/100 (24%) Mean 24% SD 5. 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD			Female			
#All Organs: Histiocytic Sarcoma												
		0/50 (0%)	1/50 (2%)			1/50 (2%)	3/50 (6%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 2.83%				
#All Organs: Malignant Lymphoma: His	tiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cel	II Type								
		1/50 (2%)	2/50 (4%)			14/50 (28%)	10/50 (20%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	24/100 (24%)	Mean 24%	SD 5.66%				
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS	; 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 0%				
All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%				
#All Organs: Osteoma				•••••				•••••				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
All Organs: Osteosarcoma							- 1					
		0/50 (0%)	0/50 (0%)	05 00/		1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Contract/Lab: All Laboratories

boratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Route: SKIN Vehicle: ETHANOL Page: 290

			Male				Female	
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Adrenal Cortex:								
		6/50 (12%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign								
		0/50 (0%)	0/49 (0%)			2/50 (4%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2%	SD 2.83%
*Adrenal Medulla: Pheochromocytoma Comple	ex							
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maligna	ant							
		1/50 (2%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/99 (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: 291

			Male				Female	
*Adrenal Medulla: Pheochromocytoma: Benigi	n, Complex		0/49 (0%)			2/50 /49/\	0/49 (0%)	
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	Mean 1%	SD 1.41%	Total	2/50 (4%) 2/99 (2.02%)	Mean 2%	SD 2.83%
*Bone Marrow: Hemangiosarcoma		1/50 (2%)	0/49 (0%)			0/50 (0%)	1/49 (2%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 292

			Male	Male Female				
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma						0/50 (00/)	0/40 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0.50 (00.1)	0/50 (001)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (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: SKIN Vehicle: ETHANOL Page: 293

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/46 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma		0(50 (00()	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Eye: Sarcoma		0/50 (00/)	4/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	1/50 (2%) Mean 1%	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	1/100 (1%)	iviean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/40 /00/	0/45 (00/)			0/50 (00/)	0/40 /00/	
Overall Incidence	Total	0/49 (0%) 0/94 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/92 (0%)	0/42 (0%) Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		7/50 (14%)	9/50 (18%)			6/50 (12%)	9/50 (18%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	15/100 (15%)	Mean 15%	SD 4.24%
#Harderian Gland: Carcinoma								
	.	0/50 (0%)	2/50 (4%)	00.000/		2/50 (4%)	1/50 (2%)	00 4 440/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%

^{*:} 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: 294

		Male				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD			Female			
#Harderian Gland: Carcinoma or Adenoma												
		7/50 (14%)	10/50 (20%)			8/50 (16%)	10/50 (20%)					
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 4.24%	Total	18/100 (18%)	Mean 18%	SD 2.83%				
*Heart: Hemangioma												
		0/50 (0%)	0/50 (0%)			` '	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Heart: Hemangiosarcoma												
		0/50 (0%)	0/50 (0%)			` ,	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				SD 0%				
*Heart: Sarcoma												
		0/50 (0%)	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` ,		SD 0%				
#Intestine Large: Cecum: Carcinoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Large: Cecum: Carcinoma or Adenoma			0/50 /02/			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} 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: 295

			Male	Male Female				
#Intestine Large: Cecum: Leiomyosarcoma								
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
	.	0/50 (0%)	1/50 (2%)	05 4 440/	T	0/50 (0%)	1/50 (2%)	00 4 4407
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Duodenum: Carcinoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	Tatal	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
	.	0/50 (0%)	0/50 (0%)	00.00/	+	0/50 (0%)	0/50 (0%)	OD .00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 296

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD			Female			
#Intestine Small: Jejunum: Adenoma											
		0/50 (0%)	0/50 (0%)			` '	,				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '		SD 0%			
#Intestine Small: Jejunum: Carcinoma											
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%			
Overali incidence	notai	0/100 (0%)		SD 0%		0/100 (0%)	wiean 0%	2D 0%			
#Intestine Small: Jejunum: Hemangiosarcoma											
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	` '	CD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	wiean 0%	SD 0%			
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%			
#Intestine Small: Jejunum: Polyp Adenomatous											
		0/50 (0%)	0/50 (0%)			` '	` '				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Intestine Small: Site Unspec Adenoma											
		0/50 (0%)	1/50 (2%)	05		0/50 (0%)	1/50 (2%)	00 4 4404			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 297

			Male				Female	
#Intestine Small: Site Unsp Carcinoma	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma								
Overell In aldenses	Tatal	0/50 (0%)	1/50 (2%)	CD 4 440/	Tatal	0/50 (0%)	1/50 (2%) Mean 1%	CD 4 440/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp								
• •		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0.00						
Owner III be add a see	T-1-1	0/50 (0%)	1/49 (2%)	00 4 440/	T-1-1	1/50 (2%)	0/50 (0%)	00 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 298

Report Date: 05/27/2022

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

		Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1 0/50 (0%) 0/49 (0%) Total 0/99 (0%) Mean 0% SD 0/50 (0%) 0/49 (0%) Total 0/99 (0%) Mean 0% SD		
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%)			` '	(/	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
	.	0/50 (0%)	1/49 (2%)	05 4 440/	T	` '	` ,	00 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	l otal	1/100 (1%)	Mean 1%	SD 1.41%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/48 (0%)			` '	` ,	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/48 (0%)			` '	` ,	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma	•							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 299

			Male Female				1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% SD 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1 31/50 (62%) 21/50 (42%)		
*Liver: Fibrous Histiocytoma									
	.	0/50 (0%)	0/50 (0%)	OD 00/		` '	` ,	00.4.440/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	I otal	1/100 (1%)	Mean 1%	SD 1.41%	
*Liver: Hemangioma									
		0/50 (0%)	0/50 (0%)			` ,	` ,		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Hemangiosarcoma		4/50 (00/)	0/50 (00/)			4/50 (001)	(00)		
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` ,	, ,	SD 0%	
Overall incidence		1/100 (1%)	wiean 1%	3D 1.41%	10tai	2/100 (2%)	wiean 2%	3D 0%	
*Liver: Hepatoblastoma		0/50 (40/)	0/50 (00/)			4/50 (00/)	0/50 (00/)		
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%		1/100 (1%)	Mean 1%	SD 1.41%	
*Liver: Hepatocellular Adenoma									
		35/50 (70%)	18/50 (36%)			, ,	, ,		
Overall Incidence	Total	53/100 (53%)	Mean 53%	SD 24.04%	Total	52/100 (52%)	Mean 52%	SD 14.14%	
*Liver: Hepatocellular Carcinoma						0/50 (100)	(0.00)		
Overell Insidence	Tatal	17/50 (34%)	20/50 (40%)	CD 4 040/	Tatal	8/50 (16%)	10/50 (20%)	CD 0.000/	
Overall Incidence	Total	37/100 (37%)	Mean 37%	SD 4.24%	Total	18/100 (18%)	Mean 18%	SD 2.83%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 300

		Male Female				9/50 (18%) 10/50 (20%) Total 19/100 (19%) Mean 19% SD 1.4 32/50 (64%) 29/50 (58%) Total 61/100 (61%) Mean 61% SD 4.2 32/50 (64%) 29/50 (58%) Total 61/100 (61%) Mean 61% SD 4.2 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 00		
*Liver: Hepatocellular Carcino	oma or Hepatoble	astoma						
•	·	19/50 (38%)	20/50 (40%)			9/50 (18%)	10/50 (20%)	
Overall Incidence	Total	39/100 (39%)	Mean 39%	SD 1.41%		` ,		SD 1.41%
Liver: Hepatocellular Carcino								
		41/50 (82%)	35/50 (70%)			32/50 (64%)	29/50 (58%)	
Overall Incidence	Total	76/100 (76%)	Mean 76%	SD 8.49%	Total	` '	` '	SD 4.24%
*Liver: Hepatocellular Carcino Overall Incidence	ma, Hepatocellu Total	ılar Adenoma, or Hepatob 41/50 (82%) 76/100 (76%)	olastoma 35/50 (70%) Mean 76%	SD 8.49%	Total	` ,	` '	SD 4.24%
*Liver: Hepatocholangiocarcir	noma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Maligna								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver:								
Sarcoma			0/=0 (00/)			0/50 (0%)	0/50 (0%)	
Sarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/30 (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: 301

			Male				Female	
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ade	enoma							
		10/50 (20%)	6/50 (12%)			2/50 (4%)	4/50 (8%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 5.66%	Total	6/100 (6%)	Mean 6%	SD 2.83%
*Lung: Alveolar/Bronchiolar Car	cinoma	0/50 (4004)	0/50 (40)			0/50 (00)	0/50 (00/)	
		6/50 (12%)	2/50 (4%)	05		3/50 (6%)	0/50 (0%)	05 4 5 404
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 5.66%	Total	3/100 (3%)	Mean 3%	SD 4.24%
*Lung: Alveolar/Bronchiolar Care	cinoma or Alv	reolar/Bronchiolar Adenor	ma					
		15/50 (30%)	8/50 (16%)			5/50 (10%)	4/50 (8%)	
Overall Incidence	Total	23/100 (23%)	Mean 23%	SD 9.9%	Total	9/100 (9%)	Mean 9%	SD 1.41%
*Lung: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma		0/50 (/0//)	0/50 (00)			4/50 /20/	0/50 (00/)	
Overell lesidenes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 302

			Male				Female	
*Lung: Hemangiosarcoma		2(20)	2/72 (224)			2/52 (224)	2/22 (224)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0D 00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		- (ac)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

^{*:} 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: 303

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Lymph Node, Mesenteric: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Mammary Gland: Carcinoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Mammary Gland: Carcinoma or Adenoma		•••••						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma						
,	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 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: SKIN Vehicle: ETHANOL Page: 304

			Male				Female	
#Mesentery: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma		0/50 (00/)				0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (00/)	0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} 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: 305

			Male				Female	
*Nose: Carcinoma								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Nose: Hemangioma								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malig	nant	0/50 (09/)	0/40 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10tai	0/99 (0/6)						
Nose: Sarcoma		0/50 (00/)	0/40 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Oral Cavity (Oral Mucos) Papilloma Squamous o		ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos	sa, Tongue, Phar							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

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: 306

			Male				Female	
#Oral Cavity (Oral Mucosa Squamous Cell Carcino			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma								
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Cystadenoma						3/50 (6%)	1/49 (2%)	
Overall Incidence					Total	4/99 (4.04%)	Mean 4.02%	SD 2.8%
*Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor B	enign					0/50 (00/)	4/40 (20/)	
Overall Incidence					Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%

^{*:} 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

Page: 307

	Male			Female	
*Ovary: Granulosa Cell Tumor Malignant			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
*Ovary: Hemangioma			0/50 (00/)	0/40 (/00/)	
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Hemangiosarcoma			0/50 (0%)	1/49 (2%)	
Overall Incidence		Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Ovary: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1/N

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 308

			Male				Female	
*Ovary: Teratoma Benign						0/50 (00)	0/40 (/00/)	
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	5/50 (10%) 9/98 (9.18%)	4/48 (8%) Mean 9.17%	SD 1.18%
*Pituitary Gland: Pars Distal Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/98 (1.02%)	1/48 (2%) Mean 1.04%	SD 1.47%

^{*:} 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: 309

			Male				Female	
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	is or Unspeci	fied Site:						
		0/50 (0%)	0/48 (0%)			5/50 (10%)	5/48 (10%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	10/98 (10.2%)	Mean 10.21%	SD 0.29%
*Pituitary Gland: Pars Interm Adenoma								
		0/50 (0%)	0/48 (0%)			1/50 (2%)	0/48 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma								
O	T-1-1	0/50 (0%)	0/48 (0%)	00.00/	T-1-1	1/50 (2%)	0/48 (0%)	00 4 440/
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
*Prostate: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma						0/50 /00/	0/50 (0%)	
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 310

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skeletal Muscle: Hemangiosarcoma		- (ac)					(00)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Ri								
•	-	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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: 05/27/2022

Page: 311

Species: MICE Strain: B6C3F1/N

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor Benign						
	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba	sosquamous T	umor Benign, or Trichoep	oithelioma					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma or	[.] Basosquamou	s Tumor (malignant or No	OS) 0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelic		oma, Basosquamous Tun	nor (benign, malignan	it or		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
		a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%)		a,		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

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: 312

			Male				Female	
#Skin: Basosquamous Tumor	Benign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma								
Occupation of decree	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fil 0/50 (0%) 1/100 (1%)	brous Histiocytoma 1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:		, or Fibrous Histiocytoma				1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
Overall incidence								
#Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			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: SKIN Vehicle: ETHANOL Page: 313

		Male				Female		
	0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%	
	2/50 (4%)	0/50 (0%)			0/50 (0%)	2/50 (4%)		
Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%	
	- (aa)	- ()			2(-2)	- ((((((((((
T-1-1		` '	OD 00/	T-1-1	` ,	` '	OD 00/	
ıotaı	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	Mean U%	SD 0%	
:	0/50 (00)	0(50 (00))			0/50 (001)	0/50 (00/)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (09/)	0/50 (0%)			0/50 (09/)	0/50 (09/)		
Total	,	` '	SD 0%	Total	` '	, ,	SD 0%	
	Total Total Total	Total 0/100 (0%) 2/50 (4%) Total 2/100 (2%) 0/50 (0%) Total 0/100 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%	O/50 (0%) O/50 (0%) Total 0/100 (0%) Mean 0% SD 0% 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) SD 0% Total 2/50 (4%) 0/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total 2/100 (2%) Total 2/50 (4%) O/50 (0%) D/50 (0%) O/50 (0%) O/50 (0%) Total 2/100 (2%) Mean 2% SD 2.83% Total 2/100 (2%) O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%) Total O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%) Total O/50 (0%) O/50 (0%) SD 0% Total O/100 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) D/50 (0%) D/50 (0%) D/50 (0%) D/50 (4%) D/50 (4%) D/50 (4%) Mean 2% Mean 2% D/50 (0%) D/50 (4%) Mean 2% D/50 (0%) D/50 (4%) D/50 (4%) Mean 2% D/50 (0%) D/50 (4%) Mean 2% D/50 (0%) D/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: SKIN Vehicle: ETHANOL Page: 314 Report Date: 05/27/2022

			Male				Female					
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)												
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skin: Neurofibrosarcoma, Neurof												
Neuronbrosarcoma, Neuron	ibioilia, or s	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skin: Osteosarcoma		0/50 (00/)	0/50 (00/)			0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
	10lai	0/100 (0/8)		30 0/6	ı Olai		iviean 070					
#Skin: Sarcoma		0/50 (00/)	0/50 (00/)			4/50 (00()	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Skin: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skin: Squamous Cell Carcinoma		0/50 (00/)	0/50 /00/			0/50 (00/)	0/50 (00()					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
Overall incluence	างเลเ	0/100 (0%)	Mean 0%	SD 0%	างเลเ	0/100 (0%)	Mean 0%	SD 0%				

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 315

Mean 0%

SD 0%

Report Date: 05/27/2022

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 0/50 1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Squamous Cell Papilloma or Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% 0/100 (0%) Overall Incidence Total 0/100 (0%) SD 0% Total Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% **#Skin: Sebaceous Gland:** Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/100 (0%)

Total

0/100 (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: SKIN Vehicle: ETHANOL Page: 316

			Male				Female			
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Spinal Cord: Meningioma Malignant										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
					10tai					
*Spleen: Fibrous Histiocytoma		0/50 (00/)	0/40 (00/)			4/50 (00)	0/40 /00/			
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%		
······										
*Spleen: Hemangioma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma										
_		1/50 (2%)	0/49 (0%)			0/50 (0%)	1/49 (2%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%		
#Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (00/)	0/50 /05()			0/50 (00)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%		
Overall incidence	Total	0/100 (0%)	Mean 0%	3D 0%	างเลเ	0/100 (0%)	Mean 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: SKIN Vehicle: ETHANOL **Page:** 317

tal 0	0/50 (0%)	0/50 (0%)					,
tal 0	` '	0/50 (00/)					
tal 0		` '			0/50 (0%)	0/50 (0%)	
	/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	1/50 (2%)			1/50 (2%)	1/50 (2%)	
tal 1	/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
	0/50 (0%)	1/50 (2%)			1/50 (2%)	1/50 (2%)	
tal 1	` ,	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
					0/50 (001)	0/50 (00/)	
tal 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%)			0/50 (0%)	0/50 (0%)	
tal 0	/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (09/)	0/50 (0%)			0/50 /00/	0/50 /00/)	
tal 0	` ,	` '	SD 00/	Total	` '	` '	SD 0%
ta -	al 1	al 1/100 (1%) 0/50 (0%) al 1/100 (1%) 0/50 (0%) al 0/100 (0%) 0/50 (0%) al 0/100 (0%)	0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% 0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0%	0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0%	0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0% Total	0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% Total 2/100 (2%) 0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% Total 2/100 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 2/100 (2%) 0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%)	0/50 (0%) 1/50 (2%) 1/50 (

^{*:} 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: 05/27/2022

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Male **Female** *Testes: Adenoma 2/50 (4%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% *Testes: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Testes: Seratoli Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Testes: **Sertoli Cell Tumor Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% *Thymus: **Thymoma Malignant** 1/47 (2%)0/47 (0%)1/47 (2%)0/46 (0%)1/93 (1.08%) **Overall Incidence** Total 1/94 (1.06%) Mean 1.06% SD 1.5% Total Mean 1.06% SD 1.5% *Thymus: Thymoma: Benign, Malignant, NOS 1/47 (2%)0/47 (0%)1/47 (2%)0/46 (0%)**Overall Incidence** Mean 1.06% SD 1.5% 1/93 (1.08%) Mean 1.06% SD 1.5% Total 1/94 (1.06%) 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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 319

			Male				Female	
*Thyroid Gland: Adenoma								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
	-	0/50 (0%)	0/49 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (00/)	0/40 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,				0/100 (0 /8)		
*Thyroid Gland: Follicular Cell Adenoma	i:							
	-	0/50 (0%)	0/49 (0%)	00.00/	-	0/50 (0%)	3/50 (6%)	00 4 0 407
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
*Thyroid Gland: Follicular Cell Carcinoma	l:							
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%

^{*:} 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: 320 Report Date: 05/27/2022

			Male				Female	
#Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (001)	0/50 (00)			0/50 (001)	0/50 (00)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
•	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 321

			Male				Female	
#Tooth: Odontoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Mana

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: 322

	Male			Female	
#Uterus: Hemangioma			0/50 (0%)	0/50 (00()	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 323

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma						0/50 (0%)	0/50 (00/)	
Overall Incidence					Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied