

# NTP Historical Controls Report

By Route and Vehicle

**MICE** 

October 2022

# REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

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	M3	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

# **Table of Contents**

Route	Vehicle	Page Number		
GAVAGE	METHYLCELLULOSE	4		
INHALATION	AIR	34		
ORAL	FEED	64		
ORAL	WATER	94		
Whole Body Exposure	AIR	124		

Contract/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: 4
Report Date: 11/18/2022

## **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	050005804 052032306	N/A 05/22/12	N/A 730	0(0) 50(1)	0(0) 35(698)	N/A 52.5	Black Cohosh Resveratrol			
	Female									
Battelle Columbus Laboratory Battelle Columbus Laboratory	050005804 052032306	04/09/12 05/21/12	729 729	50(4) 50(4)	40(703) 44(716)	58.8 58.8	Black Cohosh Resveratrol			

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

Page: 5

			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	33/50 (66%)	33/50 (66%) Mean 66%	SD 0%	Total	15/50 (30%) 32/100 (32%)	17/50 (34%) Mean 32%	SD 2.83%
#All Organs: Malignant Tumors								
Overall Incidence	Total	24/50 (48%)	24/50 (48%) Mean 48%	SD 0%	Total	22/50 (44%) 40/100 (40%)	18/50 (36%) Mean 40%	SD 5.66%
#All Organs: Malignant and Benign T	umors		41/50 (82%)			24/50 (629/)	27/50 (549/)	
Overall Incidence	Total	41/50 (82%)	Mean 82%	SD 0%	Total	31/50 (62%) 58/100 (58%)	27/50 (54%) Mean 58%	SD 5.66%
#All Organs: Hemangioma			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
All Organs: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%)	3/50 (6%) Mean 6%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#All Organs: Hemangiosarcoma or H	emangioma							
Overall Incidence	Total	3/50 (6%)	3/50 (6%) Mean 6%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 6

			Male				Female				
#All Organs: Histiocytic Sarcoma  1/50 (2%) 2/50 (4%) 2/50 (4%)											
			1/50 (2%)			2/50 (4%)	2/50 (4%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 0%			
#All Organs: Leukemia: Lymphocytic, Me			entiated								
			0/50 (0%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
Malignant Lymphoma: Histi Overall Incidence	Total	7/50 (14%)	7/50 (14%) Mean 14%	SD 0%	Total	10/50 (20%) 19/100 (19%)	9/50 (18%) Mean 19%	SD 1.41%			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	19/100 (19%)	Mean 19%	SD 1.41%			
#All Organs:		, ,									
		, ,									
#All Organs: Malignant Schwannoma		, ,		SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#All Organs:			0/50 (0%)			0/50 (0%) 0/100 (0%)	0/50 (0%)				
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma	Total	0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%			
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma			0/50 (0%) Mean 0%			0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%				
#All Organs: Malignant Schwannoma Overall Incidence #All Organs:	Total Total	0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%			
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma  Overall Incidence  #All Organs:	Total Total	0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 7

			Male				Female	
*Adrenal Cortex: Adenoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benig	gn		0/50 (004)			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malig	nant		4/50 (20/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Beni			1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Mast Cell Tumor Malignan	t		0/50 (000)			0/50 (00)	0/50 (00%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 8

			Male				Female	
#Bone: Hemangioma			0/50 (0%)		0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma								
Overall Incidence	Total	0/50 (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 (00/)			4/50 (20/)	0/50 (00/)	
Overall Incidence	Total	0/50 (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%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Brain: Meningioma: Benign, Mali	gnant, NOS		0/50 (00)			4/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page**: 9

			Male				Female	
*Clitoral/Preputial Gland: Mast Cell Tumor			0/50 (051)			0/50 (00)	0140 (001)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Epididymis: Mast Cell Tumor								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Harderian Gland: Adenoma								
Overall Incidence	Total	6/50 (12%)	6/50 (12%) Mean 12%	SD 0%	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%
#Harderian Gland: Carcinoma			2/50 (4%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	8/50 (16%)	8/50 (16%) Mean 16%	SD 0%	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%
#Harderian Gland: Mast Cell Tumor								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

act/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 10

			Male				Female		
#Intestine Small: Duodenum: Adenoma									
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
		()	wean 0%	SD 0%	ı olal	(1%)	wean 1%	3D 1.41%	
#Intestine Small: Duodenum: Carcinoma			(201)			2/20 (201)	2/22 (22/)		
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
		` '				` '			
#Intestine Small: Ileum: Adenoma									
		0.170 (001)	0/50 (0%)	<b>OD</b> 00/		0/50 (0%)	0/50 (0%)	05 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Adenoma									
			1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma									
			0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Mast Cell Tumor									
			0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 11

			Male				Female					
#Intestine Small: Site Unspecified: Adenoma  1/50 (2%)  0/50 (0%)  1/50 (2%)												
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Intestine Small: Site Uns Carcinoma	specified:											
Overall Incidence	Total	0/50 (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 Uns Carcinoma or Adenoma	•											
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Intestine Small: Site Uns Mast Cell Tumor			0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Islets, Pancreatic: Adenoma												
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%				
*Islets, Pancreatic: Carcinoma												
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 12

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma	Total	0/50 (00/)	0/50 (0%)	SD 09/	Total	0/50 (0%)	0/49 (0%)	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mast Cell Tumor			0/50 (0%)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Renal Mesenchymal Tumor			0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE

Route: GAVAGE

**Page:** 13

Report Date: 11/18/2022

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

		Male				Female	
		0/50 (09/)			0/50 (09/)	0/50 (09/)	
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Total	25/50 (50%)	25/50 (50%) Mean 50%	SD 0%	Total	6/50 (12%) 14/100 (14%)	8/50 (16%) Mean 14%	SD 2.83%
						•••••	
Total	7/50 (14%)	7/50 (14%) Mean 14%	SD 0%	Total	3/50 (6%) 6/100 (6%)	3/50 (6%) Mean 6%	SD 0%
	Total  Total  Total	Total 0/50 (0%)  Total 1/50 (2%)  Total 1/50 (2%)  Total 25/50 (50%)	Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  Total 1/50 (2%) Mean 2%  Total 1/50 (2%) Mean 2%  Total 1/50 (2%) Mean 2%  Total 25/50 (50%) Mean 50%  Total 25/50 (50%) Mean 50%	Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 1/50 (2%) Mean 2% SD 0%  Total 1/50 (2%) Mean 2% SD 0%  Total 1/50 (50%) Mean 2% SD 0%  Total 25/50 (50%) SD 0%	Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         1/50 (2%)         SD 0%         Total           Total         25/50 (50%)         Mean 2%         SD 0%         Total           Total         25/50 (50%)         Mean 50%         SD 0%         Total	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         0/100 (0%)           Total         1/50 (2%)         SD 0%         Total         0/100 (0%)           Total         25/50 (50%)         SD 0%         Total         14/100 (14%)           7/50 (14%)         SD 0%         Total         14/100 (14%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Mean 0%  Total 25/50 (50%) Mean 50% SD 0% Total 14/100 (14%) Mean 14%  Total 25/50 (50%) Mean 50% SD 0% Total 14/100 (14%) Mean 14%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Page: 14

Report Date: 11/18/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
*Liver: Hepatocellular Carcinor	na or Hepatobla	astoma						
			8/50 (16%)			3/50 (6%)	3/50 (6%)	
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 0%
*Liver: Hepatocellular Carcinor	na or Hepatoce	Ilular Adenoma						
•	•		29/50 (58%)			8/50 (16%)	9/50 (18%)	
Overall Incidence	Total	29/50 (58%)	Mean 58%	SD 0%	Total	17/100 (17%)	Mean 17%	SD 1.41%
*Liver: Hepatocellular Carcinor	na, Hepatocellu	lar Adenoma, or Hepat	oblastoma 30/50 (60%)			8/50 (16%)	9/50 (18%)	
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	17/100 (17%)	Mean 17%	SD 1.41%
*Liver: Hepatocholangiocarcine			2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign			(00)				2/22 (221)	
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	1 Ulai	1/50 (2/0)	IVICALI Z/0	3D 0/0	ı Ulal			
*Liver: Mast Cell Tumor			0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		5,55 (5,5)				-,		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page:** 15

			Male				Female	
*Lung: Alveolar/Bronchiolar Ad	enoma							
Overall Incidence	Total	8/50 (16%)	8/50 (16%) Mean 16%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca								
Aiveolai/Biolicillolai Ga	Tellionia		4/50 (8%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
Lung: Alveolar/Bronchiolar Ca						2/50 (4%)	4/50 (8%)	
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%
Lung: Hemangiosarcoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Mast Cell Tumor			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/50 (00/)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 16

			Male				Female	
#Lymph Node: Mast Cell Tumor			0/50 (0%)			0/50 (09/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Axillary: Hemangioma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor			0/50 (00)			0/50 /00/	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Mast Cell Tumor			0/50 /00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 17

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 18

Report Date: 11/18/2022

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Mesentery: Hemangioma								
			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma								
			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Polyp	•••••							
		- / / /	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 19

			Male				Female	
#Oral Cavity (Oral Mucos Papilloma Squamous o		/nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		/nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Oral Cavity (Oral Mucos Squamous Cell Carcin Overall Incidence			<b>a</b> 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Carcin	noma		0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Ovary: Cystadenoma		•••••						•••••
Overall Incidence					Total	2/49 (4%) 5/98 (5.1%)	3/49 (6%) Mean 5.1%	SD 1.44%
*Ovary:	Benian							
Granulosa Cell Tumor	• 5					0/49 (0%)	0/49 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

**Page:** 20

	Male		Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			(201)	
Overall Incidence	То		(0%) 0/49 (0%) ) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant		0/49	(0%) 0/49 (0%)	
Overall Incidence	То			SD 0%
*Ovary: Hemangioma		0/49	(0%) 0/49 (0%)	
Overall Incidence	То		` ,	SD 0%
*Ovary: Hemangiosarcoma		0/49	(0%) 0/49 (0%)	
Overall Incidence	То		` ,	SD 0%
*Ovary: Luteoma				
Overall Incidence	То		(0%) 0/49 (0%) ) Mean 0%	SD 0%
*Ovary: Thecoma Benign		0/49	(09/) 0/40 (09/)	
Overall Incidence	То		(0%) 0/49 (0%) ) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 21

			Male				Female	
*Ovary: Thecoma Malignant						0/40 //00/	0/40 (00%)	
Overall Incidence					Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/49 (0%) 1/98 (1.02%)	1/49 (2%) Mean 1.02%	SD 1.44%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Mast Cell Tumor			2/52 (224)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Carcinoma	••••••							
Overall Incidence	Total	0/40 (0%)	0/40 (0%) Mean 0%	SD 0%	Total	0/41 (0%) 0/78 (0%)	0/37 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma						, ,		
Overall Incidence	Total	0/48 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	2/49 (4%) 5/96 (5.21%)	3/47 (6%) Mean 5.23%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 22

			Male				Female	
*Pituitary Gland: Pars Dist Carcinoma or Adenoma		fied Site:						
Overall Incidence	Total	0/48 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	2/49 (4%) 5/96 (5.21%)	3/47 (6%) Mean 5.23%	SD 1.63%
*Pituitary Gland: Pars Intel								
Overall Incidence	Total	0/48 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Intel Carcinoma or Adenoma			0/48 (0%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intel Schwannoma Malignant	rmedia:		0/48 (0%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Prostate: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%				
*Prostate: Mast Cell Tumor			0/50 /00/					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 23

			Male				Female	
*Salivary Glands: Carcinoma				,				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Mast Cell Tumor			0/50 (0%)			0/50 (0%)	0/50 /09/	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Fibroma Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma	•••••		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Osteosarcoma			0/50 (00/)			0/50 (09/)	0/50 /09/	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 24

			Male				Female					
#Skeletal Muscle: Rhabdomyosarcoma  0/50 (0%)  1/50 (2%)  1/50 (2%)												
			` '			` ,	` '					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma											
			0/50 (0%)			1/50 (2%)	1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Sarcoma			0/50 (0%)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma			1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma or		Tumor Benign										
			1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma, Ba	asosquamous Tu	umor Benign, or Tricho	=			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page:** 25

			Male				Female					
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma												
,			1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S			•	a,								
	<b></b>	4/50 (00/)	1/50 (2%)	OD 00/	<b>.</b>	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Fibroma						2/-2 (221)	-((					
			0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, Ma	alignant Fibrous Histioc 0/50 (0%) Mean 0%	ytoma, or SD 0%	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%				
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or	Malignant Fibrous Histi 0/50 (0%)	ocytoma		1/50 (2%)	2/50 (4%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%				
#Skin: Fibrosarcoma			0/50 (0%)			0/50 (09/)	4/50 (20()					
O	Tarak	0/50 (00/)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 26

			Male				Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  0/50 (0%)  1/50 (2%)  2/50 (4%)												
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%				
#Skin: Hemangioma			0/50 (00/)			0(50 (00))	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Hemangiosarcoma			(00)			(20)	(20)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
#Skin: Lipoma			0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Liposarcoma			2(22)			2(22)	2/52 (224)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Malignant Fibrous Histi	ocytoma		0/50 (0%)			0/50 (00/)	4/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page:** 27

			Male				Female	
#Skin: Melanoma NOS								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Osteosarcoma	•••••							
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Pilomatrixoma			0/50 (0%)			0/50 /00/	0/50 /00/	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 28

			Male				Female	
#Spinal Cord: Schwannoma Malignant			2(20)			27-2 (201)	0.50	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Hemangiosarcoma			1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Mast Cell Tumor Malignant			0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma			1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma						0/50 (00)	0/50 /00/	
Overall Incidence	Total	1/50 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Adenoma			0/50 (00)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 29

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Testis: Adenoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Testis: Hemangioma			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Thymus: Hemangiosarcoma			0/41 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/41 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/41 (0%)	0/41 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page:** 30

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Adenoma	l:							
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
'Thyroid Gland: Follicular Cell Carcinoma	:: :							
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tongue: Squamous Cell Carcinoma c								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

**Page:** 31

			Male				Female	
#Tooth: Odontoma		0.150 (001)	0/50 (0%)	0D 00/		0/50 (0%)	0/50 (0%)	OD 004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Mast Cell Tumor			0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenocarcinoma or Ad	lenoma					0/50 (0%)	0/50 (0%)	
Overall Incidence					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: Fibroma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Be	enign							
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Report Date: 11/18/2022

**Page:** 32

	Male			Female	
#Uterus: Hemangioma			4/50 (00)	0/50 (00/)	
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyoma			0/50 (004)	0/50 (004)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal			1/50 (2%)	0/50 (0%)	
Overall Incidence		Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Sarcoma					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 33

	Male			Female	
#Vagina: Hemangioma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 34

Report Date: 11/18/2022

## **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	051047204	01/31/11	729	50(5)	40(705)	52.7	p-Chloro-a,a,a-trifluorotoluene
					Female		
Battelle Northwest	051047204	01/31/11	731	50(5)	38(700)	55.9	p-Chloro-a,a,a-trifluorotoluene

#### **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:** 35

		Male		Female				
Total	( )	Moon 64%	SD 0%	Total	` '	Moon 48%	SD 0%	
10lal	32/30 (04%)		3D 0%	10tai	24/50 (46%)	Wiedii 40%		
	25/50 (50%)				24/50 (48%)			
Total	25/50 (50%)	Mean 50%	SD 0%	Total	24/50 (48%)	Mean 48%	SD 0%	
umors	44/50 (88%)				38/50 (76%)			
Total	44/50 (88%)	Mean 88%	SD 0%	Total	38/50 (76%)	Mean 76%	SD 0%	
					0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	2/50 (4%)				3/50 (6%)			
Total	2/50 (4%)	Mean 4%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
emangioma	2/50 (40/)				2/50 /69/\			
Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	
	Total  Total  Total  emangioma	25/50 (50%) Total 25/50 (50%)  umors  44/50 (88%) Total 44/50 (88%)  0/50 (0%) Total 0/50 (0%)  Total 2/50 (4%)  Total 2/50 (4%)  emangioma  2/50 (4%)	32/50 (64%) Total 32/50 (64%) Mean 64%  25/50 (50%) Total 25/50 (50%) Mean 50%  umors  44/50 (88%) Total 44/50 (88%) Mean 88%  7 total 0/50 (0%) Total 0/50 (0%) Mean 0%  2/50 (4%) Total 2/50 (4%)  Total 2/50 (4%)  emangioma  2/50 (4%)	32/50 (64%) Total 32/50 (64%) Mean 64% SD 0%  25/50 (50%) Total 25/50 (50%) Mean 50% SD 0%  umors  44/50 (88%) Total 44/50 (88%) Mean 88% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 2/50 (4%) Mean 4% SD 0%  emangioma  2/50 (4%)	Total 32/50 (64%) Total 32/50 (64%)  Mean 64% SD 0% Total  25/50 (50%) Total 25/50 (50%)  Mean 50% SD 0% Total   umors  44/50 (88%) Total 44/50 (88%)  Mean 88% SD 0% Total   0/50 (0%)  Mean 0% SD 0% Total  2/50 (4%)  Mean 4% SD 0% Total	32/50 (64%)   Mean 64%   SD 0%   Total   24/50 (48%)	Total 32/50 (64%) Mean 64% SD 0% Total 24/50 (48%) Mean 48%    Total   25/50 (50%)   Mean 50% SD 0%   Total 24/50 (48%)   Mean 48%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 36

			Male				Female	
#All Organs: Histiocytic Sarcoma								
•		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Leukemia: Lymphocytic, Mo	onocytic. Mo	ononuclear. or Undifferer	ntiated					
, , , , , ,	, , , , , , , , ,	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: Malignant Lymphoma: Histi	ocytic, Lym	phocytic, Mixed, NOS, or 6/50 (12%)	Undifferentiated Ce	II Туре		9/50 (18%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	9/50 (18%)	Mean 18%	SD 0%
#All Organs: Malignant Schwannoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 37

				Male			Female			
*Adrenal Cortex: 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%	
*Adrenal Medulla: Pheochromocytoma Benign										
		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 Medulla: Pheochromocytoma Maligna	nt	0/50	(00/)				0/50 (09/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,					` ,			
*Adrenal Medulla: Pheochromocytoma: Benign	, Complex,	_	<b>i</b> (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Bone Marrow: Hemangiosarcoma		0/50	(00()				2/52 (224)			
Occupation of desired	T-1-1	0/50	(0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	00.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*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%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 38

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 39

			Male			Female			
*Clitoral/Preputial Gland: Mast Cell Tumor									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
*Epididymis: Mast Cell Tumor		0/50 (00/)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
#Harderian Gland: Adenoma									
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Carcinoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma									
Overall Incidence	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Mast Cell Tumor		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%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 40

				Male			Female			
#Intestine Small: Duodenum: Adenoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Carcinoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Adenoma										
	<b>-</b>		(0%)	NA 00/	05.00/	<b>+</b>	1/50 (2%)	NA 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Jejunum: Adenoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma										
		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Mast Cell Tumor										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 41

			Male				Female				
#Intestine Small: Site Unspecified: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Intestine Small: Site Uns Carcinoma											
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: Site Uns Carcinoma or Adenoma	•	1/50 (2%)				1/50 (2%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Intestine Small: Site Uns Mast Cell Tumor		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Islets, Pancreatic: 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%			
*Islets, Pancreatic: Carcinoma		0/50 (0%)				0/50 (09/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 42

			Male			Female			
*Islets, Pancreatic: Carcinoma or Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma	•••••	0/50 (0%)				1/50 (20/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Mast Cell Tumor									
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: Renal Mesenchymal Tumor		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 43

			Male			Female			
*Liver: Cholangiocarcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma		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%	
*Liver: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: 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									
Overall Incidence	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	
*Liver: Hepatocellular Carcinoma		8/50 (16%)				7/50 (14%)			
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 44

			Male			Female					
*Liver: Hepatocellular Carcinoma or Hepatoblastoma											
		9/50 (18%)				7/50 (14%)					
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%			
*Liver:											
Hepatocellular Carcino	ma or Hepatocel					40/50 (200/)					
Overall Incidence	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Maca 260/	SD 0%			
Overall incidence	Total	30/30 (60%)	iviean 60%	3D 0%	Total	10/50 (30%)	Mean 36%	3D 0%			
*Liver: Hepatocellular Carcino  Overall Incidence	oma, Hepatocellu Total	llar Adenoma, or Hepatob 31/50 (62%) 31/50 (62%)	olastoma Mean 62%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%			
						0/50 (0%)					
*Liver: Hepatocholangiocarcir Overall Incidence	noma Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver:	noma Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%				
*Liver: Hepatocholangiocarcir Overall Incidence *Liver: Ito Cell Tumor Benign	noma Total	3/50 (6%) 3/50 (6%) 0/50 (0%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocholangiocarcir Overall Incidence *Liver:	noma Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%				
*Liver: Hepatocholangiocarcir Overall Incidence *Liver: Ito Cell Tumor Benign	noma Total	3/50 (6%) 3/50 (6%) 0/50 (0%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 45

			Male			Female					
*Lung: Alveolar/Bronchiolar Adenoma											
		11/50 (22%)				5/50 (10%)					
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%			
*Lung: Alveolar/Bronchiolar Ca	rcinoma										
		6/50 (12%)				0/50 (0%)					
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung:		eolar/Bronchiolar Adenor 17/50 (34%)				5/50 (10%)					
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%			
*Lung: Hemangiosarcoma		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Lung: Mast Cell Tumor											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#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%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 46

				Male			Female			
#Lymph Node: Mast Cell Tumor		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%	
#Lymph Node, Axillary: Hemangioma		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%	
#Lymph Node, Mandibular: Mast Cell Tumor			(00()				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		0/30 (0 /8)								
#Lymph Node, Mesenteric: Hemangioma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Mast Cell Tumor	•••••	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(3,0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 47

				Male			Female			
#Lymph Node, Mesenteric: Mast Cell Tumor Malignant										
_			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma										
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma			(201)				(704)			
Overall Institutes	Tatal		(2%)	Mann 20/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma										
	<b>T</b>		(2%)		05.00/	<b>-</b>	0/50 (0%)	NA 00/	00.00/	
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma 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, Ca	arcinoma, or	Adenoma								
			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 48

			Male			Female			
#Mesentery: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Mesentery: Lipoma		0/50 (00/)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Sarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Nose: Carcinoma									
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: Polyp		0/50 (05.)				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%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 49

			Male				Female	
#Oral Cavity (Oral Mucos Papilloma Squamous o		nx, Tooth, Gingiva):						
	<b>.</b>	1/50 (2%)		<b>OD</b> 00/	<b></b>	0/50 (0%)		<b>OD</b> 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		nx, Tooth, Gingiva):						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin Overall Incidence		riving (1900); Equamous, or Papilloma 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		1750 (270)						
#Oral Mucosa: Squamous Cell Carcin	oma	2/22 (221)				2/52 (224)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	10tai						Weall 076	
*Ovary: Cystadenoma								
• " ' '					<b>-</b>	2/50 (4%)		OD 00/
Overall Incidence					Total	2/50 (4%)	Mean 4%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign							
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 50

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant			4/50 (20/)		
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Hemangioma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Ovary: Thecoma Benign			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1/N

0012022

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 51

			Male				Female	
*Ovary: Thecoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinom	a							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Mast Cell Tumor								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Carcinoma		•••••		•••••		•••••		
Overall Incidence	Total	0/36 (0%) 0/36 (0%)	Mean 0%	SD 0%	Total	0/36 (0%) 0/36 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 52

			Male				Female	
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	is or Unspecif	ied Site:						
		0/50 (0%)				4/50 (8%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
*Pituitary Gland: Pars Interm 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%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:	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%
Overall incluence		, ,				, ,		3D 0%
*Pituitary Gland: Pars Interm Schwannoma Malignant	edia:							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				` ,		
*Prostate: Hemangiosarcoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Mast Cell Tumor								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 53

			Male				Female	
*Salivary Glands: 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%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Salivary Glands: Mast Cell Tumor		2/-2 (221)				(201)		
	<b>.</b>	0/50 (0%)		<b>OD</b> 00/	<b>-</b>	0/50 (0%)	NA 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Fibroma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Osteosarcoma		2/20				(20)		
	<b>.</b>	0/50 (0%)		<b>OD</b> 00/	<b>-</b>	0/50 (0%)	NA 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 54

				Male				Female	Female		
#Skeletal Muscle: Rhabdomyosarcoma		,									
-		1/50	(2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyoma										
·	•	1/50	(2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Skeletal Muscle: Sarcoma		0/50	(00()				0/50 (00/)				
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%		
#Skin: Basal Cell Adenoma											
		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma or E		Tumor Benign									
Overall Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/50 (0%) 0/50 (0%)	Maan OO/	SD 0%		
	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma, Bas	sosquamous Tu			oithelioma			0/50 (09/)				
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Moon 09/	SD 00/		
		0/50 (0%)				Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 55

#Skin: Basal Cell Carcinoma, Basal Cell NOS), or Trichoepithelioma  Overall Incidence Tot  #Skin: Basal or Sq. Cell Carcinoma, Carc Adenoma, Papilloma, Sq Papillon  Overall Incidence Tot	0/50 al 0/50 (0 cinoma, Basosq. Tuna, Keratoacanthon	(0%) %) umor (M or B), na, Trichoepith (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence Tot #Skin: Basal or Sq. Cell Carcinoma, Carc Adenoma, Papilloma, Sq Papillon	al 0/50 (0 	umor (M or B), na, Trichoepith	Basal Cell Adeno			` ,	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carcinoma, Carc Adenoma, Papilloma, Sq Papillon	al 0/50 (0 	umor (M or B), na, Trichoepith	Basal Cell Adeno			` ,	Mean 0%	SD 0%
Basal or Sq. Cell Carcinoma, Card Adenoma, Papilloma, Sq Papillon	cinoma, Basosq. Tu na, Keratoacanthon 0/50	umor (M or B), na, Trichoepith (0%)	Basal Cell Adeno					
Adenoma, Papilloma, Sq Papillon	na, Keratoacanthon 0/50	na, Trichoepith (0%)	Basal Cell Adeno elioma	oma,				
	0/50	(0%)	elioma					
Overall Incidence Tot		, ,				0/50 (0%)		
		%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma								
Fibronia	0/50	(0%)				0/50 (0%)		
Overall Incidence Total		, ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma	ı, Myxoma, Myxosa	rcoma, Maligna	ant Fibrous Histic	ocytoma, or				
Hemangiopericytoma		_		•		. (== (== (		
Overall Institutes Tet	1/50	(2%)	Mana 200/	CD 00/	Tatal	1/50 (2%)	Mana 200/	CD 00/
Overall Incidence Tot	al 1/50 (2	%) 	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
Fibroma, Fibrosarcoma, Sarcoma	ı, Myxoma, Myxosa	rcoma, or Mali	gnant Fibrous His	stiocytoma				
	1/50	` '				1/50 (2%)		
Overall Incidence Total	al 1/50 (2°	%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma								
	0/50	(0%)				0/50 (0%)		
Overall Incidence Total		,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 56

			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma,	, or Malignant Fibrous H	istiocytoma			1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: 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%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma				•••••				•••••
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: Malignant Fibrous Histi		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 57

			Male					
#Skin: Melanoma 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: 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: Pilomatrixoma		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	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Sebaceous Gland: Adenoma		, ,				, ,		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 58

			Male				Female		
	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	1/50	(2%)				1/50 (2%)			
Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
	0/50	(0%)				0/50 (0%)			
Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	Squamous								
		(2%)		05 00/		` '		05 00/	
lotal	1/50 (2%)		Mean 2%	SD 0%	l otal	1/50 (2%)	Mean 2%	SD 0%	
	1/50	(2%)				1/50 (2%)			
Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
	0/50	(00/)				0/50 (09/)			
Total		(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
	Total  r Papilloma  Total	Total 0/50 (0%)  1/50 Total 1/50 (2%)  0/50 Total 0/50 (0%)  r Papilloma Squamous 1/50 Total 1/50 (2%)  Total 1/50 (2%)  Total 1/50 (2%)	Total 0/50 (0%)  1/50 (2%)  Total 1/50 (2%)  0/50 (0%)  Total 0/50 (0%)  r Papilloma Squamous 1/50 (2%)  Total 1/50 (2%)  Total 1/50 (2%)  Total 1/50 (2%)  0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0%  1/50 (2%) Total 1/50 (2%) Mean 2%  0/50 (0%) Total 0/50 (0%) Mean 0%  r Papilloma Squamous 1/50 (2%) Total 1/50 (2%) Mean 2%  1/50 (2%) Total 1/50 (2%) Mean 2%	Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0%  1/50 (2%)  Total 1/50 (2%)  Mean 2% SD 0%  Total 0/50 (0%)  Mean 0% SD 0%  r Papilloma Squamous 1/50 (2%)  Total 1/50 (2%)  Mean 2% SD 0%  Total 1/50 (2%)  Mean 2% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total  1/50 (2%) Mean 2% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total  Total 0/50 (0%) Mean 0% SD 0% Total  r Papilloma Squamous 1/50 (2%) Mean 2% SD 0% Total  1/50 (2%) Total 1/50 (2%) SD 0% Total  1/50 (2%) Mean 2% SD 0% Total	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 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  Total 0/50 (0%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  1/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  **Papilloma Squamous**  1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%  1/50 (2%) Mean 2%  Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 59

			Male				Female	
#Stomach, Glandular: 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%
*Testis: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Testis: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Hemangiosarcoma		0/48 (0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 60

			Male				Female		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (09	W.)			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%	
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%	)/ )			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular 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: Follicular 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%	
#Tongue: Squamous Cell Carcinoma or	r Papilloma	a <b>Squamous</b> 1/50 (29	%)			0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma		1/50 (29	%)			0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 61

			Male				Female	
#Tooth: Odontoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Mast Cell Tumor		- (a)				2/52 (221)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma or Ad	denoma					0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Fibroma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor B	enign					0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 62

	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		•••••			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 63

	Male			Female	
#Vagina: Hemangioma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

**Page:** 64

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

# 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	051098702	08/17/10	730	50(1)	44(722)	48.9	Dibutyl Phthalate
Battelle Columbus Laboratory	051026002	07/16/10	727	49(1)	34(691)	47.6	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052071204	10/25/11	731	50(1)	39(701)	50.0	Tris(Chloropropyl)phosphate
					Female		
Battelle Columbus Laboratory	051098702	08/16/10	729	50(4)	42(713)	51.5	Dibutyl Phthalate
Battelle Columbus Laboratory	051026002	07/15/10	726	50(4)	42(716)	54.7	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052071204	10/24/11	729	50(4)	46(726)	51.9	Tris(Chloropropyl)phosphate

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 11/18/2022

**Page:** 65

			Male			19/50 (38%) 11/50 (22%) 12/50 (24%) Total 42/150 (28%) Mean 28% SD 8.72%  28/50 (56%) 25/50 (50%) 27/50 (54%) Total 80/150 (53.33%) Mean 53.33% SD 3.06%			
#All Organs: Benign Tumors		26/50 (52%)	28/49 (57%)	25/50 (50%)		13/50 (26%)	17/50 (34%)	21/50 (42%)	
Overall Incidence	Total	79/149 (53.02%)	Mean 53.05%	SD 3.68%	Total	51/150 (34%)	Mean 34%	SD 8%	
#All Organs: Malignant Tumors									
Overall Incidence	Total	19/50 (38%) 58/149 (38.93%)	19/49 (39%) Mean 38.93%	20/50 (40%) SD 1.01%	Total	42/150 (28%)	Mean 28%	` '	
All Organs: Malignant and Benign Tu								07/50 (540()	
Overall Incidence	Total	33/50 (66%) 104/149 (69.8%)	37/49 (76%) Mean 69.84%	34/50 (68%) SD 5.01%	Total	` ,	,	, ,	
All Organs: Hemangioma						4/50 (20/)	2/50 /40/\	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 2/149 (1.34%)	1/49 (2%) Mean 1.35%	1/50 (2%) SD 1.17%	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	
All Organs: Hemangiosarcoma									
Overall Incidence	Total	3/50 (6%) 6/149 (4.03%)	1/49 (2%) Mean 4.01%	2/50 (4%) SD 1.98%	Total	3/50 (6%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	1/50 (2%) SD 3.06%	
All Organs: Hemangiosarcoma or Hel									
Overall Incidence	Total	3/50 (6%) 8/149 (5.37%)	2/49 (4%) Mean 5.36%	3/50 (6%) SD 1.11%	Total	4/50 (8%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	1/50 (2%) SD 3.06%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 66

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		2/50 (4%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
All Organs: Leukemia: Lymphocytic, Mo	nocytic, M	lononuclear, or Undifferer	ntiated					
	•	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Malignant Lymphoma: Histic	Total	nphocytic, Mixed, NOS, or 4/50 (8%) 12/149 (8.05%)	3/49 (6%) Mean 8.04%	5/50 (10%) SD 1.94%	Total	11/50 (22%) 24/150 (16%)	5/50 (10%) Mean 16%	8/50 (16%) SD 6%
	Total	12/149 (8.05%)	Mean 8.04%	SD 1.94%	Total	24/150 (16%)	Mean 16%	SD 6%
All Organs:								
All Organs: Malignant Schwannoma								
Malignant Schwannoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Malignant Schwannoma	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma	Total	` '	` ,	` '	Total	` '	` '	` '
Malignant Schwannoma  Overall Incidence  All Organs:	Total	` '	` ,	` '	Total	` '	` '	` '
Malignant Schwannoma  Overall Incidence  All Organs: Osteosarcoma	Total Total	0/149 (0%)	Mean 0%	SD 0%	Total Total	0/150 (0%)	Mean 0%	SD 0%
Malignant Schwannoma  Overall Incidence  #All Organs:		0/149 (0%) 0/50 (0%) 0/149 (0%)	Mean 0% 0/49 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%		0/150 (0%) 0/50 (0%) 1/150 (0.67%)	Mean 0% 0/50 (0%) Mean 0.67%	SD 0% 1/50 (2%) SD 1.15%
Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma  Overall Incidence  #All Organs:		0/149 (0%)	Mean 0%	SD 0% 0/50 (0%)		0/150 (0%) 0/50 (0%)	Mean 0% 0% 0/50 (0%)	SD 0% 1/50 (2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 67

Report Date: 11/18/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Adrenal Cortex: Adenoma								
		0/50 (0%)	1/48 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/148 (1.35%)	Mean 1.36%	SD 1.18%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Benign								
		0/50 (0%)	1/48 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
Adrenal Medulla: Pheochromocytoma Maligna	ant			2/22				
	<b>-</b>	0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma: Benigi	n, Complex	k, Malignant, NOS						
		0/50 (0%)	1/48 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
Bone Marrow: Hemangiosarcoma								
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Bone Marrow: Mast Cell Tumor Malignant		0/50 (0%)	4/47 (00)	0/50 (00%)		0/50 /00/	0/40 (00/)	0/50 (09/)
Nevall Incidence	Total	0/50 (0%)	1/47 (2%)	0/50 (0%)	Total	0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/147 (0.68%)	Mean 0.71%	SD 1.23%	Total	0/149 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Report Date: 11/18/2022

Page: 68

			Male				Female	
#Bone: Hemangioma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Bone: Osteosarcoma or Osteom	a	0(50 (00))	0(40 (004)	2(52 (22))		0/50 (00/)	0/50 (00/)	4/50 (00)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Meningioma: Benign, Mali	gnant, NOS							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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**: 69

			Male				Female	
Clitoral/Preputial Gland: Mast Cell Tumor								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Epididymis: Mast Cell Tumor								
		0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%				
#Harderian Gland: Adenoma								
		3/50 (6%)	6/49 (12%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	9/149 (6.04%)	Mean 6.08%	SD 6.12%	Total	8/150 (5.33%)	Mean 5.33%	SD 3.06%
Harderian Gland: Carcinoma		4/50 (00)	1/10 (00/)	0/50 (404)		0/50 (00/)	4/50 (00/)	0/50 (40/)
Overall Incidence	Total	1/50 (2%) 4/149 (2.68%)	1/49 (2%) Mean 2.68%	2/50 (4%) SD 1.14%	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%
		` ,				` '		
Harderian Gland: Carcinoma or Adenoma								
		4/50 (8%)	7/49 (14%)	2/50 (4%)		3/50 (6%)	2/50 (4%)	6/50 (12%)
Overall Incidence	Total	13/149 (8.72%)	Mean 8.76%	SD 5.19%	Total	11/150 (7.33%)	Mean 7.33%	SD 4.16%
Harderian Gland: Mast Cell Tumor								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 70 Report Date: 11/18/2022

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

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Mast Cell Tumor								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 71

Report Date: 11/18/2022

Route: ORAL

Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
fIntestine Small: Site Unspe Adenoma	ecified:							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Site Unsp Carcinoma	ecified:							
		1/50 (2%)	0/49 (0%)	2/50 (4%)	)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:	1/50 (2%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/149 (2.01%)	0/49 (0%) Mean 2%	SD 2%	Total	0/150 (0%)	0/30 (0%) Mean 0%	0/30 (0%) SD 0%
#Intestine Small: Site Unsp Mast Cell Tumor		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		0/50 (0%)	1/47 (2%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/147 (1.36%)	Mean 1.38%	SD 1.19%	Total	0/149 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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 Male **Female** 

**Page:** 72

			Male				i ciliale	
*Islets, Pancreatic: Carcinoma or Adenoma								
O	T-1-1	0/50 (0%)	1/47 (2%)	1/50 (2%)	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/147 (1.36%)	Mean 1.38%	SD 1.19%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
S	T-4-1	0/50 (0%)	0/48 (0%)	1/49 (2%)	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/147 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/147 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mast Cell Tumor								
		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Renal Mesenchymal Tumor								
-		0/50 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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 mal Groups Report Date: 11/18/2022

**Page:** 73

			Male				Female	
Liver: Cholangiocarcinoma								
O	Tatal	0/50 (0%)	0/49 (0%)	0/50 (0%)	T. ( -1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Liver: Hemangiosarcoma		3/50 (6%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/149 (2.01%)	0/49 (0%) Mean 2%	SD 3.46%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
·····								
*Liver: Hepatoblastoma		-1						-1
O	T-1-1	0/50 (0%)	1/49 (2%)	1/50 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		18/50 (36%)	21/49 (43%)	21/50 (42%)		3/50 (6%)	3/50 (6%)	11/50 (22%)
Overall Incidence	Total	60/149 (40.27%)	Mean 40.29%	SD 3.74%	Total	17/150 (11.33%)	Mean 11.33%	SD 9.24%
*Liver: Hepatocellular Carcinoma								
		10/50 (20%)	8/49 (16%)	5/50 (10%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	23/149 (15.44%)	Mean 15.44%	SD 5.06%	Total	3/150 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Page: 74

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** \*Liver: Hepatocellular Carcinoma or Hepatoblastoma 10/50 (20%)8/49 (16%)6/50 (12%) 1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 24/149 (16.11%) Mean 16.11% SD 4% Total 3/150 (2%) Mean 2% SD 0% \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 24/50 (48%)26/49 (53%)23/50 (46%)4/50 (8%)4/50 (8%)12/50 (24%)**Overall Incidence** 73/149 (48.99%) Mean 49.02% SD 3.64% 20/150 (13.33%) Mean 13.33% SD 9.24% Total Total \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 24/50 (48%) 26/49 (53%)24/50 (48%)4/50 (8%)4/50 (8%)12/50 (24%) **Overall Incidence** 74/149 (49.66%) Mean 49.69% SD 2.92% 20/150 (13.33%) Mean 13.33% SD 9.24% Total Total ...... \*Liver: Hepatocholangiocarcinoma 0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.68% Total 0/150 (0%) Mean 0% SD 0% 1/149 (0.67%) SD 1.18% \*Liver: Ito Cell Tumor Benign 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Liver: **Mast Cell Tumor** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total SD 0% SD 0% 0/149 (0%) Mean 0% Total 0/150 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

**Toxicology Data Management System** 

**Page:** 75

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
*Lung: Alveolar/Bronchiolar Ad	enoma	9/50 (18%)	7/49 (14%)	8/50 (16%)		2/50 (4%)	5/50 (10%)	3/50 (6%)
Overall Incidence	Total	24/149 (16.11%)	Mean 16.1%	SD 1.86%	Total	10/150 (6.67%)	Mean 6.67%	SD 3.06%
Lung: Alveolar/Bronchiolar Ca	rcinoma	3/50 (6%)	5/49 (10%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	9/149 (6.04%)	Mean 6.07%	SD 4.1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lung: Alveolar/Bronchiolar Ca Overall Incidence	rcinoma or Al	veolar/Bronchiolar Adeno 11/50 (22%) 31/149 (20.81%)	<b>ma</b> 11/49 (22%) Mean 20.82%	9/50 (18%) SD 2.45%	Total	2/50 (4%) 11/150 (7.33%)	5/50 (10%) Mean 7.33%	4/50 (8%) SD 3.06%
Lung: Hemangiosarcoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Mast Cell Tumor		2/52 (221)	2/12 (221)	2/22 (221)		2/22 (22)	2/52 (221)	2(72 (22))
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Hemangiosarcoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 76

			Male			Female				
#Lymph Node: Mast Cell Tumor										
Overall Incidence	Total	0/50 (0%)	0/49 (0%)	0/50 (0%	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Axillary: Hemangioma										
		0/50 (0%)	0/49 (0%)	0/50 (0%	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Mandibular: Mast Cell Tumor		-1		- /				- 1		
	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Mandibular: Mast Cell Tumor Malignant				- 4						
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0% SD 0%	%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
	10tai	0/149 (0%)		SD 0%	ı otal	0/150 (0%)		SD 0%		
Lymph Node, Mesenteric: Hemangioma										
		0/50 (0%)	0/49 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Mesenteric: Mast Cell Tumor										
		0/50 (0%)	0/49 (0%)	0/50 (0%	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 77

			Male				Female	
#Lymph Node, Mesenteric: Mast Cell Tumor Malignant		2/72 (201)	2/12 (221)	2(-2)		2/22 (22)	2/22 (221)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%
Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	3/50 (6%) 3/150 (2%)	0/50 (0%) Mean 2%	0/50 (0%) SD 3.46%
Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	4/50 (8%) 7/150 (4.67%)	1/50 (2%) Mean 4.67%	2/50 (4%) SD 3.06%
Mammary Gland: Fibroma, Fibroadenoma or <i>I</i>			•••••			•••••		
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%
#Mammary Gland: Fibroma, Fibroadenoma, Ca		r Adenoma						
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	4/50 (8%) 7/150 (4.67%)	1/50 (2%) Mean 4.67%	2/50 (4%) SD 3.06%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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**: 78

			Male				Female	
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Nose: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Nose: Polyp								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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: FEED

Report Date: 11/18/2022 Route: ORAL

**Page**: 79

			Male				Female	
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
	•	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcino		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Ovary: Cystadenoma								
						3/48 (6%)	4/48 (8%)	0/49 (0%)
verall Incidence					Total	7/145 (4.83%)	Mean 4.86%	SD 4.34%
Ovary: Granulosa Cell Tumor	Benign							
						0/48 (0%)	0/48 (0%)	1/49 (2%)
Overall Incidence					Total	1/145 (0.69%)	Mean 0.68%	SD 1.18%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 11/18/2022

Page: 80

Species: MICE Strain: B6C3F1/N

Vehicle: FEED

Length of Study: CHRONIC

Male			Female	
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Total	0/48 (0%) 1/145 (0.69%)	0/48 (0%) Mean 0.68%	1/49 (2%) SD 1.18%
Ovary: Granulosa-Theca Tumor Malignant				
verall Incidence	Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Hemangioma				
Overall Incidence	Total	0/48 (0%) 1/145 (0.69%)	1/48 (2%) Mean 0.69%	0/49 (0%) SD 1.2%
Ovary: Hemangiosarcoma		0/40 (/0/)	0/10 /00/	0/40 /00/)
verall Incidence	Total	2/48 (4%) 2/145 (1.38%)	0/48 (0%) Mean 1.39%	0/49 (0%) SD 2.41%
Ovary: Luteoma				
overall Incidence	Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Thecoma Benign		•••••		
Overall Incidence	Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 81

			Male				Female	
Ovary: Thecoma Malignant						0/40 //00/	0/40 (00%)	0/40 (00)
Overall Incidence					Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Tubulostromal Carcinoma						0/40 (00)	0/40 /00/	0/40 (00/)
Overall Incidence					Total	0/48 (0%) 0/145 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%
Pancreas: Mast Cell Tumor						0/50 (00)	0(10 (00))	0/50 (001)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
Parathyroid Gland: Carcinoma								
Overall Incidence	Total	0/40 (0%) 1/114 (0.88%)	0/32 (0%) Mean 0.79%	1/42 (2%) SD 1.37%	Total	0/43 (0%) 0/107 (0%)	0/21 (0%) Mean 0%	0/43 (0%) SD 0%
Pituitary Gland: Pars Distalis Adenoma								
Overall Incidence	Total	0/48 (0%) 0/143 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/49 (2%) 4/146 (2.74%)	0/47 (0%) Mean 2.68%	3/50 (6%) SD 3.05%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

### **Toxicology Data Management System**

Page: 82

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC Male **Female** \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/48 (0%)0/45 (0%)0/50 (0%)1/49 (2%)0/47 (0%)3/50 (6%)**Overall Incidence** Total 0/143 (0%) Mean 0% SD 0% Total 4/146 (2.74%) Mean 2.68% SD 3.05% \*Pituitary Gland: Pars Intermedia: Adenoma 0/48 (0%)0/45 (0%)0/50 (0%)0/49 (0%)1/47 (2%)0/50 (0%)**Overall Incidence** Total 0/143 (0%) Mean 0% SD 0% Total 1/146 (0.68%) Mean 0.71% SD 1.23% \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/48 (0%)0/45 (0%)0/50 (0%)0/49 (0%)1/47 (2%)0/50 (0%)**Overall Incidence** Total 0/143 (0%) Mean 0% SD 0% Total 1/146 (0.68%) Mean 0.71% SD 1.23% ..... \*Pituitary Gland: Pars Intermedia: **Schwannoma Malignant** (0%) 0/48 (0%)0/45 (0%)0/50 (0%)0/49 (0%)0/47 (0%)0/50 **Overall Incidence** Total 0/143 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% \*Prostate: Hemangiosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% \*Prostate:

0/50

SD 0%

(0%)

Total

0/50

0/149 (0%)

(0%)

0/49

Mean 0%

(0%)

**Mast Cell Tumor** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 83

Report Date: 11/18/2022

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC Male **Female** \*Salivary Glands: Carcinoma 0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% \*Salivary Glands: Carcinoma or Adenoma 0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% \*Salivary Glands: **Mast Cell Tumor** 0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% **#Seminal Vesicle: Fibroma** 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#Skeletal Muscle:** Osteosarcoma

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/149 (0%)

(0%)

0/49

Mean 0%

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Page: 84

Mean 0%

SD 0%

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female #Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 2/150 (1.33%) Mean 1.33% SD 1.15% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% 2/150 (1.33%) Mean 1.33% SD 1.15% Total **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total Mean 0.67% SD 1.15% 1/150 (0.67%) ...... #Skin: **Basal Cell Adenoma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/149 (0%) #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/150 (0%)

Mean 0%

Total

0/149 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1/N

Species: MICE

**Toxicology Data Management System** 

**Page:** 85

Report Date: 11/18/2022

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/149 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% ...... Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: **Fibroma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma 0/50 (0%)(0%)2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)2/149 (1.34%) Mean 1.33% SD 2.31% 2/150 (1.33%) Mean 1.33% SD 2.31% Overall Incidence Total Total Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 0/50 (0%)0/49 (0%)2/50 (4%)2/50 (4%)0/50 (0%)0/50 (0%)2/149 (1.34%) Mean 1.33% SD 2.31% 2/150 (1.33%) SD 2.31% **Overall Incidence** Total Total Mean 1.33% #Skin: **Fibrosarcoma** 0/50 (0%)0/49 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 2.31%

Total

0/150 (0%)

Mean 0%

SD 0%

Total

2/149 (1.34%)

Mean 1.33%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 86

Report Date: 11/18/2022

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

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	a, or Malignant Fibrous Hi	_	2/52 (49())		0/50 (40/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 2/149 (1.34%)	0/49 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
#Skin: Hemangioma		2/-2 (22)		2(72 (22))		0.750 (001)		(001)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Hemangiosarcoma		0/50 (00)	0/40 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Lipoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (004)	0/40 (00%)	0(50 (00))		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Malignant Fibrous Histi	ocytoma							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

#Skin:

#Skin:

#Skin:

#Skin: Sarcoma

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

**Melanoma NOS** 

**Overall Incidence** 

Osteosarcoma

**Overall Incidence** 

Pilomatrixoma

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

Adenoma

**#Spinal Cord:** 

.....

#Skin: Sebaceous Gland:

.....

**Astrocytoma Malignant** 

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/149 (0%) 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Page: 87

Report Date: 11/18/2022

Total

0/50

0/149 (0%)

(0%)

0/49

Mean 0%

(0%)

0/50

SD 0%

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 88 Report Date: 11/18/2022

			Male				Female	
#Spinal Cord: Schwannoma Malignant								
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%)	1/48 (2%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	3/148 (2.03%)	Mean 2.03%	SD 2%	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%
#Stomach, Forestomach: Mast Cell Tumor Malignant							0/50 (09/)	0/50 /09/
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` '						
#Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillon	•						
	<b>-</b>	1/50 (2%)	2/49 (4%)	0/50 (0%)	<b>+</b>	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2.03%	SD 2.04%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Stomach, Forestomach: Squamous Cell Papilloma								
		1/50 (2%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/149 (2.01%)	Mean 2.03%	SD 2.04%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

OCI2022

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

**Page:** 89

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)	0/50 (0	0/ \	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Testis:								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0 SD 0%	%)			
Testis: Hemangioma								
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0 SD 1.18%	%)			
Thymus: Hemangiosarcoma				0/40 /0	o()	0/45 (00/)	2/42 /22/	0/40 (00/)
Overall Incidence	Total	0/45 (0%) 0/136 (0%)	0/45 (0%) Mean 0%	0/46 (0 SD 0%	%) Total	0/45 (0%) 0/141 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Thymus: Thymoma Benign								
Overall Incidence	Total	0/45 (0%) 0/136 (0%)	0/45 (0%) Mean 0%	0/46 (0 SD 0%	%) Total	0/45 (0%) 0/141 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0 SD 0%	%) Total	1/50 (2%) 1/147 (0.68%)	0/48 (0%) Mean 0.67%	0/49 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 90

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
Thyroid Gland: Follicular Cell Adenoma	:							
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.69%	SD 1.2%
Thyroid Gland: Follicular Cell Carcinoma	:							
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/147 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	1/48 (2%)	0/49 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/147 (0.68%)	Mean 0.69%	SD 1.2%
#Tongue: Squamous Cell Carcinoma o								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
rtongue: Squamous Cell Papilloma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 91

			Male				Female		
Tooth: Odontoma				0/50 (09/)					
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Urinary Bladder: Mast Cell Tumor									
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/48 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
Uterus: Adenocarcinoma or Ad	enoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Uterus: Fibroma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Uterus: Granular Cell Tumor Be	enign								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incid

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED **Page:** 92

	Male			Female	
#Uterus: Hemangioma			0/50 (00/)	0/50 (00())	0/50 (00/)
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
∤Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyoma			4/50 (00%)	0/50 (00()	0/50 (0%)
Overall Incidence		Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Uterus: Polyp Stromal			0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence		Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal				4/50 (00()	4/50 (00)
Overall Incidence		Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 93

	Male		Female	
#Vagina: Hemangioma		1/50 (2%) (	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 94

Report Date: 11/18/2022

# **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	050303804 051105402	01/17/12 05/19/15	730 730	50(1) 50(1)	26(683) 34(701)	54.6 56.1	Sodium Tungstate Dihydrate Sulfolane
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	050303804 051105402	01/16/12 05/18/15	729 728	50(4) 50(4)	38(700) 35(702)	61.6 61.8	Sodium Tungstate Dihydrate Sulfolane

**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:** 95

			Male				Female	
#All Organs: Benign Tumors								
Overell Inclidence	Tatal	31/50 (62%)	32/50 (64%)	CD 4 440/	Tatal	20/50 (40%)	25/50 (50%)	CD 7.070/
Overall Incidence	Total	63/100 (63%)	Mean 63%	SD 1.41%	Total	45/100 (45%)	Mean 45%	SD 7.07%
#All Organs: Malignant Tumors								
		30/50 (60%)	22/50 (44%)			15/50 (30%)	18/50 (36%)	
Overall Incidence	Total	52/100 (52%)	Mean 52%	SD 11.31%	Total	33/100 (33%)	Mean 33%	SD 4.24%
#All Organs: Malignant and Benign T								
		42/50 (84%)	41/50 (82%)			32/50 (64%)	34/50 (68%)	
Overall Incidence	Total	83/100 (83%)	Mean 83%	SD 1.41%	Total	66/100 (66%)	Mean 66%	SD 2.83%
#All Organs: Hemangioma					•••••			
O	T-1-1	1/50 (2%)	2/50 (4%)	OD 4 440/	T-1-1	0/50 (0%)	3/50 (6%)	00 4040/
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#All Organs: Hemangiosarcoma								
		5/50 (10%)	3/50 (6%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
-	-	6/50 (12%)	4/50 (8%)			1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 4.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

# **Toxicology Data Management System**

**Page:** 96

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
#All Organs: Histiocytic Sarcoma								
•		1/50 (2%)	0/50 (0%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 0%
#All Organs: Leukemia: Lymphocytic, M	onocytic. Ma	ononuclear, or Undifferen	tiated					
zoakomia. Zympnooyao, m	,	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: Malignant Lymphoma: Hist	iocytic, Lym	phocytic, Mixed, NOS, or 5/50 (10%)	Undifferentiated Cel	I Туре		4/50 (8%)	5/50 (10%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 4.24%	Total	9/100 (9%)	Mean 9%	SD 1.41%
	Total	7/100 (7%)	Mean 7%	SD 4.24%	Total			SD 1.41%
All Organs: Malignant Schwannoma	Total Total	` '	` ,	SD 4.24% SD 1.41%	Total Total	9/100 (9%) 0/50 (0%) 0/100 (0%)	Mean 9% 0/50 (0%) Mean 0%	SD 1.41% SD 0%
#All Organs: Malignant Schwannoma Overall Incidence		7/100 (7%) 1/50 (2%)	Mean 7%			0/50 (0%)	0/50 (0%)	
FAII Organs: Malignant Schwannoma  Overall Incidence  FAII Organs:		7/100 (7%) 1/50 (2%)	Mean 7%			0/50 (0%)	0/50 (0%)	
All Organs: Malignant Schwannoma  Overall Incidence  All Organs: Osteosarcoma		7/100 (7%) 1/50 (2%) 1/100 (1%)	Mean 7%  0/50 (0%)  Mean 1%			0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	
Overall Incidence #All Organs:	Total Total	7/100 (7%)  1/50 (2%)  1/100 (1%)  0/50 (0%)	Mean 7%  0/50 (0%)  Mean 1%  0/50 (0%)	SD 1.41%	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
#All Organs: Malignant Schwannoma  Overall Incidence  #All Organs: Osteosarcoma  Overall Incidence  #All Organs:	Total Total	7/100 (7%)  1/50 (2%)  1/100 (1%)  0/50 (0%)	Mean 7%  0/50 (0%)  Mean 1%  0/50 (0%)	SD 1.41%	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 97

Report Date: 11/18/2022

Species: MICE

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Adrenal Cortex: Adenoma								
		1/50 (2%)	0/47 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	1/97 (1.03%)	Mean 1%	SD 1.41%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benigr	1							
Overell Instidence	Tatal	0/49 (0%)	0/47 (0%)	CD 00/	Tatal	0/50 (0%)	0/48 (0%)	CD 00/
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malign	ant							
		0/49 (0%)	0/47 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benig			0/47 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%)			0/48 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
*Bone Marrow: Mast Cell Tumor Malignant								
_		1/50 (2%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/98 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 98

			Male				Female	
#Bone: Hemangioma								
		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: 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%
#Bone: Osteosarcoma								
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%
#Bone: Osteosarcoma or Osteoma		0/50 (001)	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%
*Brain: 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%
*Brain: Meningioma: Benign, Maligı	nant, NOS							
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>+</b>	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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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**: 99 Report Date: 11/18/2022

			Male				Female	
*Clitoral/Preputial Gland: Mast Cell Tumor								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/92 (0%)	0/43 (0%) Mean 0%	SD 0%
*Epididymis: Mast Cell Tumor								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Harderian Gland: Adenoma								
Overall Incidence	Total	2/50 (4%) 7/100 (7%)	5/50 (10%) Mean 7%	SD 4.24%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Harderian Gland: Adenocarcinoma		4/50 (00/)	4/50 (00)			0/50 (00/)	0/50 (00/)	
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%
#Harderian Gland: Adenoma or Adenocarcir								
Overall Incidence	Total	3/50 (6%) 9/100 (9%)	6/50 (12%) Mean 9%	SD 4.24%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Harderian Gland: Mast Cell 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 100

			Male				Female	
#Intestine Small: Duodenum: 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%
#Intestine Small: Duodenum: Adenocarcinoma								
		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: 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: 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: Jejunum: Adenocarcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Intestine Small: Jejunum: Mast Cell Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 101

			Male				Female	
#Intestine Small: Any Site: Adenoma								
		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	<b>OD</b> 007
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Any Site: Adenocarcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Intestine Small: Any Site: Adenoma or Adenocarcino	ma	0/50 (00)	0/50 (00/)			0(50 (00))	0/50 (40/)	
Overall Incidence	Total	0/50 (0%)	3/50 (6%) Mean 3%	CD 4 240/	Total	0/50 (0%)	2/50 (4%) Mean 2%	CD 2 020/
Overali incidence		3/100 (3%)	3%	SD 4.24%	Total	2/100 (2%)	wean 2%	SD 2.83%
#Intestine Small: Any Site: Mast Cell Tumor								
Occupil be of the con-	T-1-1	0/50 (0%)	0/50 (0%)	OD 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%
*Islets, Pancreatic: Adenoma								
		1/47 (2%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	1/97 (1.03%)	Mean 1.06%	SD 1.5%	Total	0/98 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/47 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Oct2022 Toxicology Data M

Contract/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: 102

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma								
		1/47 (2%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	1/97 (1.03%)	Mean 1.06%	SD 1.5%	Total	0/98 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
Occupation of decision	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	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%
*Kidney: Renal Tubule: Carcinoma or Adenoma		-1	- ()					
One will be add a second	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	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%
*Kidney: Renal Tubule: Hemangiosarcoma		(00)	2/52 (221)			(201)	(201)	
Overell Incidence	Total	1/50 (2%)	0/50 (0%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mast Cell Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Renal Mesenchymal Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 103

			Male	Female				
*Liver: Cholangiocarcinoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Liver: Hemangioma		(201)					(20)	
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatoblastoma								
Overall Incidence	Total	4/50 (8%) 11/100 (11%)	7/50 (14%) Mean 11%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	26/50 (52%) 48/100 (48%)	22/50 (44%) Mean 48%	SD 5.66%	Total	11/50 (22%) 21/100 (21%)	10/50 (20%) Mean 21%	SD 1.41%
*Liver: Hepatocellular Carcinoma								
Overall Incidence	Total	15/50 (30%) 26/100 (26%)	11/50 (22%) Mean 26%	SD 5.66%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 104

			Male	Female								
*Liver: Hepatocellular Carcinoma or Hepatoblastoma												
•	•	17/50 (34%)	18/50 (36%)			2/50 (4%)	2/50 (4%)					
Overall Incidence	Total	35/100 (35%)	Mean 35%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 0%				
Liver: Hepatocellular Carcino												
,		33/50 (66%)	30/50 (60%)			13/50 (26%)	11/50 (22%)					
Overall Incidence	Total	63/100 (63%)	Mean 63%	SD 4.24%	Total	24/100 (24%)	Mean 24%	SD 2.83%				
*Liver: Hepatocellular Carcino Overall Incidence	oma, Hepatocellu Total	llar Adenoma, or Hepatob 34/50 (68%) 70/100 (70%)	36/50 (72%) Mean 70%	SD 2.83%	Total	13/50 (26%) 24/100 (24%)	11/50 (22%) Mean 24%	SD 2.83%				
Liver: Hepatocholangiocarcir	noma	0/50 (00)	4/50 (00)			0/50 (00/)	0/50 (00)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
Liver: Ito Cell Tumor Benign												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
				OD 00/	Total	0/100 (0%)	Mean 0%	SD 0%				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%								
Overall Incidence *Liver: Mast Cell Tumor	Total			SD 0%	- Total							
Liver:	Total	0/100 (0%)  0/50 (0%) 0/100 (0%)	Mean 0%  0/50 (0%)  Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 105

			Male				Female				
*Lung: Alveolar/Bronchiolar Adenoma  5/50 (10%) 9/50 (18%) 2/50 (4%) 0/50 (0%)											
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 5.66%	Total	2/100 (2%)	Mean 2%	SD 2.83%			
Lung: Alveolar/Bronchiolar Ca	rcinoma										
		2/50 (4%)	1/50 (2%)			2/50 (4%)	2/50 (4%)				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 0%			
Lung: Alveolar/Bronchiolar Ca	rcinoma or Alv	reolar/Bronchiolar Adenor 7/50 (14%)	<b>na</b> 10/50 (20%)			4/50 (8%)	2/50 (4%)				
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 4.24%	Total	6/100 (6%)	Mean 6%	SD 2.83%			
Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
Lung: Mast Cell Tumor		2(22)					(201)				
		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: 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%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 106

			Male		Female				
#Lymph Node: Mast Cell Tumor							-15-		
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, Axillary: Hemangioma		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%	
#Lymph Node, Mandibular: Mast Cell 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%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		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%	
#Lymph Node, Mesenteric: 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%	
#Lymph Node, Mesenteric: Mast Cell 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%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 107

Report Date: 11/18/2022

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male	Female								
#Lymph Node, Mesenteric: Mast Cell Tumor Malignant												
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
						` '						
#Mammary Gland: 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%				
#Mammary Gland: Adenocarcinoma		0/50 (0%)	0/50 (00/)			4/50 (00()	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	1/50 (2%)	0/50 (0%)	CD 4 440/				
	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Mammary Gland: Adenoma or Adenocard	inoma	0/50 (00)	0/50 (00/)			4/50 (001)	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%				
#Mammary Gland: Fibroma, Fibroadenoma	a 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%				
#Mammary Gland: Fibroma, Fibroadenoma	a, Adenocarcino	ma, or Adenoma 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%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 108

			Male				Female		
#Mesentery: Hemangioma									
-		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%	
#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: Lipoma									
Occupation and the second	Taral	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Mesentery: Sarcoma									
O	Taral	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	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%	
*Nose: 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%	
*Nose: Polyp									
O	Taral	0/50 (0%)	1/50 (2%)	OD 4 440/	Taral	0/50 (0%)	0/50 (0%)	OD 00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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:** 109

			Male				Female	
#Oral Cavity (Oral Mucosa Papilloma Squamous or		/nx, Tooth, Gingiva):						
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%
#Oral Cavity (Oral Mucosa Squamous Cell Carcino		/nx, Tooth, Gingiva):						
Squamous Cen Carcino	,iiia	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 Mucosa Squamous Cell Carcino Overall Incidence			0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	3/49 (6%) 6/97 (6.19%)	3/48 (6%) Mean 6.19%	SD 0.09%
*Ovary: Granulosa Cell Tumor E	3enign					0/40 (00%)	0/40 (00/)	
Overall Incidence					Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 110

Mal	е		Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/40 /00/	0/40 (00/)	
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant				
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Hemangioma		0/40 /00/	0/40 /40/)	
Overall Incidence	Total	0/49 (0%) 2/97 (2.06%)	2/48 (4%) Mean 2.08%	SD 2.95%
*Ovary: Hemangiosarcoma		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma				
Overall Incidence	Total	1/49 (2%) 1/97 (1.03%)	0/48 (0%) Mean 1.02%	SD 1.44%
*Ovary: Thecoma Benign		0/40 /02/	4/49 (20/)	
Overall Incidence	Total	0/49 (0%) 1/97 (1.03%)	1/48 (2%) Mean 1.04%	SD 1.47%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 111

			Male				Female	
*Ovary: Thecoma Malignant						0/40 (00/)	0/40 (/00/)	
Overall Incidence					Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma	•••••							
Overall Incidence					Total	0/49 (0%) 1/97 (1.03%)	1/48 (2%) Mean 1.04%	SD 1.47%
*Pancreas: Mast Cell 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%
*Parathyroid Gland: Carcinoma	• • • • • • • • • • • • • • • • • • • •							
Overall Incidence	Total	0/44 (0%) 0/82 (0%)	0/38 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/80 (0%)	0/35 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma								
Overall Incidence	Total	0/48 (0%) 0/91 (0%)	0/43 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 9/96 (9.38%)	7/46 (15%) Mean 9.61%	SD 7.93%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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 Groups Report Date: 11/18/2022

Page: 112

			Male				Female	
*Pituitary Gland: Pars Dista Carcinoma or Adenoma	ilis or Unspeci	fied Site:						
Occupation of decision	Taral	0/48 (0%)	0/43 (0%)	00.00/	T-1-1	2/50 (4%)	7/46 (15%)	OD 7.000/
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	9/96 (9.38%)	Mean 9.61%	SD 7.93%
*Pituitary Gland: Pars Interi Adenoma	media:							
		0/48 (0%)	0/43 (0%)			0/50 (0%)	1/46 (2%)	
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	1/96 (1.04%)	Mean 1.09%	SD 1.54%
*Pituitary Gland: Pars Interi Carcinoma or Adenoma	media:	0/48 (0%)	0/43 (0%)			0/50 (0%)	1/46 (2%)	
Overall Incidence	Total	0/48 (0%) 0/91 (0%)	0/43 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/96 (1.04%)	1/46 (2%) Mean 1.09%	SD 1.54%
*Pituitary Gland: Pars Interi Schwannoma Malignant	media:							
• " " "	<b>.</b>	0/48 (0%)	0/43 (0%)	00.00/	<b>-</b>	0/50 (0%)	0/46 (0%)	00.00/
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Prostate: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Mast Cell Tumor								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 113

			Male				Female	
*Salivary Glands: Adenocarcinoma								
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%
						, ,		
*Salivary Glands: Adenoma or Adenocarc	inoma							
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%
*Salivary Glands: Mast Cell 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%
#Seminal Vesicle: Fibroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		•••••						
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Osteosarcoma		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 114

			Male				Female		
#Skeletal Muscle: Rhabdomyosarcoma									
		0/50 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyoma								
•	-	0/50 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Skeletal Muscle: 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: Basal Cell 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%	
#Skin: Basal Cell Adenoma or E									
	•	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, Bas						0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	
		0/100 (0%)				` ,			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

**Page:** 115

Report Date: 11/18/2022

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli	Basal Cell Adeno oma	ma, Basosquamous Tum	or (benign, malignan	t or				
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%
·····								
		a, Basosq. Tumor (M or B atoacanthoma, Trichoepi 0/50 (0%)		a,		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 Hemangiopericytoma	a, Sarcoma, Myxo	oma, Myxosarcoma, Malig	nant Fibrous Histioc	ytoma, or		1/50 (2%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 2.83%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or Ma 0/50 (0%)				1/50 (2%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 2.83%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 116

			Male				Female				
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  0/50 (0%) 0/50 (0%)  1/50 (2%) 3/50 (6%)											
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 2.83%			
#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			(00)			(20)	(201)				
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%			
#Skin: Lipoma		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: Liposarcoma											
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: Malignant Fibrous Histi	ocytoma	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%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 117

			Male				Female	
#Skin: Melanoma								
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%
#Skin: Osteosarcoma								
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: Pilomatrixoma								
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: Sarcoma						0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant		0/50 (09/)	0/50 (00/)			0/50 /09/\	0/50 (/09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 118

			Male			Female			
#Spinal Cord: Schwannoma Malignant									
		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%	
*Spleen: Hemangiosarcoma									
		4/49 (8%)	0/49 (0%)	25		0/50 (0%)	0/50 (0%)	05 00/	
Overall Incidence	Total	4/98 (4.08%)	Mean 4.08%	SD 5.77%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Mast Cell Tumor Malignant		4/50 (00)	0/50 (00/)			0/50 (001)	0/50 (00/)		
Overell Institutes	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillom	=	0/50 (00/)			4/50 (001)	0/50 (00/)		
Overell Institutes	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%	
#Stomach, Forestomach: Squamous Cell Papilloma									
		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%	
#Stomach, Glandular: Adenoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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:** 119

		·	Male				Female	
#Stomach, Glandular: 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%
*Testis: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Testis: Hemangioma		0/50 (00)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Thymus: Hemangiosarcoma		0/45 (0%)	1/46 (2%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	1/91 (1.1%)	Mean 1.09%	SD 1.54%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/45 (0%) 0/91 (0%)	0/46 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/96 (1.04%)	1/47 (2%) Mean 1.06%	SD 1.5%
*Thyroid Gland: C-Cell: Carcinoma								
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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 120

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma or 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: Follicular Cell: Adenoma								
		0/50 (0%)	0/50 (0%)			1/49 (2%)	1/49 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/98 (2.04%)	Mean 2.04%	SD 0%
*Thyroid Gland: Follicular Cell: 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%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (09/)	0/50 (00/)			4/40 (20/)	4/40 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 2/98 (2.04%)	1/49 (2%) Mean 2.04%	SD 0%
#Tongue: Squamous Cell Carcinoma or	r Papillom	-						
		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%
#Tongue: Squamous Cell Papilloma		0/50 (09/)	0/50 (00/)			4/50 (20/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	1/50 (2%)	0/50 (0%)	SD 1.410/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 121

			Male				Female	
#Tooth: Odontoma Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	Total			3D 1.41%	Total	0/100 (0%)		5D 0%
*Urinary Bladder: Mast Cell Tumor		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%
#Uterus: Adenocarcinoma or Ad						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Adenoma						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Fibroma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Be	enign					0/50 (00/)	0/50 (/00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 122

	Male			Female	
#Uterus: Hemangioma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Leiomyoma			0/50 /00/\	0/50 (00/)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Polyp Stromal				0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal			0/50 (000)	0/50 (00)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/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: 123

	Male			Female	
#Vagina: Hemangioma			0/50 (0%) 0.	/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Page: 124

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure Vehicle: AIR

# **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		
I. I. T. Research Institute	052010578	06/18/12	729	90(1)	66(687)	51.5	Radiofrequency Radiation
					Female		
I. I. T. Research Institute	052010578	06/18/12	739	90(1)	67(704)	62.6	Radiofrequency Radiation

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Page: 125

Report Date: 11/18/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female		
#All Organs: Benign Tumors									
		61/90 (68%)				36/90 (40%)			
Overall Incidence	Total	61/90 (67.78%)	Mean 67.78%	SD 0%	Total	36/90 (40%)	Mean 40%	SD 0%	
#All Organs: Malignant Tumors									
		49/90 (54%)				33/90 (37%)			
Overall Incidence	Total	49/90 (54.44%)	Mean 54.44%	SD 0%	Total	33/90 (36.67%)	Mean 36.67%	SD 0%	
All Organs: Malignant and Benign T									
		79/90 (88%)				59/90 (66%)			
Overall Incidence	Total	79/90 (87.78%)	Mean 87.78%	SD 0%	Total	59/90 (65.56%)	Mean 65.56%	SD 0%	
All Organs: Hemangioma		1/90 (1%)				4/90 (4%)			
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	4/90 (4.44%)	Mean 4.44%	SD 0%	
All Organs: Hemangiosarcoma		0/00 (0%)							
O	T-1-1	2/90 (2%)	M 0.000/	00.00/	T-1-1	2/90 (2%)	M 0.000/	OD 00/	
verall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	
All Organs: Hemangiosarcoma or H	emangioma								
		3/90 (3%)				6/90 (7%)			
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 126

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/90 (0%)				8/90 (9%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	8/90 (8.89%)	Mean 8.89%	SD 0%
#All Organs: Leukemia: Lymphocytic, M	onocytic M	ononuclear or Undiffere	ntiated					
Leukeilla. Lymphocytic, W	oriocytic, ivic	0/90 (0%)	illialeu			0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lym	6/90 (7%)		II Туре		2/90 (2%)		
Overall Incidence	Total	6/90 (6.67%)	Mean 6.67%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#All Organs: Malignant Schwannoma		0/90 (0%)				0/90 (0%)		
Malignant Schwannoma	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
Malignant Schwannoma Overall Incidence	Total	, ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Malignant Schwannoma  Overall Incidence  #All Organs:	Total	, ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Malignant Schwannoma Overall Incidence #All Organs: Osteosarcoma	Total Total	0/90 (0%)	Mean 0% Mean 0%	SD 0% SD 0%	Total Total	0/90 (0%)	Mean 0% Mean 3.33%	SD 0% SD 0%
Overall Incidence #All Organs:	Total	0/90 (0%)				0/90 (0%) 3/90 (3%)		
Malignant Schwannoma  Overall Incidence  #All Organs:    Osteosarcoma  Overall Incidence  #All Organs:	Total	0/90 (0%)				0/90 (0%) 3/90 (3%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Page: 127

Report Date: 11/18/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/90 (0%)				1/84 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/84 (1.19%)	Mean 1.19%	SD 0%
Adrenal Medulla: Pheochromocytoma Benign		0/00 (00)				0/00 (00/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/83 (0%) 0/83 (0%)	Mean 0%	SD 0%
		` '				` ,		
Adrenal Medulla: Pheochromocytoma Maligna	ant							
		0/90 (0%)				2/83 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/83 (2.41%)	Mean 2.41%	SD 0%
Adrenal Medulla: Pheochromocytoma: Benigr						2/83 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/83 (2.41%)	Mean 2.41%	SD 0%
Bone Marrow: Hemangiosarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Bone Marrow: Mast Cell Tumor Malignant		2/22				2/22		
	<b>-</b>	0/90 (0%)		<b>OD</b> 00/	<b>.</b>	0/90 (0%)		00.007
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 128

Report Date: 11/18/2022

Route: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Bone: Hemangioma Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
#Bone: Hemangiosarcoma	•••••				•••••			
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Brain: Meningioma Malignant		0/90 (0%)				0/87 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Malig	nant, NOS	0/00 (00%)				0/07 /00/		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

**Page:** 129

Report Date: 11/18/2022

Vehicle: AIR

			Male			Female			
*Clitoral/Preputial Gland: Mast Cell Tumor						2(22 (22))			
Overall Incidence	Total	1/89 (1%) 1/89 (1.12%)	Mean 1.12%	SD 0%	Total	0/82 (0%) 0/82 (0%)	Mean 0%	SD 0%	
*Epididymis: Mast Cell Tumor		4/00 (40)							
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%					
#Harderian Gland: Adenoma		0/00 (70/)				4/00 (40()			
Overall Incidence	Total	6/90 (7%) 6/90 (6.67%)	Mean 6.67%	SD 0%	Total	4/90 (4%) 4/90 (4.44%)	Mean 4.44%	SD 0%	
#Harderian Gland: Carcinoma	•••••	0/00 (00/)			•••••	0/00 (00/)			
Overall Incidence	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma		0/00 (40%)				4/00 (40()			
Overall Incidence	Total	9/90 (10%) 9/90 (10%)	Mean 10%	SD 0%	Total	4/90 (4%) 4/90 (4.44%)	Mean 4.44%	SD 0%	
#Harderian Gland: Mast Cell Tumor									
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

**Page:** 130

			Male				Female			
#Intestine Small: Duodenum: Adenoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Carcinoma										
		1/90 (1%)				0/90 (0%)				
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Adenoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Adenoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma										
		2/90 (2%)				0/90 (0%)				
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Mast Cell Tumor										
		1/90 (1%)				0/90 (0%)				
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N **Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 131

Report Date: 11/18/2022

Route: Whole Body Exposure

Vehicle: AIR

			Male				Female				
#Intestine Small: Site Unspecified: Adenoma  0/90 (0%)  0/90 (0%)											
Normall Implications	Tatal	` '	Mana 00/	CD 00/	Tatal	` '	Mana 00/	CD 00/			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
Intestine Small: Site Un Carcinoma	specified:										
		3/90 (3%)				0/90 (0%)					
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
fintestine Small: Site Un Carcinoma or Adenom	•										
		3/90 (3%)				0/90 (0%)					
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
Intestine Small: Site Un Mast Cell Tumor											
		1/90 (1%)				0/90 (0%)					
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
Islets, Pancreatic: Adenoma											
		0/88 (0%)				0/87 (0%)					
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%			
'Islets, Pancreatic: Carcinoma		0/88 (0%)				1/87 (1%)					
		0/00 (0%)				1/07 (1/0)					

SD 0%

1/87 (1.15%)

Total

Mean 1.15%

SD 0%

Total

0/88 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 132

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/88 (0%)				1/87 (1%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1.15%)	Mean 1.15%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/90 (0%)				2/89 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/89 (2.25%)	Mean 2.25%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/00 /00/				2/02 /20/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	2/89 (2%) 2/89 (2.25%)	Mean 2.25%	SD 0%
·····		` '				, ,		
*Kidney: Renal Tubule: Hemangiosarcoma		0/00 (00/)				0/00 /00/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mast Cell Tumor		1/90 (1%)				0/89 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Renal Mesenchymal Tumor	•••••	0/90 (0%)				1/89 (1%)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/89 (1%) 1/89 (1.12%)	Mean 1.12%	SD 0%
Sveran incluence	i Ulai	` '				1/09 (1.12%)	IVICALI 1.12/0	30 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 133

			Male				Female	
*Liver: Cholangiocarcinoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		4/00 (40()				0/00 (0%)		
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma		6/90 (7%)				1/89 (1%)		
Overall Incidence	Total	6/90 (6.67%)	Mean 6.67%	SD 0%	Total	1/89 (1.12%)	Mean 1.12%	SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	52/90 (58%) 52/90 (57.78%)	Mean 57.78%	SD 0%	Total	19/89 (21%) 19/89 (21.35%)	Mean 21.35%	SD 0%
*Liver: Hepatocellular Carcinoma		28/90 (31%)				8/89 (9%)		
Overall Incidence	Total	28/90 (31.11%)	Mean 31.11%	SD 0%	Total	8/89 (8.99%)	Mean 8.99%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 134

			Male				Female	
*Liver: Hepatocellular Carcinoma	a or Hepatobl	lastoma						
		32/90 (36%)				9/89 (10%)		
Overall Incidence	Total	32/90 (35.56%)	Mean 35.56%	SD 0%	Total	9/89 (10.11%)	Mean 10.11%	SD 0%
*Liver:								
Hepatocellular Carcinoma	or Hepatoce							
		67/90 (74%)				25/89 (28%)		
Overall Incidence	Total	67/90 (74.44%)	Mean 74.44%	SD 0%	Total	25/89 (28.09%)	Mean 28.09%	SD 0%
*Liver:								
Hepatocellular Carcinoma	a, Hepatocell	ular Adenoma, or Hepato	blastoma					
•	•	68/90 (76%)				25/89 (28%)		
Overall Incidence	Total	68/90 (75.56%)	Mean 75.56%	SD 0%	Total	25/89 (28.09%)	Mean 28.09%	SD 0%
*Liver:								
Hepatocholangiocarcinon	na							
		1/90 (1%)				0/89 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
*Liver:								
Ito Cell Tumor Benign								
no cen rumor benign		0/90 (0%)				0/89 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
		0/50 (0/0)						
*Liver:								
*Liver: Mast Cell Tumor								
		1/90 (1%)				0/89 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

**Page:** 135

			Male				Female	
*Lung: Alveolar/Bronchiolar Ad	enoma							
		13/90 (14%)				3/90 (3%)		
Overall Incidence	Total	13/90 (14.44%)	Mean 14.44%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	rcinoma							
		13/90 (14%)				3/90 (3%)		
Overall Incidence	Total	13/90 (14.44%)	Mean 14.44%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%
		veolar/Bronchiolar Adence 23/90 (26%)		00.00	<b>-</b>	6/90 (7%)	M 0.070;	00.00
Overall Incidence	Total	23/90 (25.56%)	Mean 25.56%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%
*Lung: Hemangiosarcoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Lung: Mast Cell Tumor		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 136

			Male				Female	
#Lymph Node: Mast Cell Tumor								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Axillary: Hemangioma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor		(10)				2(22 (224)		
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma				•••••				
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Mast Cell Tumor		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.7%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Overall incidence	TOTAL	1/90 (1.11%)	wean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 137

			Male				Female					
#Lymph Node, Mesenteric: Mast Cell Tumor Malignant  0/90 (0%)  0/90 (0%)												
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenoma		0/00 (00/)				0/00 /00/						
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Carcinoma												
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Carcinoma or Adenoma		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma											
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma 0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

**Page:** 138

			Male				Female	
#Mesentery: Hemangioma								
_		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Mesentery: Hemangiosarcoma								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Nose: Carcinoma								•••••
		0/90 (0%)				0/89 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
*Nose: Polyp	•••••	0/00 (00/)				0/00 (00/)		
	<b>.</b>	0/90 (0%)		00.00/	<b>+</b>	0/89 (0%)	NA 00/	00.00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

**Page:** 139

			Male				Female	
#Oral Cavity (Oral Mucos		vnx, Tooth, Gingiva):						
	<b>-</b>	0/90 (0%)		<b>OD</b> 00/	<b>+</b>	0/90 (0%)		<b>OD</b> 00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		vnx, Tooth, Gingiva):						
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Overall Incidence #Oral Mucosa:	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Oral Mucosa:						•••••		
Squamous Cell Carcin	oma	0/00 (00/)				0/00 (00/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
						2/75 (3%)		
Overall Incidence					Total	2/75 (2.67%)	Mean 2.67%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign							
						1/75 (1%)		
Overall Incidence					Total	1/75 (1.33%)	Mean 1.33%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 140

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			(10)		
Overall Incidence		Total	1/75 (1%) 1/75 (1.33%)	Mean 1.33%	SD 0%
*Ovary:					
Granulosa-Theca Tumor Malignant			0/75 (0%)		
Overall Incidence		Total	0/75 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma					
Overall Incidence		Total	2/75 (3%) 2/75 (2.67%)	Mean 2.67%	SD 0%
*Ovary: Hemangiosarcoma					
nemangiosa coma			0/75 (0%)		
Overall Incidence		Total	0/75 (0%)	Mean 0%	SD 0%
*Ovary:			•••••		
Luteoma			2/== (22/)		
Overall In aidense		Tatal	0/75 (0%)	Mana 00/	CD 00/
Overall Incidence		Total	0/75 (0%)	Mean 0%	SD 0%
*Ovary:					
Thecoma Benign					
			0/75 (0%)		
Overall Incidence		Total	0/75 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N **Toxicology Data Management System** 

Page: 141

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC Male Female \*Ovary: **Thecoma Malignant** 1/75 (1%)**Overall Incidence** Total 1/75 (1.33%) Mean 1.33% SD 0% \*Ovary: **Tubulostromal Adenoma** 0/75 (0%)**Overall Incidence** Total 0/75 (0%) Mean 0% SD 0% \*Ovary: **Tubulostromal Carcinoma** 0/75 (0%)**Overall Incidence** Total 0/75 (0%) Mean 0% SD 0% ..... \*Pancreas: **Mast Cell Tumor** 1/87 (1%) 0/87 (0%)**Overall Incidence** Total 1/87 (1.15%) Mean 1.15% SD 0% Total 0/87 (0%) Mean 0% SD 0% \*Parathyroid Gland: Carcinoma 0/68 (0%)0/60 (0%)**Overall Incidence** Total 0/68 (0%) Mean 0% SD 0% Total 0/60 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma

SD 0%

6/80

6/80 (7.5%)

Total

(8%)

Mean 7.5%

SD 0%

Total

0/86

0/86 (0%)

(0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

#### **Toxicology Data Management System**

Page: 142

Report Date: 11/18/2022

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC Male **Female** \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/86 (0%)6/80 (8%) 0/86 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 6/80 (7.5%) Mean 7.5% SD 0% ..... \*Pituitary Gland: Pars Intermedia: Adenoma 0/86 (0%)0/80 (0%)**Overall Incidence** Total 0/86 (0%) Mean 0% SD 0% Total 0/80 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/86 (0%)0/80 (0%)Overall Incidence Total 0/86 (0%) Mean 0% SD 0% Total 0/80 (0%) Mean 0% SD 0% ..... \*Pituitary Gland: Pars Intermedia: **Schwannoma Malignant** 0/86 (0%)0/80 (0%)SD 0% **Overall Incidence** Total 0/86 (0%) Mean 0% SD 0% Total Mean 0% 0/80 (0%) ...... \*Prostate: Hemangiosarcoma 0/90 (0%)**Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% \*Prostate: **Mast Cell Tumor** 

SD 0%

Total

1/90

1/90 (1.11%)

(1%)

Mean 1.11%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Page: 143

Report Date: 11/18/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%
Salivary Glands: Mast Cell Tumor		1/90 (1%)				0/89 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/89 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Fibroma								
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%				
Skeletal Muscle: Hemangiosarcoma								
Ŭ		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Osteosarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Length of Study: CHRONIC

Vehicle: AIR

Page: 144

			Male				Female					
#Skeletal Muscle: Rhabdomyosarcoma												
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomyoma											
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Sarcoma												
		1/90 (1%)				0/90 (0%)						
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma												
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skin:				•••••								
Basal Cell Adenoma or B	asosquamous	0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
		·····										
#Skin: Basal Cell Adenoma, Bas	sosquamous T		pithelioma									
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC

Page: 145

			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli	Basal Cell Adendoma	oma, Basosquamous Tui	mor (benign, maligna	nt or				
,,		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
•••••		•••••	•••••	•••••			•••••	
Skin:								
Basal or Sq. Cell Carcil	noma, Carcinom	a, Basosq. Tumor (M or I ratoacanthoma, Trichoep	B), Basal Cell Adenor	ma,				
Adenoma, Papinoma, S	ny rapilioilia, ke	0/90 (0%)	omenoma			0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
		0/30 (0/0)						
Skin:								
Fibroma								
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
							•••••	
#Skin:				_				
Hemangiopericytoma	i, Sarcoma, Myx	oma, Myxosarcoma, Mali	ignant Fibrous Histio	cytoma, or				
ricinarigioperioytoma		1/90 (1%)				6/90 (7%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%
#Skin:								
Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or N	lalignant Fibrous His	tiocytoma				
		1/90 (1%)				6/90 (7%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%
Skin: Fibrosarcoma		0/00 (00/)				0/00 /00/		
		0/90 (0%)		<b>OD O</b>		3/90 (3%)		05.00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

**Page:** 146

Report Date: 11/18/2022

Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	a, or Malignant Fibrous Hi	istiocytoma			5/90 (6%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Skin: Lipoma		1/90 (1%)		OD 00/	T-1-1	1/90 (1%)		OD 00/
Overall Incidence #Skin: Liposarcoma	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histi	ocytoma	1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 147

		Male			Female  0/90 (0%) 0/90 (0%) Mean 0% SD 0%  1/90 (1%) 1/90 (1.11%) Mean 1.11% SD 0%				
Total	0/90 (0%)	Moon 0%	SD 0%	Total	( ,	Moon 0%	SD 0%		
TOLAI									
	` ,		00.00		, ,		00.00		
Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%		
	4/00 (40)				0/00 /00/)				
Total	, ,	Moon 1 110/	SD 0%	Total	` ,	Moon 0%	SD 0%		
	` '			·····					
	2(22 (22))				2/22 (224)				
Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%		
	0/90 (0%)				0/90 (0%)				
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
	0/00 (00/)				0/00 /00/)				
Total	` ,	Mean 0%	SD 0%	Total	( ,	Mean 0%	SD 0%		
	Total	Total 0/90 (0%)  0/90 (0%)  Total 0/90 (0%)  1/90 (1%)  Total 1/90 (1.11%)  0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)  0/90 (0%)	O/90 (0%) Total O/90 (0%)  Mean 0%  O/90 (0%)  Total O/90 (0%)  Mean 0%  1/90 (1%)  Total 1/90 (1.11%)  Mean 1.11%  O/90 (0%)  Total O/90 (0%)  Mean 0%  O/90 (0%)  Total O/90 (0%)  Mean 0%	0/90 (0%)         Total       0/90 (0%)       Mean 0%       SD 0%         Total       0/90 (0%)       Mean 0%       SD 0%         1/90 (1%)         Total       1/90 (1.11%)       Mean 1.11%       SD 0%         Total       0/90 (0%)         Mean 0%       SD 0%         Total         0/90 (0%)       Mean 0%       SD 0%         O/90 (0%)         Total       0/90 (0%)       Mean 0%       SD 0%	Total 0/90 (0%) Mean 0% SD 0% Total  0/90 (0%) Mean 0% SD 0% Total  1/90 (1%) SD 0% Total  1/90 (1.11%) Mean 1.11% SD 0% Total  0/90 (0%) Mean 0% SD 0% Total  7 total 0/90 (0%) Mean 0% SD 0% Total  0/90 (0%) Mean 0% SD 0% Total	O/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)           Total         0/90 (0%)         Mean 0%         SD 0%         Total         1/90 (1%)           Total         0/90 (0%)         Mean 0%         SD 0%         Total         1/90 (1.11%)           Total         1/90 (1.11%)         Mean 1.11%         SD 0%         Total         0/90 (0%)           Total         0/90 (0%)         Mean 0%         SD 0%         Total         2/90 (2.22%)           Total         0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)           Total         0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)           0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)	O/90 (0%)         Mean 0%         SD 0%         Total         O/90 (0%)         Mean 0%           Total         O/90 (0%)         Mean 0%         SD 0%         Total         1/90 (0%)         Mean 0%           Total         O/90 (0%)         Mean 0%         SD 0%         Total         1/90 (1.11%)         Mean 1.11%           Total         1/90 (1%)         Mean 1.11%         SD 0%         Total         0/90 (0%)         Mean 0%           Total         0/90 (0%)         Mean 0%         SD 0%         Total         2/90 (2.22%)         Mean 0%           Total         0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)         Mean 0%           Total         0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)         Mean 0%           0/90 (0%)         Mean 0%         SD 0%         Total         0/90 (0%)         Mean 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure Vehicle: AIR

Page: 148

Report Date: 11/18/2022

Length of Study: CHRONIC

			Male				0 (0%) Mean 0% SD 0% 66 (0%) Mean 0% SD 0% 60 (0%) Mean 0% SD 0% 60 (0%) Mean 0% SD 0% 60 (1%)			
#Spinal Cord: Schwannoma Malignant										
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	` '	Moon 09/	SD 00/		
	TOlal	0/90 (0%)	Weall 0%	۵D 0%		0/90 (0%)		JD 0%		
*Spleen: Hemangiosarcoma										
		0/87 (0%)				` '				
Overall Incidence	Total	0/87 (0%)	Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Mast Cell Tumor Malignant		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Squamous Cell Carcinoma		a Squamous				4/00 (40()				
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%		
······		` '								
#Stomach, Forestomach: Squamous Cell Papilloma										
		0/90 (0%)				1/90 (1%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%		
#Stomach, Glandular: Adenoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

**Page:** 149

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		0/00 (01/)						
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%				
*Testis: Hemangioma		0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%				
*Thymus: Hemangiosarcoma		0/75 (0%)				0/85 (0%)		
Overall Incidence	Total	0/75 (0%)	Mean 0%	SD 0%	Total	0/85 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/75 (00)				0/05 (00/)		
Overall Incidence	Total	0/75 (0%) 0/75 (0%)	Mean 0%	SD 0%	Total	0/85 (0%) 0/85 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	1/86 (1%) 1/86 (1.16%)	Mean 1.16%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 150

				Male				(0%)			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	Total		(0%)	Magn 00/	CD 00/	Total	` '	Magn. 4.450/	SD 00/		
Overall Incidence	Total	0/89 (0%)		Mean 0%	SD 0%	Total	1/86 (1.16%)		SD 0%		
*Thyroid Gland: Follicular Cell Adenoma	:	0/89	(0%)				0/86 (0%)				
Overall Incidence	Total	0/89 (0%)	(0,0)	Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Cell Carcinoma	:	0/89	(0%)				0/86 (0%)				
Overall Incidence	Total	0/89 (0%)	,	Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma			(0%)				0/86 (0%)				
Overall Incidence	Total	0/89 (0%)		Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Carcinoma o		a Squamous	(0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	(-,-)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Papilloma		0/90	(0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	` /	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure Vehicle: AIR

Page: 151

			Male			Female       0/90 (0%)     0/90 (0%)     Mean 0%     SD 0%       0/86 (0%)     0/86 (0%)     Mean 0%     SD 0%       0/90 (0%)     0/90 (0%)     Mean 0%     SD 0%			
#Tooth: Odontoma									
		0/90 (0%)				0/90 (0%)			
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	, ,			
*Urinary Bladder: Mast Cell Tumor									
		1/87 (1%)		05.00/		` ,		05 00/	
Overall Incidence	Total	1/87 (1.15%)	Mean 1.15%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%	
#Uterus: Adenocarcinoma or Ad	lenoma					0/90 (0%)			
Overall Incidence					Total	0/90 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma						0/90 (0%)			
Overall Incidence					Total	0/90 (0%)	Mean 0%	SD 0%	
#Uterus: Fibroma									
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
#Uterus: Granular Cell Tumor Be									
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: Whole Body Exposure

Vehicle: AIR

Page: 152

	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma				•••••	•••••
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1/N

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Page: 153

	Male			Female	
#Vagina: Hemangioma			0/90 (0%)		
Overall Incidence		Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied