Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 44

Report Date: 11/11/2014

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	052020304	07/10/07	730	50(1)	33(694)	52.6	Green tea extract
					Female		
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green tea extract

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 45

			Male			Female			
#All Organs: Benign Tumors									
		43/50 (86%)				20/50 (40%)			
Overall Incidence	Total	43/50 (86%)	Mean 86%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%	
#All Organs: Malignant Tumors		20/50 /500/				40/50 /00%			
Overell Incidence	Total	28/50 (56%)	Maan EGO/	CD 00/	Total	18/50 (36%)	Maan 260/	CD 00/	
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%	
#All Organs: Malignant and Benign T	umors								
		49/50 (98%)				29/50 (58%)			
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%	
#All Organs: Hemangioma									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		2/30 (4%)				` '			
#All Organs: Hemangiosarcoma									
		5/50 (10%)				2/50 (4%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma								
		7/50 (14%)				2/50 (4%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 46

Report Date: 11/11/2014

Route: GAVAGE Vehicle: WATER

			Male		Female			
#All Organs: Histiocytic 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%
#All Organs:								
Malignant Lymphoma: Histi	iocytic, Lym	phocytic, Mixed, NOS, o 4/50 (8%)	r Undifferentiated Ce	ell Type		7/50 (14%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
#All Organs: Mesothelioma: Benign		•••••		•••••		•••••		
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Mal						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%
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incluence		0/30 (0/0)	IVICALI U/0	0 / 0 ط		0/30 (0/0)	ivicail U/0	3D 070

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Page: 47
Report Date: 11/11/2014

Species: MICE Strain: B6C3F1

Vehicle: WATER

			Male				Female			
#All Organs: Osteosarcoma	Total	0/50 (0%)	Maan 00/	SD 00/	Total	0/50 (0%)	Mann 00/	SD 00/		
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%		
*Adrenal Cortex: Adenoma										
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Benign		0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Maligna	ant	0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: Benigi	n, Complex	, Malignant, NOS 0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 48

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Route: GAVAGE Vehicle: WATER

			Male		Male							
#Blood Vessel: 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 Marrow: 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%				
*Bone Marrow: Hemangiosarcoma		•••••										
		1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Bone Marrow: 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%				
#Bone: Fibroma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
		0/30 (0/0)	IVICALI U70	JD 070	1 Olai	0,00 (0,70)	IVICALI U/0	JD 070				

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 49

			Male			Female			
#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: Osteoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma									
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: Granular Cell Tumor Benigr		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 50

			Male			Female			
*Brain: Meningioma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Mal			•••••	•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma Malig		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Glion		toma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Clitoral/Preputial Gland: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 51

Report Date: 11/11/2014

Route: GAVAGE Vehicle: WATER

			Male			Female			
#Coagulating Gland: Granular 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%	
#Coagulating Gland: Sarcoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Adenoma		7/50 (14%)				2/50 (4%)			
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma		8/50 (16%)				4/50 (8%)			
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 52

			ľ	Male			Female			
*Heart: Hemangiosarcoma										
Overall Institutes	Tatal	0/50 (0%	,	0/ CD 00/	Tatal	0/50 (0%)	Maar 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0		Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Adenoma										
		0/50 (0%	,			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0		Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Carcinoma										
Overall Incidence	Total	0/50 (0% 0/50 (0%)	∘) Mean 0	% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
		` ,								
#Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (0%	6)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0		Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Leiomyosarcoma										
-		0/50 (0%	(o)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0		Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Adenoma										
		0/50 (0%	,			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0		Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 53

			Male			Female			
#Intestine Small: Duodenum: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Carcinoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,			TOLAI	0/50 (0%)	iviean 0%		
#Intestine Small: Jejunum: Adenoma		2/22 (221)				0.750 (001)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		` '				, ,			
#Intestine Small: Jejunum: Carcinoma									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma						(70)			
Overall Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Total	1/50 (2%)	Mana 20/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 54

				Male			Female			
#Intestine Small: Site Uns	specified:									
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Uns Carcinoma	specified:									
Overall Incidence	Total	2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Uns Carcinoma or Adenoma	specified:		(4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	` ,	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Uns Leiomyosarcoma			(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Islets, Pancreatic: Adenoma										
Overall Incidence	Total	1/50 (1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Islets, Pancreatic: Carcinoma		4/50	(00/)				0/50 /00/			
Overall Incidence	Total	1/50 (1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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

Route: GAVAGE

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: WATER

Page: 55

			Male				Female				
*Islets, Pancreatic: Carcinoma or Adenoma											
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
*Kidney: Pelvis and Transitio		m:									
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: Pelvis and Transitio Carcinoma or Adenoma		m:									
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: Adenoma		1/50 (2%)				0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma											
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma											
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 56

0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
0/50 (0%		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
`	<i>(</i>)					
`	/ \					
0/50 (0%)		25 22/		0/50 (0%)		05 00/
	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
2/50 (49)	(1)			0/50 (0%)		
*	Mean 4%	SD 0%	Total	` '	Mean 0%	SD 0%
, ,						
2/50 (60)	/ }			4/50 (20/)		
3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
,	,			0/50 (0%)		
2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
05/50 /700	0			10/50 (0.10())		
		SD 0%	Total		Moon 24%	SD 0%
	2/50 (4%) 3/50 (6%) 3/50 (6%) 2/50 (4%) 2/50 (4%) 35/50 (70%)	2/50 (4%) 2/50 (4%) Mean 4% 3/50 (6%) 3/50 (6%) Mean 6% 2/50 (4%) 2/50 (4%) Mean 4% 35/50 (70%) 35/50 (70%) Mean 70%	2/50 (4%) 2/50 (4%) Mean 4% SD 0% 3/50 (6%) Mean 6% SD 0% 2/50 (4%) 2/50 (4%) Mean 4% SD 0% 35/50 (70%) 35/50 (70%) Mean 70% SD 0%	2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 3/50 (6%) 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total	2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) 3/50 (6%) 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) 1/50 (24%) 1/50 (24%) 1/50 (24%)	2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% 3/50 (6%) 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) 1/50 (2%) Mean 2% 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% 35/50 (70%) 12/50 (24%)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 57 Report Date: 11/11/2014

			Male				Female	
*Liver: Hepatocellular Carcinon	na							
•		15/50 (30%)				5/50 (10%)		
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Liver: Hepatocellular Carcinon								
	с. торисово	17/50 (34%)				5/50 (10%)		
Overall Incidence	Total	17/50 (34%)	Mean 34%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Liver: Hepatocellular Carcinon Overall Incidence	na or Hepatoce	Ilular Adenoma 40/50 (80%) 40/50 (80%)	Mean 80%	SD 0%	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%
*Liver: Hepatocellular Carcinon Overall Incidence				SD 0%	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%
*Liver: Hepatocholangiocarcino		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign								
		0/50 (0%)				0/50 (0%)		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 58

otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)											
otal	(,	Mean 0%	SD 0%													
otal ·····	0/50 (0%)	Mean 0%	SD 0%	Total												
				I Ulai	0/50 (0%)	Mean 0%	SD 0%									
	0/50 (0%)				0/50 (0%)											
otal	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%									
	12/50 (24%)				5/50 (10%)											
otal	12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%									
1					1/50 (2%)											
otal	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%									
	ır/Bronchiolar Adenon				6/50 (12%)											
otal	14/50 (28%)	Mean 28%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%									
	0/50 (00/)				0/50 (00/)											
atal .	(,	Maan Oo/	CD 00/	Total	` '	Maan 00/	SD 0%									
1	otal 	12/50 (24%) total 12/50 (24%) total 12/50 (24%) 2/50 (4%) total 2/50 (4%) a or Alveolar/Bronchiolar Adenomental 14/50 (28%) total 14/50 (28%)	12/50 (24%) total 12/50 (24%) total 12/50 (24%) Mean 24% 2/50 (4%) Mean 4% A or Alveolar/Bronchiolar Adenoma 14/50 (28%) total 14/50 (28%) Mean 28%	12/50 (24%) total 12/50 (24%) Mean 24% SD 0% 12/50 (4%) Mean 4% SD 0% 12/50 (4%) Mean 4% SD 0% 14/50 (28%) Mean 4% SD 0% 14/50 (28%) Mean 28% SD 0%	tal 0/50 (0%) Mean 0% SD 0% Total 12/50 (24%) tal 12/50 (24%) Mean 24% SD 0% Total 2/50 (4%) tal 2/50 (4%) Mean 4% SD 0% Total 1 or Alveolar/Bronchiolar Adenoma 14/50 (28%) tal 14/50 (28%) Mean 28% SD 0% Total	12/50 (24%) Mean 0% SD 0% Total 0/50 (0%)	12/50 (24%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 12/50 (24%) Mean 24% SD 0% Total 5/50 (10%) Mean 10% 12/50 (4%) Mean 24% SD 0% Total 5/50 (10%) Mean 10% 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) Mean 2% 1/50 (28%) Mean 2% Mean 2% 1/50 (28%) Mean 28% SD 0% Total 6/50 (12%) Mean 12% 1/50 (28%) Mean 28% SD 0% Total 6/50 (12%) Mean 12% 1/50 (28%) Mean 28% SD 0% Mean 2% Mean 12% 1/50 (28%) Mean 28% SD 0% Mean 12% 1/50 (0%) Mean 12% Mean 12% Mean 12% 1/50 (0%) Mean 12% Mean 12% Mean 12% 1/50 (0%) Mean 12% Mean 12									

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 59

				Male				Female	
#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%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		1/50	(20/)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma							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%
#Mammary Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Ca	rcinoma, or	Adenoma 0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(370)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page**: 60

			Male				Female	
#Mesentery: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: 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%
#Mesentery: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma		0/50 (0%)				1/48 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/48 (2.08%)	Mean 2.08%	SD 0%
*Nose: Hemangiosarcoma		0/50 (0%)				0/48 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 61

			Male				Female	
#Oral Cavity (Oral Mucosa, Papilloma Squamous or F		nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom		nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinom	Tongue, Phary	nx, Tooth, Gingiva):				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcinom		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 62

	Male			Female	
*Ovary: Cystadenoma					
Overall Incidence		Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma				•••••	
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 63

			Male				Female	
*Ovary: Sarcoma						,		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: 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%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Adenoma								
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 64

			Male				Female	
*Pituitary Gland: Pars Distal Carcinoma or Adenoma	lis or Unspec	ified Site:						
		1/49 (2%)				0/50 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intern Adenoma	nedia:							
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intern Carcinoma or Adenoma								
		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: 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%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: 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%
Overall illelucite	ı olai	0/30 (0/0)	IVICALI U/U	JD 070	ı Ulai	0/30 (0/0)	IVICALI U/U	JD 070

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 65

			Male				Female	
*Salivary Glands: Myxoma								
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma							
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 66

			Male				Female	
#Skin: Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	IOS)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				` '		
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (benign, maligna	ant or				
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Auchoma, Fapinoma, 3	oy rapiliolila, Nel	ratoacanthoma, Trichoe	pitiieiiOiiia			2/22 (22/)		
		0/50 (0%)				0/50 (0%)		
#Skin:		0/50 (0%)			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:	•••••	0/50 (0%)			Total	` '	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom	•••••	0/50 (0%) Doma, Myxosarcoma, or F			Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom Overall Incidence	a, Sarcoma, Myxc	0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma			0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Skin: Fibroma, Fibrosarcom Overall Incidence #Skin: Fibrosarcoma	a, Sarcoma, Myxo	0/50 (0%) Doma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom Overall Incidence #Skin:	a, Sarcoma, Myxc	0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma			0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Skin: Fibroma, Fibrosarcom Overall Incidence #Skin: Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	0/50 (0%) Dma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma Mean 0% Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom Overall Incidence #Skin: Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	0/50 (0%) Doma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma Mean 0% Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 67

			Male				Female	
#Skin: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Granular Cell Tumor Beni	ign	0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: 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		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: Keratoacanthoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (00%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 68

			Male				Female	
#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: Mast Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign						0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 69

eport Date: 11/11/2014

			Male				Female			
#Skin: Neurofibroma or Schwannoma benign 0/50 (0%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%										
Overali incidence	ıotaı	0/50 (0%)		SD 0%	ı otal	0/50 (0%)	wean 0%	SD 0%		
#Skin: Neurofibrosarcoma or	Schwannoma (m	alignant or NOS)								
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma, Ne	eurofibroma, or S	schwannoma (benign, ma 0/50 (0%)	alignant or NOS)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Schwannoma Benign		0/50 (0%)				0/50 (0%)				
		U/SU (U%)								

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Page: 70

			Male			Female			
#Skin: Schwannoma Malignant		0(50 (001)				0/50 (00)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell C	Carcinoma, Basosquamo	ous Tumor (malignan	it or 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%	
#Skin: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma o	or Papilloma	0/50 (00/)				0/50 (00)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma,	Papilloma, S	quamous Cell Carcinom 0/50 (0%)	na or Keratoacanthor	na		0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papilloma,	Papilloma, o					0/50 (09/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Control Animal Groups Report Date: 11/11/2014

Page: 71

			Male			Female			
#Spinal Cord: Hemangiosarcoma		0/50 /00/				0/50 (/0//)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangiosarcoma									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Spleen: 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%	
#Stomach, Forestomach: Squamous Cell Carcinoma						4/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma						0/50 /40/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
Stomach, Forestomach: Squamous Cell Papilloma		0/50 /(00/)				4/50 (00)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Animal Groups Report Date: 11/11/2014

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			Male			Female			
#Stomach, Glandular: Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma									
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05 00/		0/50 (0%)		00.004	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 /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%	
					ı Olai		Wealt 076		
*Testes: Adenoma									
		1/50 (2%)							
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%					
*Testes: Hemangioma									
		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Neoplasm NOS									
		0/44 (0%)				0/47 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 73

			Male			Female			
*Thymus: Thymoma Benign Overall Incidence	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/44 (0%)				0/47 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/44 (0%)				0/47 (0%)			
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 74

				Male			Female			
*Thyroid Gland: Follicular Cel Adenoma	l:									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	l:									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Fibrosarcoma		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%	
#Tissue NOS: 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%	
#Tongue: Squamous Cell Carcinoma		a Squamous	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Papilloma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: GAVAGE Vehicle: WATER

			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%	
#Urethra: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma	•••••					0/50 (0%)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangioma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 77
Report Date: 11/11/2014

			Male		Female			
#Zymbal's Gland: Carcinoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
······		` '				` ,		
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied