Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 180

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	059903204	09/21/04	729	50(1)	37(698)	56.4	Pyrogallol	
					Female			
Battelle Columbus Laboratory	059903204	09/20/04	729	50(1)	33(675)	69.3	Pyrogallol	

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 11/11/2014

Length of Study: CHRONIC

Vehicle: ETHANOL

			Male			Female			
#All Organs: Benign Tumors Overall Incidence	Total	42/50 (84%) 42/50 (84%)	Mean 84%	SD 0%	Total	34/50 (68%) 34/50 (68%)	Mean 68%	SD 0%	
#All Organs: Malignant Tumors		33/50 (66%)				34/50 (68%)			
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	34/50 (68%)	Mean 68%	SD 0%	
#All Organs: Malignant and Benign T		47/50 (94%)				42/50 (84%)			
Overall Incidence	Total	47/50 (94%)	Mean 94%	SD 0%	Total	42/50 (84%)	Mean 84%	SD 0%	
#All Organs: Hemangioma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Hemangiosarcoma		5/50 (10%)				6/50 (12%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%	
#All Organs: Hemangiosarcoma or H	emangioma	6/50 (12%)				7/50 (14%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	7/50 (14%)	Mean 14%	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: SKIN Vehicle: ETHANOL Page: 182

				Male			Female			
#All Organs: Histiocytic Sarcoma		1/50	(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Malignant Lymphoma: Histioc	ytic, Lymp			Undifferentiated Ce	ell Type					
Occupation of decree	T - 1 - 1		(4%)	Mara 407	OD 00/	T-1-1	13/50 (26%)	Maran 000/	00,007	
Overall Incidence	Total 	2/50 (4%)		Mean 4%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%	
#All Organs: Mesothelioma: Benign		0/50	(0%)				0/50 (0%)			
	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, Malign		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Malignant		0/50	(00/)				0/50 (0%)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
·····				······				······································		
#All Organs: Osteoma		0/50	(00()				0/50 (0%)			
Overall Incidence	Total	0/50	(0%)	Moon 09/	SD 0%	Total	0/50 (0%)	Moon 09/	SD 0%	
Overali incidence	Total	0/50 (0%)		Mean 0%		Total	0/50 (0%)	Mean 0%	2D 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: SKIN Vehicle: ETHANOL **Page:** 183

			Male			Female			
#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 (00/)				0(50 (00))			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	10tai	0/50 (0%)		3D 0%	ı otal	0/50 (0%)	wiean 0%		
*Adrenal Cortex: Adenoma									
		9/50 (18%)				1/50 (2%)			
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign									
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Maligna									
,		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benigi						2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Male Female

Page: 184

			Male				Female			
#Blood Vessel: Hemangioma		0/50 (001)				2/52 (224)				
		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		2/22 (22)				2(72)				
		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: Hemangiosarcoma		0/50 (0%)				3/50 (6%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%		
		` '				` '				
*Bone Marrow: Mast Cell Tumor Malignant										
made don ramor manghane		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%)		OD		0/50 (0%)		05 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Control Animal Groups Report Date: 11/11/2014

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			Male			Female			
#Bone: Hemangiosarcoma		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	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: SKIN Vehicle: ETHANOL Page: 186

			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, Ma	lignant, 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%	
*Brain: Oligodendroglioma Maliç	gnant	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, Glio						0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Hemangioma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Hemangiosarcoma		1/50 (2%)				0/49 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Page: 187

			Male			Female			
#Coagulating Gland: Granular Cell Tumor									
Overell hasideness	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Coagulating Gland: Sarcoma									
		0/50 (0%)	••	00.007		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	00.007	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Eye: Melanoma Malignant									
Overell Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	SD 0%	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%		
#Harderian Gland: Adenoma		6/50 (12%)				1/50 (2%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
						` '			
#Harderian Gland: Carcinoma									
		2/50 (4%)				2/50 (4%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma		8/50 (16%)				3/50 (6%)			
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
		0/30 (10%)				` '			

^{*:} 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: SKIN Vehicle: ETHANOL Report Date: 11/11/2014

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

ute: SKIN

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			Male				Female			
#Intestine Small: Duodenum: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: 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	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Adenoma	Total	0/50 (0%)	iviean 0%	30 0%	Total	0/50 (0%)	iviean 0%	30 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%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

SD 0%

Mean 0%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female** #Intestine Small: Site Unspecified: 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: Site Unspecified: Carcinoma 1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% #Intestine Small: Site Unspecified: 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 Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Islets, Pancreatic: 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% *Islets, Pancreatic: Carcinoma 1/50 (2%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

1/50 (2%)

Mean 2%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 191

(0%)

Mean 0%

0/50

0/50 (0%)

Total

Report Date: 11/11/2014

SD 0%

			Male				Female					
*Islets, Pancreatic: Carcinoma or Adenoma 2/50 (4%) 1/50 (2%)												
Overall Incidence	Total	2/50 (4 2/50 (4%)	4%) Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
		2/30 (4/0)				1/30 (2/0)						
*Kidney: Pelvis and Transitio Carcinoma	nal Epitheliu	ım:										
		0/50 (0	0%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Kidney: Pelvis and Transitio Carcinoma or Adenoma			0%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Kidney: Renal Tubule: Adenoma			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: Carcinoma												
		0/50 (0	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: Carcinoma or Adenoma												

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 192

			Male				Female			
*Kidney: Renal Tubule: 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%		
*Kidney: Renal Tubule: Hemangiosarcoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*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										
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
Overali incidence		` ,				` '				
*Liver: Hepatoblastoma										
		4/50 (8%)		OD O		1/50 (2%)		00.007		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Liver: Hepatocellular Adenoma										
	.	39/50 (78%)	700/	00.00/	-	30/50 (60%)	NA 000/	00.00/		
Overall Incidence	Total	39/50 (78%)	Mean 78%	SD 0%	Total	30/50 (60%)	Mean 60%	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: SKIN

Page: 193

Report Date: 11/11/2014

SD 0%

Mean 0%

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: **Hepatocellular Carcinoma** 20/50 (40%)17/50 (34%)**Overall Incidence** Total 20/50 (40%) Mean 40% SD 0% Total 17/50 (34%) Mean 34% SD 0% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 21/50 (42%) 18/50 (36%)**Overall Incidence** Total 21/50 (42%) Mean 42% SD 0% Total 18/50 (36%) Mean 36% SD 0% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 43/50 (86%)35/50 (70%)**Overall Incidence** Total 43/50 (86%) Mean 86% SD 0% Total 35/50 (70%) Mean 70% SD 0% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 43/50 (86%) 35/50 (70%) **Overall Incidence** Total 43/50 (86%) Mean 86% SD 0% Total 35/50 (70%) Mean 70% SD 0% *Liver: Hepatocholangiocarcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: **Ito Cell Tumor Benign** 0/50 (0%)0/50 (0%)

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Report Date: 11/11/2014

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Species: MICE Strain: B6C3F1

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
*Liver: Mast Cell Tumor Malignan	t	-1						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Aden								
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Carc								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Carc						4/50 (8%)		
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
*Lung: Hemangiosarcoma		0/50 (00%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} 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: SKIN Vehicle: ETHANOL **Page:** 195

			Mal	e			Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (09	0/ \			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant		0/50 (09				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (09	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma		0/50 (09	,			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (09 0/50 (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 (09	%)			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

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

Length of Study: CHRONIC

			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	•••••							
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		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: 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%
*Nose: Hemangiosarcoma		(0-1)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 197

Report Date: 11/11/2014

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 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 Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Ovary: Choriocarcinoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Cystadenocarcinoma 0/50 (0%)**Overall Incidence** Total SD 0% 0/50 (0%) Mean 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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Animal Groups Report Date: 11/11/2014

Page: 198

	Male			Female		
*Ovary: Cystadenoma						
Overall Incidence	-	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
*Ovary: Granulosa Cell Tumor Benign			(20)			
Overall Incidence	-	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS						
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Ovary: Hemangioma						
Overall Incidence	-	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Ovary: Hemangiosarcoma						
Overall Incidence	-	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 199

			Male				Female	
*Ovary: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	a							
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 Dis 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%

^{*:} 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

Vehicle: ETHANOL

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 200

			Male			Female				
*Pituitary Gland: Pars Distal Carcinoma or Adenoma	lis or Unspecif	fied 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 Intern Adenoma	nedia:	2/ ()				2/22 (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%		
*Pituitary Gland: Pars Intern 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%		
*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%)		25. 22/		0/50 (0%)		05 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 201

			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%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		, ,							
#Skeletal Muscle: Rhabdomyosarcoma or R	Rhabdomyoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma		0/50 (00)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overali incidence	Total	0/50 (0%)			Total	0/50 (0%)			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

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

Length of Study: CHRONIC

			Male				Female	
#Skin:	_							
Basal Cell Carcinoma	or Basosquamou	is Tumor (malignant or	NOS)			0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Maan 00/	SD 0%
Overall incidence		` '					Mean 0%	3D 0%
#Skin:								
Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Adendioma	oma, Basosquamous Tu	ımor (benign, maligna	ant or				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#01-2		•••••	•••••	•••••				
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe		ma,				
, , ap	- q . up	0/50 (0%)	·			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Fibroma, Fibrosarcom	a, Sarcoma, Myxo	oma, Myxosarcoma, or	Fibrous Histiocytoma					
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma								
i ibi osai coma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
	a. Myxosarcoma	, or Fibrous Histiocyton	na					
i ibrosarcoma, sarcom	ia, inykosai coilla	1/50 (2%)	···u			1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
						······		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 203

				Male				Female	
#Skin: Fibrous Histiocytoma			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Granular Cell Tumor Benig	gn	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%
#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%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	,	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Keratoacanthoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50	(00/)				0/50 (09/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 11/11/2014

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

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			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 Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma 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: 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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Skin: Neurofibroma or Schwar	nnoma 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%
#Skin: Neurofibrosarcoma or S	chwannoma (m	alignant 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: Neurofibrosarcoma, Neu	rofibroma, or S	chwannoma (benign, ma 0/50 (0%)	lignant or NOS)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
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: Schwannoma Benign		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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Page: 206

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

r Incidence for Selected Control Animal Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignan	t							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (Carcinoma, Basosquamo	us Tumor (malignan	et or NOS),				
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon	ma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma or Papilloma	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma, Papilloma, S	equamous Cell Carcinoma	a or Keratoacanthon	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 Papillor	ma, Papilloma, o	r Keratoacanthoma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Contract/Lab: All Laboratori
Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 207
Report Date: 11/11/2014

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

		Male					Female			
#Stomach, Glandular: 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%		
#Stomach, Glandular: 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%		
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Testes: Adenoma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Testes: Hemangioma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
*Thymus: Neoplasm NOS										
Overall Incidence	Total	0/48 (0%) 0/48 (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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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	Male					Female			
*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%	
*Thymus: Thymoma Malignant		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, Maligna	ant, NOS	0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

R

Report Date: 11/11/2014

Page: 210

			Male	Female				
*Thyroid Gland: Follicular Cell Adenoma	l:					,		
		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 Cel Carcinoma or Adenoma	l:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma		0/50 (00/)				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incluence		0/30 (0%)			ı Olai	0/30 (0%)	iviean 0%	ال طق U%
#Tissue NOS: Hemangiosarcoma		0/50 (00/)				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%
#Tongue: Squamous Cell Carcinoma o						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 /00/				0/50 /00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overali incidence	Total	0/50 (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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female				
#Tooth: Odontoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						1/50 (2%)		
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%
#Uterus: Hemangioma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 11/11/2014

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	Male			Female				
#Uterus: Hemangiosarcoma			0/50 (00/)					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Leiomyoma			0/50 (00)					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Polyp Stromal			2/50 (60/)					
Overall Incidence		Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%			
#Uterus: Sarcoma			0/50 (0%)					
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal			0/50 (00/)					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal or Polyp Stromal			0/50 (00)					
Overall Incidence		Total	3/50 (6%) 3/50 (6%)	Mean 6%	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: SKIN Vehicle: ETHANOL

Report Date: 11/11/2014

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			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								
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