

# NTP Historical Controls Report

By Route and Vehicle

**MICE** 

July 2015

### REPORT DESCRIPTION

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

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

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

Male
M1
M2
M3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male		Female					
M1	M2	М3	F1	F2	F3			
M4	M5		F4	F5				

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

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

## **Table of Contents**

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Strain: B6C3F1

**Toxicology Data Management System** 

Page: 4

Report Date: 06/29/2015

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

#### **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	059903104	03/17/05	726	50(1)	34(687)	54.6	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl Oxide (Technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					Female		
Battelle Columbus Laboratory	059903104	03/18/05	727	50(5)	31(628)	64.5	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl Oxide (Technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Strain: B6C3F1

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Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		38/50 (76%) 38/50 (76%)	33/50 (66%)	30/50 (60%)		25/50 (50%) 22/50 (44%)	17/50 (34%)	24/50 (48%)
Overall Incidence	Total	139/200 (69.5%)	Mean 69.5%	SD 7.9%	Total	88/200 (44%)	Mean 44%	SD 7.12%
#All Organs: Malignant Tumors								
		35/50 (70%) 21/50 (42%)	27/50 (54%)	27/50 (54%)		28/50 (56%) 18/50 (36%)	19/50 (38%)	16/50 (32%)
Overall Incidence	Total	110/200 (55%)	Mean 55%	SD 11.49%	Total	81/200 (40.5%)	Mean 40.5%	SD 10.63%
#All Organs: Malignant and Benign T		44/50 (88%)	48/50 (96%)	40/50 (80%)		35/50 (70%)	30/50 (60%)	34/50 (68%)
		47/50 (94%)	10,00 (00,70)	(00,00		32/50 (64%)	(30,00	0.000 (0070)
Overall Incidence	Total	179/200 (89.5%)	Mean 89.5%	SD 7.19%	Total	131/200 (65.5%)	Mean 65.5%	SD 4.43%
#All Organs: Hemangioma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#All Organs: Hemangiosarcoma								
		9/50 (18%) 1/50 (2%)	4/50 (8%)	1/50 (2%)		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 7.55%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

			Male				Female	
#All Organs: Hemangiosarcoma or H	lemangioma							
		9/50 (18%) 3/50 (6%)	4/50 (8%)	1/50 (2%)		2/50 (4%) 2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	17/200 (8.5%)	Mean 8.5%	SD 6.81%	Total	6/200 (3%)	Mean 3%	SD 1.15%
#All Organs: Histiocytic Sarcoma		0/50 (00/)	0/50 /40/	4/50 (00/)		4/50 (00()	4/50 (00/)	4/50 /00()
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	4/200 (2%)	Mean 2%	SD 0%
	Histiocytic, Lym	phocytic, Mixed, NOS, or 1/50 (2%)	Undifferentiated Cel 3/50 (6%)	I <b>Type</b> 5/50 (10%)		11/50 (22%)	6/50 (12%)	7/50 (14%)
	Histiocytic, Lym					11/50 (22%) 9/50 (18%)	6/50 (12%)	7/50 (14%)
Malignant Lymphoma: I	Histiocytic, Lym	1/50 (2%)			Total	` '	6/50 (12%) Mean 16.5%	7/50 (14%) SD 4.43%
Malignant Lymphoma: I	Total	1/50 (2%) 3/50 (6%) 12/200 (6%)	3/50 (6%)	5/50 (10%)	Total	9/50 (18%)	,	,
Malignant Lymphoma: I  Overall Incidence  #All Organs:	Total	1/50 (2%) 3/50 (6%) 12/200 (6%)	3/50 (6%)	5/50 (10%)	Total	9/50 (18%)	,	,
Malignant Lymphoma: h  Overall Incidence  #All Organs:  Mesothelioma: Benign,	Total	1/50 (2%) 3/50 (6%) 12/200 (6%) 	3/50 (6%) Mean 6%	5/50 (10%) SD 3.27%	Total Total	9/50 (18%) 33/200 (16.5%) 0/50 (0%)	Mean 16.5%	SD 4.43%
Malignant Lymphoma: h Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence	Total  Malignant, NOS  Total	1/50 (2%) 3/50 (6%) 12/200 (6%) 0/50 (0%) 0/50 (0%)	3/50 (6%)  Mean 6%  0/50 (0%)	5/50 (10%) SD 3.27%  0/50 (0%)		9/50 (18%) 33/200 (16.5%) 0/50 (0%) 0/50 (0%)	Mean 16.5%  0/50 (0%)	SD 4.43% 0/50 (0%)
Overall Incidence  #All Organs:    Mesothelioma: Benign,  Overall Incidence  #All Organs:	Total  Malignant, NOS  Total	1/50 (2%) 3/50 (6%) 12/200 (6%) 0/50 (0%) 0/50 (0%)	3/50 (6%)  Mean 6%  0/50 (0%)	5/50 (10%) SD 3.27%  0/50 (0%)		9/50 (18%) 33/200 (16.5%) 0/50 (0%) 0/50 (0%)	Mean 16.5%  0/50 (0%)	SD 4.43% 0/50 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%
Adrenal Medulla: Pheochromocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
*Adrenal Medulla: Pheochromocytoma Maligna	ınt							
. •		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS											
	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/49 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%			
#Blood Vessel: Hemangioma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Blood Vessel: Hemangiosarcoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
Bone Marrow: Hemangiosarcoma											
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%			
Bone Marrow:  Mast Cell Tumor Malignant											
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

			Male				Female	
Bone Marrow: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
#Bone: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
*Brain: Granular Cell Tumor Beni	ign							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Mali	ignant, NOS							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
#Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		4/50 (8%) 7/50 (14%)	6/50 (12%)	5/50 (10%)		5/50 (10%) 2/50 (4%)	3/50 (6%)	9/50 (18%)
Overall Incidence	Total	22/200 (11%)	Mean 11%	SD 2.58%	Total	19/200 (9.5%)	Mean 9.5%	SD 6.19%
#Harderian Gland: Carcinoma								
		3/50 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%) 8/50 (16%)	7/50 (14%)	6/50 (12%)		6/50 (12%) 3/50 (6%)	3/50 (6%)	10/50 (20%)
Overall Incidence	Total	28/200 (14%)	Mean 14%	SD 1.63%	Total	22/200 (11%)	Mean 11%	SD 6.63%
*Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 13 Report Date: 06/29/2015

			Male			Female	
#Intestine Small: Ileum: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma							
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma							
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1% SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma							
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14 Report Date: 06/29/2015

			Male				Female	
fintestine Small: Site Uns	pecified:							
		0/50 (0%) 1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
fintestine Small: Site Uns Carcinoma	pecified:							
		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma or Adenoma	pecified:	1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	3/30 (0/6)	0/30 (0 %)		1/50 (2%)	0/30 (0 /8)	0/30 (0 /8)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Small: Site Uns Leiomyosarcoma	pecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Islets, Pancreatic: Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
'Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Kidney: Pelvis and Transitio Carcinoma	nal Epitheliu		0/50 (00%)	0/50 (00/)		0/50 (00%)	0/50 (00)	0(50 (00))
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheliu	ım:						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00()	0/50 (00/)	0 (50 (00))		0/50 (00/)	0/50 (00)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma					•••••			
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
*Liver: Hemangiosarcoma								
		9/50 (18%) 0/50 (0%)	4/50 (8%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 8.54%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma								
		3/50 (6%) 2/50 (4%)	3/50 (6%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Liver: Hepatocellular Adenoma								
		31/50 (62%) 32/50 (64%)	26/50 (52%)	23/50 (46%)		17/50 (34%) 13/50 (26%)	7/50 (14%)	5/50 (10%)
Overall Incidence	Total	112/200 (56%)	Mean 56%	SD 8.49%	Total	42/200 (21%)	Mean 21%	SD 11.02%
*Liver: Hepatocellular Carcinoma								
		22/50 (44%) 11/50 (22%)	12/50 (24%)	18/50 (36%)		9/50 (18%) 2/50 (4%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	63/200 (31.5%)	Mean 31.5%	SD 10.38%	Total	21/200 (10.5%)	Mean 10.5%	SD 5.97%
*Liver: Hepatocellular Carcinoma o	or Hepatob	lastoma						
·	-	24/50 (48%) 12/50 (24%)	15/50 (30%)	18/50 (36%)		10/50 (20%) 2/50 (4%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	69/200 (34.5%)	Mean 34.5%	SD 10.25%	Total	22/200 (11%)	Mean 11%	SD 6.83%

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

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

Strain: B6C3F1

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Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18

			Male				Female			
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma										
·	·	39/50 (78%) 39/50 (78%)	35/50 (70%)	31/50 (62%)		20/50 (40%) 15/50 (30%)	12/50 (24%)	8/50 (16%)		
Overall Incidence	Total	144/200 (72%)	Mean 72%	SD 7.66%	Total	55/200 (27.5%)	Mean 27.5%	SD 10.12%		
Liver: Hepatocellular Carcinor		ular Adenoma, or Hepatok								
		39/50 (78%) 39/50 (78%)	36/50 (72%)	31/50 (62%)		20/50 (40%) 15/50 (30%)	12/50 (24%)	8/50 (16%)		
Overall Incidence	Total	145/200 (72.5%)	Mean 72.5%	SD 7.55%	Total	55/200 (27.5%)	Mean 27.5%	SD 10.12%		
Liver: Hepatocholangiocarcin		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%		
Liver: Ito Cell Tumor Benign				•••••		•••••				
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%		
Liver: Mast Cell Tumor Malign	ant									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Control Animal Groups Report Date: 06/29/2015

**Page:** 19

			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
		8/50 (16%) 6/50 (12%)	4/50 (8%)	5/50 (10%)		0/50 (0%) 5/50 (10%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	23/200 (11.5%)	Mean 11.5%	SD 3.42%	Total	7/200 (3.5%)	Mean 3.5%	SD 4.43%
*Lung: Alveolar/Bronchiolar Ca		11/50 (22%)	4/50 (8%)	5/50 (10%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		4/50 (8%)	., 66 (676)	0,00 (10,0)		1/50 (2%)	_,00 (1,0)	(676)
Overall Incidence	Total	24/200 (12%)	Mean 12%	SD 6.73%	Total	4/200 (2%)	Mean 2%	SD 1.63%
Alveolar/Bronchiolar Ca	arcinoma or Al	veolar/Bronchiolar Adeno						
	arcinoma or Al <sup>,</sup> Total	veolar/Bronchiolar Adeno 17/50 (34%) 10/50 (20%) 45/200 (22.5%)	ma 8/50 (16%) Mean 22.5%	10/50 (20%) SD 7.9%	Total	1/50 (2%) 6/50 (12%) 11/200 (5.5%)	3/50 (6%) Mean 5.5%	1/50 (2%) SD 4.73%
Overall Incidence 		17/50 (34%) 10/50 (20%)	8/50 (16%)	,	Total	6/50 (12%)	,	( 12,
Overall Incidence		17/50 (34%) 10/50 (20%)	8/50 (16%)	,	Total	6/50 (12%)	,	( 12,
Overall Incidence *Lung: Hemangiosarcoma Overall Incidence	Total Total	17/50 (34%) 10/50 (20%) 45/200 (22.5%) 1/50 (2%)	8/50 (16%) Mean 22.5%	SD 7.9%	Total Total	6/50 (12%) 11/200 (5.5%) 0/50 (0%)	Mean 5.5%	SD 4.73%
Overall Incidence *Lung: Hemangiosarcoma Overall Incidence	Total Total	17/50 (34%) 10/50 (20%) 45/200 (22.5%) 1/50 (2%) 0/50 (0%) 1/200 (0.5%)	8/50 (16%)  Mean 22.5%  0/50 (0%)  Mean 0.5%	SD 7.9% 0/50 (0%) SD 1%		6/50 (12%) 11/200 (5.5%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 5.5% 0/50 (0%) Mean 0%	SD 4.73% 0/50 (0%) SD 0%
Overall Incidence *Lung: Hemangiosarcoma  Overall Incidence #Lymph Node:	Total Total	17/50 (34%) 10/50 (20%) 45/200 (22.5%) 1/50 (2%) 0/50 (0%)	8/50 (16%)  Mean 22.5%  0/50 (0%)	SD 7.9% 0/50 (0%)		6/50 (12%) 11/200 (5.5%) 0/50 (0%) 0/50 (0%)	Mean 5.5%  0/50 (0%)	SD 4.73% 0/50 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 20

			Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant			- ( ( ( ( ( ( ( ( ( (	()		2/ (221)	2/52 (201)	(22)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Mesentery: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
*Nose: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phary	ynx, Tooth, Gingiva):						
	·	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Carcin Overall Incidence	oma Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/50 (2%) 2/200 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.15%
Oral Cavity (Oral Mucos Squamous Cell Carcin		Squamous, or Papilloma		- ()				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page**: 23

	Male	F	emale
Ovary: Choriocarcinoma			
		1/50 (2%) 0/50 0/50 (0%)	(0%) 0/48 (0%)
Overall Incidence	Tota	,	
Ovary: Cystadenocarcinoma			
		0/50 (0%) 0/50 0/50 (0%)	(0%) 0/48 (0%)
Overall Incidence	Tota	0/198 (0%) Mear	n 0% SD 0%
*Ovary: Cystadenoma			
•		2/50 (4%) 1/50 2/50 (4%)	(2%) 2/48 (4%)
Overall Incidence	Tota		3.54% SD 1.03%
Ovary: Granulosa Cell Tumor Benign			
		0/50 (0%) 0/50 0/50 (0%)	(0%) 1/48 (2%)
Overall Incidence	Tota	1/198 (0.51%) Mean	0.52% SD 1.04%
'Ovary: Granulosa Cell Tumor Malignant			
<u>-</u>		0/50 (0%) 0/50 0/50 (0%)	(0%) 0/48 (0%)
Overall Incidence	Tota		n 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** 

Route: GAVAGE

Vehicle: CORN OIL

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/29/2015

Page: 24

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	1/48 (2%)
Overall Incidence		Total	1/198 (0.51%)	Mean 0.52%	SD 1.04%
*Ovary: Hemangiosarcoma					
-			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence		Total	1/198 (0.51%)	Mean 0.5%	SD 1%
*Ovary: Luteoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence		Total	0/198 (0%)	Mean 0%	SD 0%
*Ovary: Sarcoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence		Total	0/198 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma					
			0/50 (0%) 0/50 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence		Total	1/198 (0.51%)	Mean 0.5%	SD 1%

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

<sup>#:</sup> 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: CORN OIL **Page: 25** 

Mean 6.53%

SD 3.41%

Report Date: 06/29/2015

Length of Study: CHRONIC

Male **Female** \*Ovary: Yolk Sac Carcinoma 0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/198 (0%) Mean 0% SD 0% \*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Mean 0% Overall Incidence Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% ...... \*Pancreas: Carcinoma or Adenoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% \*Parathyroid Gland: Adenoma 0/36 (0%)0/48 (0%)0/48 (0%)0/47 (0%)0/43 (0%)0/44 (0%)0/45 (0%)0/34 (0%)Overall Incidence Total 0/177 (0%) Mean 0% SD 0% Total 0/168 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 (0%)0/50 (0%)0/47 (0%)4/50 (8%)3/49 (6%)(10%)0/50 (0%)1/50 (2%)

SD 0%

Total

13/199 (6.53%)

Total

0/196 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspeci	fied Site:						
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspeci	fied Site:						
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		4/50 (8%) 1/50 (2%)	3/49 (6%)	5/50 (10%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	13/199 (6.53%)	Mean 6.53%	SD 3.41%
*Pituitary Gland: Pars Int Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Pituitary Gland: Pars Int Carcinoma or Adenom								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Salivary Glands: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female		
Salivary Glands: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
Salivary Glands: Hemangiosarcoma									
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
Salivary Glands: Myxoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
Salivary Glands: Myxosarcoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
Seminal Vesicle: Adenoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Skeletal Muscle: Sarcoma		•••••					•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
‡Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 29

			Male				Female					
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)												
	·	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel	Basal Cell Adend	oma, Basosquamous Tun										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%				
¢Skin: Basal or Sq. Cell Carci	inoma, Carcinom	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep	3), Basal Cell Adenon oithelioma	na,								
‡Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	inoma, Carcinom Sq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%)	B), Basal Cell Adenon oithelioma 0/50 (0%)	na, 0/50 (0%)	Total	1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	inoma, Carcinom	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%)	3), Basal Cell Adenon oithelioma	na,	Total		0/50 (0%) Mean 1%	0/50 (0%) SD 1.15%				
#Skin:  Basal or Sq. Cell Carci Adenoma, Papilloma, S  Overall Incidence  #Skin:	inoma, Carcinom Sq Papilloma, Ke Total	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%) 1/200 (0.5%)	B), Basal Cell Adenon oithelioma 0/50 (0%) Mean 0.5%	na, 0/50 (0%)	Total	1/50 (2%)	, ,	, ,				
Adenoma, Papilloma, S  Overall Incidence  #Skin:	inoma, Carcinom Sq Papilloma, Ke Total	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%)	B), Basal Cell Adenon oithelioma 0/50 (0%) Mean 0.5%	na, 0/50 (0%)	Total	1/50 (2%)	, ,	, ,				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S  Overall Incidence  #Skin: Fibroma, Fibrosarcoma	inoma, Carcinom Sq Papilloma, Ke Total	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%) 1/200 (0.5%) oma, Myxosarcoma, or Fi 0/50 (0%)	B), Basal Cell Adenon bithelioma 0/50 (0%) Mean 0.5%	na, 0/50 (0%) SD 1%	Total Total	1/50 (2%) 2/200 (1%) 3/50 (6%)	Mean 1%	SD 1.15%				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S  Overall Incidence  #Skin: Fibroma, Fibrosarcoma	inoma, Carcinom Sq Papilloma, Ke Total a, Sarcoma, Myxo	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%) 1/200 (0.5%) oma, Myxosarcoma, or Fi 0/50 (0%) 1/50 (2%)	B), Basal Cell Adenon oithelioma 0/50 (0%) Mean 0.5% ibrous Histiocytoma 1/50 (2%)	na, 0/50 (0%) SD 1% 0/50 (0%)		1/50 (2%) 2/200 (1%) 3/50 (6%) 1/50 (2%)	Mean 1%	SD 1.15%				
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S  Overall Incidence  #Skin: Fibroma, Fibrosarcoma  Overall Incidence	inoma, Carcinom Sq Papilloma, Ke Total a, Sarcoma, Myxo	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/50 (2%) 1/200 (0.5%) oma, Myxosarcoma, or Fi 0/50 (0%) 1/50 (2%)	B), Basal Cell Adenon oithelioma 0/50 (0%) Mean 0.5% ibrous Histiocytoma 1/50 (2%)	na, 0/50 (0%) SD 1% 0/50 (0%)		1/50 (2%) 2/200 (1%) 3/50 (6%) 1/50 (2%)	Mean 1%	SD 1.15%				

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

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

C131011. 0012013

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: CORN OIL **Page:** 30

			Male				Female				
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma											
	·	0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		3/50 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	6/200 (3%)	Mean 3%	SD 2%			
#Skin: Fibrous Histiocytoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Hemangioma											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Hemangiosarcoma	•••••										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Keratoacanthoma											
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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 **Toxicology Data Management System** 

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin:	Sahurannam - (-	action and an NOS						
Neurofibrosarcoma or S	scnwannoma (m		0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin:	urofibromo or (	Sahwannama (hanian m	olignant or NOS)					
neuronbrosarcoma, ne	uronbroma, or s	Schwannoma (benign, ma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0 %)	0/30 (0 /8)		1/50 (2%)	0/30 (0 /8)	0/30 (0 /8)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		3/50 (6%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	4/200 (2%)	Mean 2%	SD 2.83%
#Skin: Schwannoma Malignan								
<b></b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin:								
Squamous Cell Carcino or Carcinoma	ma, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant o	or NOS),				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%

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

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

31011: 3012013

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: CORN OIL Page: 33

			Male				Female	
#Skin: Squamous Cell Papillo	ma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma	1						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Papilloi Overall Incidence	ma, Papilloma, S	Squamous Cell Carcinom 0/50 (0%) 1/50 (2%) 1/200 (0.5%)	a or Keratoacanthoma 0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
-	na Panilloma o	r Keratoacanthoma						
şskin: Squamous Cell Papilloi	ma, Papilloma, o	or Keratoacanthoma 0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Papillo	ma, Papilloma, o Total	0/50 (0%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%	Total		0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Squamous Cell Papillon		0/50 (0%) 1/50 (2%)	,	(3.1.)	Total	0/50 (0%)	(3.1.)	,
Overall Incidence *Spleen:		0/50 (0%) 1/50 (2%)	,	(3.1.)	Total	0/50 (0%)	(3.1.)	,

<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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 34

			Male				Female	
*Spleen: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (00/)	4/50 (00/)	0(50 (00))		0/50 (00/)	0(50 (00))	0(50 (00))
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma o	Total	0/50 (0%) 5/50 (10%) 9/200 (4.5%)	2/50 (4%) Mean 4.5%	2/50 (4%) SD 4.12%	Total	2/50 (4%) 0/50 (0%) 3/200 (1.5%)	1/50 (2%) Mean 1.5%	0/50 (0%) SD 1.91%
#Stomach, Forestomach: Squamous Cell Papilloma								
Squamous Cen r apinoma		0/50 (0%) 5/50 (10%)	1/50 (2%)	2/50 (4%)		2/50 (4%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 4.32%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 35

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)				
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%				
*Testes: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
		0/50 (0%) 0/47 (0%)	0/49 (0%)	0/40 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/186 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/50 (0%) 0/47 (0%)	1/49 (2%)	0/40 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/186 (0.54%)	Mean 0.51%	SD 1.02%	Total	0/197 (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 Length of Study: CHRONIC

**Toxicology Data Management System** Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Route: GAVAGE

Vehicle: CORN OIL

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Report Date: 06/29/2015

Male **Female** \*Thymus: **Thymoma NOS** 0/50 (0%)0/49 (0%)0/40 (0%)0/50 (0%)0/49 (0%)0/48 (0%)0/47 (0%)0/50 (0%)Overall Incidence Total 0/186 (0%) Mean 0% SD 0% Total 0/197 (0%) Mean 0% SD 0% \*Thymus: Thymoma: Benign, Malignant, NOS 0/50 (0%)1/49 (2%)0/40 (0%)0/50 (0%)0/49 0/48(0%)0/47 (0%)0/50 (0%)Mean 0% Overall Incidence Total 1/186 (0.54%) Mean 0.51% SD 1.02% Total 0/197 (0%) SD 0% .......... \*Thyroid Gland: C-Cell: Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/199 (0.5%) Mean 0.5% SD 1% \*Thyroid Gland: C-Cell: Carcinoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/199 (0.5%) Mean 0.5% SD 1% \*Thyroid Gland: C-Cell: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 2/199 (1.01%) Mean 1% 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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/29/2015 Route: GAVAGE Vehicle: CORN OIL Male **Female** 

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*Thyroid Gland: Follicular Ce Adenoma	II:							
		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/199 (1.01%)	Mean 1%	SD 1.15%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:							
		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/199 (1.01%)	Mean 1%	SD 1.15%
#Tongue: Squamous Cell Carcinoma	or Papillom	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tongue: Squamous Cell Papilloma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tooth: Odontoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

#Urethra:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Hemangiosarcoma

**Overall Incidence** 

\*Urinary Bladder: Hemangiosarcoma

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Granular Cell Tumor Benign** 

#Uterus: Adenoma

#Uterus:

#Uterus: Hemangioma Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)1/50 (2%)(0%)0/50 Total 1/200 (0.5%) Mean 0.5% SD 1%

0/50

0/50

0/50

0/50

1/200 (0.5%)

0/200 (0%)

Total

Total

(0%)

(0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0.5%

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Report Date: 06/29/2015

0/50

1/50

SD 0%

SD 1%

(0%)

(2%)

*: Denominator is number of animals with tissues examined microscopically	/

Total

Total

0/50

0/50

0/200 (0%)

0/50

0/50

0/200 (0%)

(0%)

(0%)

(0%)

(0%)

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

**Toxicology Data Management System** 

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Report Date: 06/29/2015

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

	Male	ı	Female
#Uterus: Hemangiosarcoma		0/50 (001) 0/50	(00)
		0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%) Mea	an 0% SD 0%
#Uterus: Leiomyoma			
		0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%)
Overall Incidence	Total	` '	an 0% SD 0%
#Uterus: Polyp Stromal			
		1/50 (2%) 0/50 0/50 (0%)	(0%) 0/50 (0%)
Overall Incidence	Total	1/200 (0.5%) Mea	n 0.5% SD 1%
#Uterus: Sarcoma Stromal			
		1/50 (2%) 0/50 2/50 (4%)	(0%) 0/50 (0%)
Overall Incidence	Total	,	n 1.5% SD 1.91%
#Uterus: Sarcoma Stromal or Polyp Stromal			
		2/50 (4%) 0/50 2/50 (4%)	(0%) 0/50 (0%)
Overall Incidence	Total	4/200 (2%) Mea	an 2% SD 2.31%

<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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 40

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

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Report Date: 06/29/2015

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Species: MICE Strain: B6C3F1

Vehicle: WATER

Length of Study: CHRONIC

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	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

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: 06/29/2015

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female			
#All Organs: Benign Tumors Overall Incidence	Total	43/50 (86%) 43/50 (86%)	Mean 86%	SD 0%	Total	20/50 (40%) 20/50 (40%)	Mean 40%	SD 0%
	10lai	43/30 (00%)		3D 0%	10tai	20/50 (40%)	40%	
#All Organs: Malignant Tumors		28/50 (56%)				18/50 (36%)		
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
#All Organs: Malignant and Benign T		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		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		F/F0 (400)				0/50 (40/)		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%) 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%

<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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 43

			Male		Female			
#All Organs: Histiocytic Sarcoma		0/50 (0%)		25 24		0/50 (0%)		22.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: His	tiocytic, Lymp	hocytic, Mixed, NOS 4/50 (8%)	, or Undifferentiated Co	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, 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%
#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								
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: Osteosarcoma or Osteom	a	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

**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: 44

			Male	Female				
*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 Ben	ign							
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Mali	ignant	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: Ber	nign, Complex	, <b>Malignant, NOS</b> 0/49 (0%)				0/49 (0%)		22
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Blood Vessel: 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%
#Blood Vessel: 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male		Female			
*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								
	<b>.</b>	0/50 (0%)		OD 00/	<b>-</b>	0/50 (0%)	NA 00/	00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Fibroma		0/50 (00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%)		<b>25 20</b> /		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (00/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overali incidence		, ,				, ,		3D 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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 46

			Male		Female			
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ben	nign							
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 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		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: Granular 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%
#Coagulating Gland: Sarcoma						(0)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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

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Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 47

			Male	Female				
#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								
		1/50 (2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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%
*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: 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%

<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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 48

				Male	Female				
#Intestine Large: Cecum: 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%
#Intestine Large: Cecum: Leiomyosarcoma									
		•	0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma									
		•	0%)		05 00/		0/50 (0%)		05 00/
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									
		0/50 (0	0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	ı	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma									
		•	0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

<sup>#:</sup> 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:** 49

				Male			Female			
#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										
		,	(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										
Overall Incidence	Total	0/50 (	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Site Unspec Adenoma Overall Incidence	cified: 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 Unspec										
			(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 Unspec Carcinoma or Adenoma										
Overall Incidence	Total	2/50 ( 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Overali 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

				Male				Female	
#Intestine Small: Site Unspec	cified:								
		,	0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Adenoma									
		,	2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Carcinoma									
		,	2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma									
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Kidney: Pelvis and Transition 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: Pelvis and Transition Carcinoma or Adenoma		m:	00()				0/50 (0%)		
Overall Insidence	Tatal	,	0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 51

			Male			Female			
*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									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		, ,							
*Kidney: Renal Tubule: 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%	
*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		2/22 (101)				(201)			
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Overall incluence	าบเสเ	2/30 (4%)	IVIEdII 4%	0% ط3	Total	0/30 (0%)	iviean 0%	3D 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 52

			Male			Female			
*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%	
*Liver: Hepatoblastoma									
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma		35/50 (70%)				12/50 (24%)			
Overall Incidence	Total	35/50 (70%)	Mean 70%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%	
*Liver: Hepatocellular Carcinoma		15/50 (30%)				5/50 (10%)			
Overall Incidence	Total	15/50 (30%)	Mean 30%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
*Liver: Hepatocellular Carcinoma c		astoma							
Overall Incidence	Total	17/50 (34%) 17/50 (34%)	Mean 34%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	
*Liver: Hepatocellular Carcinoma c	or Hepatoce	Ilular Adenoma 40/50 (80%)				14/50 (28%)			
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	14/50 (28%)	Mean 28%	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 **Route:** GAVAGE Page: 53 Report Date: 06/29/2015

Species: MICE Strain: B6C3F1

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcinoma,	Hepatocellu	ılar Adenoma, or Hepatob 40/50 (80%)	lastoma			14/50 (28%)		
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	14/50 (28%)	Mean 28%	SD 0%
*Liver: Hepatocholangiocarcinom	a	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: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Mast Cell Tumor Malignant	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%
*Lung: Alveolar/Bronchiolar Aden	oma	12/50 /240/)				5/50 (10%)		
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
*Lung: Alveolar/Bronchiolar Carci								
Occupation of the second	T-1-1	2/50 (4%)	Mara 40/	OD 00/	T-1-1	1/50 (2%)	Marana 00/	OD 00/
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

<sup>#:</sup> 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

Male Female

**Page:** 54

			Male				Female	
*Lung: Alveolar/Bronchiolar Carcin	oma or Alv		oma			0/50 (400/)		
		14/50 (28%)				6/50 (12%)		
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
*Lung: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: 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%
#Lymph Node, Mediastinal: 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%
#Lymph Node, Mesenteric: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Insidence	T-4-1	` ,	Maar 00/	CD 00/	Tatal	` ,	Maaa 00/	CD 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

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page:** 55

Report Date: 06/29/2015

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: WATER

			Male			Female			
#Lymph Node, Mesenteric: Hemangiosarcoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma, C		Adenoma				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Hemangioma		•••••		•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		32 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

Length of Study: CHRONIC

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups

> Route: GAVAGE Vehicle: WATER

**Page:** 56

			Male				Female			
#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%		
*Nose: Adenoma		0/50 (00/)				4/40 (004)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%		
#Oral Cavity (Oral Mucosa, Papilloma Squamous or		nx, Tooth, Gingiva):  0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinon	Tongue, Phary	nx, Tooth, Gingiva):				0/50 /00/				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucosa, Squamous Cell Carcinon	•					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 Carcinon	na	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 57

	Male			Female		
*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%	
*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 Malignant						
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%	

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

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

			Male			Female			
*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%	
*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%	

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

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

			Male				Female			
*Pancreas: Carcinoma or Adenoma	ı						Mean 0% Mean 0%			
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Parathyroid Gland: Adenoma										
		0/41 (0%)				0/35 (0%)				
Overall Incidence	Total	0/41 (0%)	Mean 0%	SD 0%	Total	0/35 (0%)		SD 0%		
*Pituitary Gland: Pars Dis Adenoma	talis or Unspeci	fied Site:								
		1/49 (2%)				0/50 (0%)				
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)		SD 0%		
*Pituitary Gland: Pars Dis Carcinoma										
		0/49 (0%)				0/50 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		fied 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 Inte Adenoma	rmedia:									
		0/49 (0%)				0/50 (0%)				
Overall Incidence	Total	0/49 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

		Male		Female			
lia:							
	,	,			0/50 (0%)		
Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	,	,			` ,		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (00	<b>(1)</b>			0/50 (09/)		
Total	,	,	SD 0%	Total	` '	Mean 0%	SD 0%
	0/50 (0%	6)			0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
					0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 /09	······			0/50 (0%)		
Total	•	,	SD 0%	Total	, ,	Mean 0%	SD 0%
	Total  Total  Total	0/49 (0%) Total 0/49 (0%)  0/50 (0%)  Total 0/50 (0%)	0/49 (0%) Total 0/49 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%  0/50 (0%)  Total 0/50 (0%) Mean 0%  0/50 (0%)  Total 0/50 (0%) Mean 0%  0/50 (0%)  Total 0/50 (0%) Mean 0%  0/50 (0%)  Mean 0%	0/49 (0%)       Total     0/49 (0%)     Mean 0%     SD 0%       O/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       Total     0/50 (0%)     Mean 0%     SD 0%	Total         0/49 (0%)         Mean 0%         SD 0%         Total           0/49 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         Mean 0%         SD 0%         Total	Total 0/49 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total         0/49 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)         Mean 0%

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

<sup>#:</sup> 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	
#Seminal Vesicle: Adenoma								
		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: Rhabdomyosarcoma		0/50 /00/)				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%
·····		, ,					Wearr 470	
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma							
		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								
• " ' '	<b>.</b>	0/50 (0%)		OD 00/	<b>+</b>	0/50 (0%)		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

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: 62

			Male				Female				
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)  0/50 (0%)  0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tur	nor (benign, maligna	nt or		0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
Adenoma, Papilloma, S	<b>Sq Papilloma, Ker</b> Total	a, Basosq. Tumor (M or B atoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	ithelioma Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
		0/50 (0%)				` '	Mean 0%	SD 0%			
	a, Sarcoma, Myxo	oma, Myxosarcoma, or F	brous Histiocytoma			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Fibrosarcoma		0/50 (0%)				0/50 (0%)					
Fibrosarcoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
Fibrosarcoma  Overall Incidence  #Skin:		` '		SD 0%	Total	,	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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 63

			Male				Female	
#Skin: Fibrous Histiocytoma		0/50 (651)				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: 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%
#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								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 64

			Male			Female			
#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		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neurofibrosarcoma or S	Schwannoma (m	alignant or NOS) 0/50 (0%)		<b>05</b>		0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neurofibrosarcoma, Net	urofibroma, 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: Sarcoma		0/50 (051)				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

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:** 65

			Male				Female	
#Skin: Schwannoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell C	•	us Tumor (malignan	t 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 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 Overall Incidence	or Papilloma	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%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	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%

<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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 66

				Male				Female	
*Spleen: Hemangiosarcoma									
			(4%)		22 22/		0/50 (0%)		00.00
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: 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%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		a Squamous	(0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		•••••							
		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Glandular: Carcinoma		0/50	(00/)				0/50 (09/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

<sup>#:</sup> 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:** 67

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence	10tai	0/50 (0%)			Total	0/50 (0%)		3D 0%
*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%
*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 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%

<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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 68

			Male	•			Female	
*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/ \			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce 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%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma		1/50 (2	041			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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page**: 69

Report Date: 06/29/2015

Species: MICE

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female				
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous  0/50 (0%)  0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Papillom	a	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%			
#Tooth: Odontoma		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%			
#Urethra: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Urinary Bladder: 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 (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

**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:** 70

	Male			Female	
#Uterus: Granular Cell Tumor Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Sarcoma 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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Report Date: 06/29/2015

**Page:** 71

			Male				Female	
#Uterus: Sarcoma Stromal or Poly	p Stromal							
Overall Incidence					Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Zymbal's Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma						0/50 (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

**Toxicology Data Management System** 

**Page:** 72

Report Date: 06/29/2015

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

Length of Study: CHRONIC

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052060104 056031106 052051504 052052304 052030306	10/06/08 05/15/06 05/05/08 08/03/09 06/20/05	729 729 729 729 729	50(5) 50(5) 50(5) 50(5) 50(5)	38(708) 39(715) 39(709) 38(692) 29(680)	52.1 54.3 52.6 52.4 53.1	Antimony trioxide Cobalt Metal Working Fluids: CIMSTAR 3800 Metal Working Fluids: Trim VX Vinylidene Chloride
					Female		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052060104 056031106 052051504 052052304 052030306	10/06/08 05/15/06 05/05/08 08/03/09 06/20/05	731 731 731 731 731	50(5) 50(5) 50(5) 50(5) 50(5)	36(692) 36(686) 39(696) 35(692) 36(687)	54.1 66.7 59.2 57.9 66.0	Antimony trioxide Cobalt Metal Working Fluids: CIMSTAR 3800 Metal Working Fluids: Trim VX Vinylidene Chloride

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 73

			Male				Female	
#All Organs: Benign Tumors								
		37/50 (74%) 32/50 (64%)	35/50 (70%) 43/50 (86%)	39/50 (78%)		25/50 (50%) 23/50 (46%)	29/50 (58%) 32/50 (64%)	26/50 (52%)
Overall Incidence	Total	186/250 (74.4%)	Mean 74.4%	SD 8.29%	Total	135/250 (54%)	Mean 54%	SD 7.07%
#All Organs: Malignant Tumors								
		25/50 (50%) 32/50 (64%)	36/50 (72%) 37/50 (74%)	26/50 (52%)		25/50 (50%) 27/50 (54%)	31/50 (62%) 33/50 (66%)	30/50 (60%)
Overall Incidence	Total	156/250 (62.4%)	Mean 62.4%	SD 11.08%	Total	146/250 (58.4%)	Mean 58.4%	SD 6.39%
#All Organs: Malignant and Benign T	umors							
		45/50 (90%) 42/50 (84%)	45/50 (90%) 49/50 (98%)	46/50 (92%)		35/50 (70%) 38/50 (76%)	40/50 (80%) 45/50 (90%)	41/50 (82%)
Overall Incidence	Total	227/250 (90.8%)	Mean 90.8%	SD 5.02%	Total	199/250 (79.6%)	Mean 79.6%	SD 7.4%
#All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#All Organs: Hemangiosarcoma								
-		2/50 (4%) 0/50 (0%)	7/50 (14%) 2/50 (4%)	1/50 (2%)		4/50 (8%) 2/50 (4%)	3/50 (6%) 4/50 (8%)	3/50 (6%)
Overall Incidence	Total	12/250 (4.8%)	Mean 4.8%	SD 5.4%	Total	16/250 (6.4%)	Mean 6.4%	SD 1.67%

<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

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

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Mean 0%

SD 0%

Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Length of Study: CHRONIC Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 2/50 (4%)7/50 (14%)2/50 (4%)4/50 (8%)3/50 (6%)3/50 (6%)0/50 (0%)3/50 (6%)3/50 (6%)4/50 (8%)14/250 (5.6%) Overall Incidence Total Mean 5.6% SD 5.18% Total 17/250 (6.8%) Mean 6.8% SD 1.1% #All Organs: **Histiocytic Sarcoma** 1/50 (2%)1/50 (2%)1/50 (2%)3/50 (6%)1/50 (2%)2/50 (4%)0/50 (0%)2/50 (4%)4/50 (8%)2/50 (4%)Overall Incidence Total 5/250 (2%) Mean 2% SD 1.41% Total 12/250 (4.8%) Mean 4.8% SD 2.28% ...... #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 4/50 (8%)4/50 (8%)3/50 (6%)7/50 (14%)14/50 (28%)18/50 (36%)6/50 (12%)2/50 (4%)10/50 (20%)14/50 (28%)**Overall Incidence** Total 19/250 (7.6%) Mean 7.6% SD 2.97% Total 63/250 (25.2%) Mean 25.2% SD 8.44% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/250 (0%)

Total

0/250 (0%)

Mean 0%

**Overall Incidence** 

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

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

Strain: B6C3F1

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:** 75

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma				•••••				
		4/49 (8%)	1/50 (2%)	9/49 (18%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	3/50 (6%) 18/248 (7.26%)	1/50 (2%) Mean 7.31%	SD 6.73%	Total	0/50 (0%) 2/249 (0.8%)	1/50 (2%) Mean 0.8%	SD 1.1%
*Adrenal Medulla: Pheochromocytoma Benign	························							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/48 (2%)		0/50 (0%) 2/50 (4%)	1/50 (2%) 1/50 (2%)	1/49 (2%)
Overall Incidence	Total	2/247 (0.81%)	Mean 0.82%	SD 1.12%	Total	5/249 (2.01%)	Mean 2.01%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Maligna	ant							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%)
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/249 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%

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

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

\*Adrenal Medulla:

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

\*Bone Marrow:

**Overall Incidence** 

\*Bone Marrow: Hemangiosarcoma

#Blood Vessel: Hemangiosarcoma

#Blood Vessel: Hemangioma

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Male **Female** 0/50 (0%)1/48 (2%)0/50 (0%)1/50 (2%)1/49 (2%)2/50 (4%)2/50 (4%)2/50 (4%)Mean 1.22% 6/249 (2.41%) SD 1.8% Total Mean 2.41% SD 1.67% (0%) (0%) 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89%

0/50

0/49

0/50

0/49

1/249 (0.4%)

0/249 (0%)

Total

Total

(0%)

(0%)

(0%)

(0%)

0/50

0/50

1/50

0/50

(0%)

(0%)

(2%)

(0%)

Mean 0%

Mean 0.4%

0/50

0/50

SD 0%

SD 0.89%

(0%)

(0%)

*.	De	nom	inato	r is	numb	er o	f ani	imals	with	tissues	examined	l microscopio	cally

Pheochromocytoma: Benign, Complex, Malignant, NOS

Total

Total

Total

Total

Total

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(2%)

1/50

1/50

0/50

0/50

Mean 0.4%

Mean 0.8%

(2%)

(2%)

(0%)

(0%)

0/50

SD 1.1%

0/50

SD 0.89%

(0%)

(0%)

0/50

3/247 (1.21%)

0/50

0/50

0/250 (0%)

0/50

0/50

0/250 (0%)

0/49

0/50

2/249 (0.8%)

0/49

1/50

1/249 (0.4%)

**Mast Cell Tumor Malignant** 

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<sup>#:</sup> 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: INHALATION Vehicle: AIR

Page: 77

			Male				Female	
Bone Marrow: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
#Bone: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 78

			Male				Female	
Brain: Granular Cell Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	9%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	9%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maligna	ant, NOS	0/50 (00/)	0/50 (00/)	0/50 /0		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	9%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	9%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	9%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 79

			Male				Female	
#Eye: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		6/50 (12%) 4/50 (8%)	6/50 (12%) 7/50 (14%)	7/50 (14%)		3/50 (6%) 1/50 (2%)	3/50 (6%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	30/250 (12%)	Mean 12%	SD 2.45%	Total	10/250 (4%)	Mean 4%	SD 2%
#Harderian Gland: Carcinoma								
		1/50 (2%) 2/50 (4%)	2/50 (4%) 0/50 (0%)	5/50 (10%)		4/50 (8%) 3/50 (6%)	0/50 (0%) 3/50 (6%)	0/50 (0%)
Overall Incidence	Total	10/250 (4%)	Mean 4%	SD 3.74%	Total	10/250 (4%)	Mean 4%	SD 3.74%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%) 6/50 (12%)	8/50 (16%) 7/50 (14%)	12/50 (24%)		7/50 (14%) 4/50 (8%)	3/50 (6%) 4/50 (8%)	2/50 (4%)
Overall Incidence	Total	40/250 (16%)	Mean 16%	SD 4.69%	Total	20/250 (8%)	Mean 8%	SD 3.74%
Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (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

cision: saizo15

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

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			Male				Female	
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Large: Cecum: Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		2/50 (4%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
fintestine Small: Ileum: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Intestine Small: Jejunum: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Site Uns Adenoma	pecified:							
		2/50 (4%) 2/50 (4%)	2/50 (4%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 1.1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Intestine Small: Site Uns Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Intestine Small: Site Uns Carcinoma or Adenoma								
		3/50 (6%) 2/50 (4%)	2/50 (4%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	1/50 (2%)
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 1.67%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
#Intestine Small: Site Uns Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Adenoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 2/50 (4%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	4/248 (1.61%)	Mean 1.6%	SD 2.19%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 83

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 2/50 (4%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	4/248 (1.61%)	Mean 1.6%	SD 2.19%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Kidney: Pelvis and Transition Carcinoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/49 (0%) 1/249 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
Kidney: Pelvis and Transitio Carcinoma or Adenoma	onal Epitheli	um:						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
Kidney: Renal Tubule:								
Adenoma			0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Adenoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/30 (0 /8)		0/49 (0%)	0/50 (0%)	0/30 (0/8)

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/249 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 85

			Male				Female	
*Liver: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	4/50 (8%) 2/50 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.58%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
*Liver: Hepatoblastoma								
		2/50 (4%) 0/50 (0%)	2/50 (4%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Liver: Hepatocellular Adenoma								
		30/50 (60%) 23/50 (46%)	28/50 (56%) 37/50 (74%)	24/50 (48%)		11/50 (22%) 9/50 (18%)	19/50 (38%) 25/50 (50%)	14/50 (28%)
Overall Incidence	Total	142/250 (56.8%)	Mean 56.8%	SD 11.19%	Total	78/250 (31.2%)	Mean 31.2%	SD 12.93%
Liver:  Hepatocellular Carcinoma								
		15/50 (30%) 21/50 (42%)	25/50 (50%) 26/50 (52%)	11/50 (22%)		6/50 (12%) 7/50 (14%)	10/50 (20%) 8/50 (16%)	10/50 (20%)
Overall Incidence	Total	98/250 (39.2%)	Mean 39.2%	SD 12.93%	Total	41/250 (16.4%)	Mean 16.4%	SD 3.58%
Liver: Hepatocellular Carcinoma o	or Hepatob	lastoma						
-	•	16/50 (32%) 21/50 (42%)	27/50 (54%) 27/50 (54%)	11/50 (22%)		6/50 (12%) 7/50 (14%)	10/50 (20%) 8/50 (16%)	10/50 (20%)
Overall Incidence	Total	102/250 (40.8%)	Mean 40.8%	SD 13.97%	Total	41/250 (16.4%)	Mean 16.4%	SD 3.58%

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

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

\*Liver:

\*Liver:

\*Liver:

\*Liver:

\*Liver:

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

**Overall Incidence** 

**Overall Incidence** 

Overall Incidence

**Overall Incidence** 

**Overall Incidence** 

Ito Cell Tumor Benign

**Mast Cell Tumor Malignant** 

Hepatocholangiocarcinoma

Length of Study: CHRONIC

Hepatocellular Carcinoma or Hepatocellular Adenoma

Total

Total

Total

Total

Total

......

39/50

34/50

187/250 (74.8%)

39/50

34/50

189/250 (75.6%)

1/50

0/50

2/250 (0.8%)

0/50

0/50

0/250 (0%)

0/50

0/50

0/250 (0%)

(78%)

(68%)

(78%)

(68%)

(2%)

(0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

0/50

SD 0%

(0%)

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

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Male **Female** 38/50 (76%)32/50 (64%)14/50 (28%)25/50 (50%)20/50 (40%)(30%)44/50 (88%)15/50 28/50 (56%)Mean 74.8% SD 9.34% Total 102/250 (40.8%) Mean 40.8% SD 12.21% Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 39/50 (78%)32/50 (64%)14/50 (28%)25/50 (50%)(40%)45/50 (90%)15/50 (30%)28/50 (56%)Mean 75.6% SD 10.14% Total 102/250 (40.8%) Mean 40.8% SD 12.21% 0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Mean 0.8% SD 1.1% Total 1/250 (0.4%) Mean 0.4% SD 0.89% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0%

0/50

0/50

1/250 (0.4%)

Total

(0%)

(0%)

1/50

0/50

(2%)

(0%)

Mean 0.4%

0/50

SD 0.89%

(0%)

Page: 86

*.	Danaminatar	ia mumahan	of online old	ith ticoco	avaminad	microscopically

<sup>#:</sup> 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: INHALATION Vehicle: AIR

Page: 87 Report Date: 06/29/2015

			Male				Female	
Lung:								
Alveolar/Bronchiolar A	Adenoma	10/50 (000()	7/50 (4.40()	E/E0 (4004)		4/50 (00/)	0/40 (00/)	4/50 (00/)
		10/50 (20%)	7/50 (14%)	5/50 (10%)		1/50 (2%)	3/49 (6%)	1/50 (2%)
		6/50 (12%)	7/50 (14%)			4/50 (8%)	3/50 (6%)	
verall Incidence	Total	35/250 (14%)	Mean 14%	SD 3.74%	Total	12/249 (4.82%)	Mean 4.82%	SD 2.7%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		4/50 (8%)	11/50 (22%)	8/50 (16%)		2/50 (4%)	5/49 (10%)	4/50 (8%)
		10/50 (20%)	9/50 (18%)	, ,		5/50 (10%)	1/50 (2%)	` '
Overall Incidence	Total	42/250 (16.8%)	Mean 16.8%	SD 5.4%	Total	17/249 (6.83%)	Mean 6.84%	SD 3.68%
•••••				•••••		•••••		
Lung:	Parainama ar Ab	voolor/Bronchiolor Adono						
•	Carcinoma or Alv	veolar/Bronchiolar Adeno		13/50 (26%)		3/50 (6%)	8/49 (16%)	4/50 (8%)
•	Carcinoma or Alv	13/50 (26%)	16/50 (32%)	13/50 (26%)		3/50 (6%)	8/49 (16%) 4/50 (8%)	4/50 (8%)
Alveolar/Bronchiolar C		13/50 (26%) 14/50 (28%)	16/50 (32%) 13/50 (26%)	,	Total	9/50 (18%)	4/50 (8%)	(,
Alveolar/Bronchiolar C	Carcinoma or Alv	13/50 (26%)	16/50 (32%)	13/50 (26%) SD 2.61%	Total	()	` ,	4/50 (8%) SD 5.48%
•		13/50 (26%) 14/50 (28%)	16/50 (32%) 13/50 (26%)	,	Total	9/50 (18%)	4/50 (8%)	(,
Alveolar/Bronchiolar Converall Incidence		13/50 (26%) 14/50 (28%)	16/50 (32%) 13/50 (26%)	,	Total	9/50 (18%)	4/50 (8%)	(,
Alveolar/Bronchiolar Coverall Incidence		13/50 (26%) 14/50 (28%) 69/250 (27.6%)	16/50 (32%) 13/50 (26%) Mean 27.6%	SD 2.61%	Total	9/50 (18%) 28/249 (11.24%)	4/50 (8%) Mean 11.27%	SD 5.48%
Alveolar/Bronchiolar C Overall Incidence Lung: Hemangiosarcoma		13/50 (26%) 14/50 (28%) 69/250 (27.6%) 0/50 (0%)	16/50 (32%) 13/50 (26%) Mean 27.6%	SD 2.61%	Total Total	9/50 (18%) 28/249 (11.24%) 0/50 (0%)	4/50 (8%) Mean 11.27% 0/49 (0%)	SD 5.48%
Alveolar/Bronchiolar Coverall Incidence Lung: Hemangiosarcoma Overall Incidence	Total	13/50 (26%) 14/50 (28%) 69/250 (27.6%) 0/50 (0%) 0/50 (0%)	16/50 (32%) 13/50 (26%) Mean 27.6% 0/50 (0%) 1/50 (2%)	SD 2.61% 0/50 (0%)		9/50 (18%) 28/249 (11.24%) 0/50 (0%) 0/50 (0%)	4/50 (8%) Mean 11.27% 0/49 (0%) 0/50 (0%)	SD 5.48% 0/50 (0%)
Alveolar/Bronchiolar Coverall Incidence Lung: Hemangiosarcoma Overall Incidence	Total	13/50 (26%) 14/50 (28%) 69/250 (27.6%) 0/50 (0%) 0/50 (0%)	16/50 (32%) 13/50 (26%) Mean 27.6% 0/50 (0%) 1/50 (2%)	SD 2.61% 0/50 (0%)		9/50 (18%) 28/249 (11.24%) 0/50 (0%) 0/50 (0%)	4/50 (8%) Mean 11.27% 0/49 (0%) 0/50 (0%)	SD 5.48% 0/50 (0%)
Alveolar/Bronchiolar Coverall Incidence Lung: Hemangiosarcoma Overall Incidence	Total	13/50 (26%) 14/50 (28%) 69/250 (27.6%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	16/50 (32%) 13/50 (26%) Mean 27.6% 0/50 (0%) 1/50 (2%) Mean 0.4%	SD 2.61% 0/50 (0%) SD 0.89%		9/50 (18%) 28/249 (11.24%) 0/50 (0%) 0/50 (0%) 0/249 (0%)	4/50 (8%) Mean 11.27%  0/49 (0%) 0/50 (0%) Mean 0%	SD 5.48% 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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	5/250 (2%)	Mean 2%	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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	5/250 (2%)	Mean 2%	SD 1.41%
#Mammary Gland:								
Fibroma, Fibroadenoma,	, Carcinoma, oı	7 <b>Adenoma</b> 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	5/250 (2%)	Mean 2%	SD 1.41%
#Mesentery: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 90

			Male				Female					
*Nose: Adenoma												
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Oral Cavity (Oral Mucosa Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):										
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Oral Cavity (Oral Mucosa Squamous Cell Carcino		ynx, Tooth, Gingiva):  0/50 (0%)  0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
FOral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phar		0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Oral Mucosa: Squamous Cell Carcino	oma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 91

	Male		Female	
Ovary: Choriocarcinoma				
		0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Cystadenocarcinoma				
		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%
'Ovary: Cystadenoma				
•		1/50 (2%)	1/48 (2%)	2/50 (4%)
		1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	6/248 (2.42%)	Mean 2.42%	SD 0.89%
Ovary: Granulosa Cell Tumor Benign				
•		0/50 (0%)	0/48 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/248 (0.81%)	Mean 0.8%	SD 1.1%
Ovary: Granulosa Cell Tumor Malignant				
· ·		1/50 (2%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

<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 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups
Route: INHALATION
Vehicle: AIR

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	Male			F	emale		
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
		1/50 1/50	(2%) (2%)	0/48 0/50	(0%) (0%)	1/50	(2%)
Overall Incidence	To	otal 3/248 (	, ,	Mean	. ,	SD 1	.1%
Ovary:							
Hemangiosarcoma		1/50	(2%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)		()
Overall Incidence		otal 1/248 (			0.4%	SD 0.	.89%
Ovary: Luteoma							
Lateonia		0/50	(0%)	0/48	(0%)	1/50	(2%)
		0/50	(0%)	1/50	(2%)		
Overall Incidence	Тс	otal 2/248 (	0.81%)	Mean	0.8%	SD 1	.1%
Ovary: Sarcoma							
		0/50	(0%)	0/48	(0%)	0/50	(0%)
		0/50	, ,	0/50	(0%)		
Overall Incidence	Тс	otal 0/248	(0%)	Mea	า 0%	SD	0% 
Ovary: Tubulostromal Adenoma							
		0/50	(0%)	0/48	(0%)	0/50	(0%)
Normall Inc. donor	<del>-</del>	0/50		0/50	(0%)	0.0	00/
Overall Incidence	IC	otal 0/248	` '		า 0%	SD	υ%

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 93 Report Date: 06/29/2015

			Male				Female	
Ovary: Yolk Sac Carcinoma								
						0/50 (0%) 0/50 (0%)	1/48 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/248 (0.4%)	Mean 0.42%	SD 0.93%
Pancreas: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Pancreas: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%
Parathyroid Gland: Adenoma								
		0/27 (0%) 0/28 (0%)	0/29 (0%) 0/26 (0%)	0/34 (0%)		0/27 (0%) 1/35 (3%)	0/28 (0%) 0/24 (0%)	0/26 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%	Total	1/140 (0.71%)	Mean 0.57%	SD 1.28%
Pituitary Gland: Pars Distal Adenoma								
		0/49 (0%) 1/50 (2%)	0/47 (0%) 0/49 (0%)	0/50 (0%)		9/49 (18%) 8/48 (17%)	3/47 (6%) 8/50 (16%)	5/50 (10%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%	Total	33/244 (13.52%)	Mean 13.48%	SD 5.07%

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

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

Strain: B6C3F1

131011. 0012010

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

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			Male				Female	
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspec	ified Site:						
		0/49 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 3/48 (6%)	0/47 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	3/244 (1.23%)	Mean 1.25%	SD 2.8%
Pituitary Gland: Pars Dis Carcinoma or Adenom	stalis or Unspec							
		0/49 (0%) 1/50 (2%)	0/47 (0%) 0/49 (0%)	0/50 (0%)		9/49 (18%) 11/48 (23%)	3/47 (6%) 8/50 (16%)	5/50 (10%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%	Total	36/244 (14.75%)	Mean 14.73%	SD 6.59%
*Pituitary Gland: Pars Int Adenoma								
		0/49 (0%) 0/50 (0%)	0/47 (0%) 1/49 (2%)	0/50 (0%)		0/49 (0%) 0/48 (0%)	0/47 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/244 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Int Carcinoma or Adenom								
		0/49 (0%) 0/50 (0%)	0/47 (0%) 1/49 (2%)	0/50 (0%)		0/49 (0%) 0/48 (0%)	0/47 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/244 (0%)	Mean 0%	SD 0%
*Salivary Glands: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 95

			Male					Female	
Salivary Glands: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
Salivary Glands: Hemangiosarcoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
*Salivary Glands: Myxoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Salivary Glands: Myxosarcoma				•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Seminal Vesicle: Adenoma									
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)				
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%					

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 96

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SI	D 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma		0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

### **Toxicology Data Management System**

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Report Date: 06/29/2015

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/250 (0%) Mean 0% SD 0% 0/250 (0%) **Overall Incidence** Total Total Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosg. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 0/50 0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)2/50 (4%)0/50 (0%)(2%)1/50 (2%)0/50 (0%)2/50 (4%)1/50 6/250 (2.4%) **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total Mean 2.4% SD 2.19% #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)(2%)0/50 (0%) (0%)(2%)1/50 0/50 1/50 **Overall Incidence** Total SD 0.89% SD 1.1% 1/250 (0.4%) Mean 0.4% Total 2/250 (0.8%) Mean 0.8%

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups Report Date: 06/29/2015 Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibrosarcoma, Sarcoma,	, Myxosarcoma	a, or Fibrous Histiocytoma	a					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%
#Skin: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Hemangioma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	<b>OD</b>		0/50 (0%)	0/50 (0%)	05 / 500/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
#Skin: Keratoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	0/30 (0%) Mean 0%	SD 0%
Over all illicidence	i Ulai	1/230 (0.4/0)	WEATT 0.470	JD 0.03/0	TUlai	0/200 (0/0)	IVICALI U/0	3D 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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 99

			Male				Female	
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign								
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor	•••••							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

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

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

Strain: B6C3F1

**31011.** 3012013

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:** 100

			Male				Female	
#Skin:								
Neurofibrosarcoma or So	:hwannoma (m	•						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma, Neur	rofibroma, or s	` •	•	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/250 (1.2%)	1/50 (2%) Mean 1.2%	SD 1.79%
#Skin: Schwannoma Malignant				•••••				
Schwannoma Mangham		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell (	Carcinoma, Basosquamo	us Tumor (malignant c	or NOS),				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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

### **Toxicology Data Management System**

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Report Date: 06/29/2015

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** #Skin: Squamous Cell Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/250 (0.4%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0.4% SD 0.89% #Skin: Squamous Cell Papilloma or Papilloma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)(0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 1/250 (0.4%) Mean 0.4% SD 0.89% \*Spleen: Hemangiosarcoma 2/49 (4%)3/50 (6%)0/50 (0%)0/50 (0%)2/49 (4%)1/50 (2%)

SD 2.69%

0/50

6/249 (2.41%)

Total

(0%)

3/50

(6%)

SD 2.62%

Mean 2.42%

Total

0/49

7/248 (2.82%)

(0%)

2/50

Mean 2.82%

(4%)

**Overall Incidence** 

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

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

\*Spleen:

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

#Stomach, Glandular: Carcinoma

#Stomach, Forestomach: Squamous Cell Papilloma

#Stomach, Forestomach: **Squamous Cell Carcinoma** 

#Stomach, Forestomach:

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Mast Cell Tumor Malignant** 

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

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Male **Female** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/249 (0.4%) 0/248 (0%) Mean 0% SD 0% Total Mean 0.41% SD 0.91% (0%) (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% **Squamous Cell Carcinoma or Papilloma Squamous** 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)3/250 (1.2%) Mean 1.2% SD 1.1% Total 3/250 (1.2%) Mean 1.2% SD 1.1% 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)3/250 (1.2%) Mean 1.2% SD 1.1% Total 3/250 (1.2%) Mean 1.2% SD 1.1%

0/50

0/50

1/250 (0.4%)

Total

(0%)

(0%)

0/50

1/50

(0%)

(2%)

Mean 0.4%

0/50

SD 0.89%

(0%)

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Report Date: 06/29/2015

Total

Total

Total

Total

Total

0/50

0/50

1/250 (0.4%)

......

(0%)

(0%)

0/50

0/50

Mean 0.4%

(0%)

(0%)

1/50

SD 0.89%

(2%)

<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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 103

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Testes: Adenoma								
		0/49 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%				
*Testes: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%				
*Thymus: Neoplasm NOS								
		0/41 (0%) 0/44 (0%)	0/42 (0%) 0/39 (0%)	0/41 (0%)		0/47 (0%) 0/48 (0%)	1/46 (2%) 0/47 (0%)	0/44 (0%)
Overall Incidence	Total	0/207 (0%)	Mean 0%	SD 0%	Total	1/232 (0.43%)	Mean 0.43%	SD 0.97%
*Thymus: Thymoma Benign								
		0/41 (0%) 0/44 (0%)	0/42 (0%) 0/39 (0%)	0/41 (0%)		0/47 (0%) 0/48 (0%)	0/46 (0%) 0/47 (0%)	0/44 (0%)
Overall Incidence	Total	0/207 (0%)	Mean 0%	SD 0%	Total	0/232 (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

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 104

			Male				Female	
Thymus: Thymoma NOS								
		0/41 (0%) 0/44 (0%)	0/42 (0%) 0/39 (0%)	0/41 (0%)		1/47 (2%) 0/48 (0%)	0/46 (0%) 0/47 (0%)	0/44 (0%)
Overall Incidence	Total	0/207 (0%)	Mean 0%	SD 0%	Total	1/232 (0.43%)	Mean 0.43%	SD 0.95%
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/41 (0%) 0/44 (0%)	0/42 (0%) 0/39 (0%)	0/41 (0%)		1/47 (2%) 0/48 (0%)	0/46 (0%) 0/47 (0%)	0/44 (0%)
Overall Incidence	Total	0/207 (0%)	Mean 0%	SD 0%	Total	1/232 (0.43%)	Mean 0.43%	SD 0.95%
Thyroid Gland: C-Cell:								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

<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

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male					Female	
*Thyroid Gland: Follicular Cell Adenoma	l:								
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50	(0%)		0/48 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%		Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma									
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50	(0%)		0/48 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%		Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Squamous Cell Carcinoma of the Control of the Contr	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Papilloma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 106

			Male				Female	
#Urethra: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma						2/52 (221)		0.50
		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
fUterus: Granular Cell Tumor Be	nign							
	-					1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Uterus: Hemangioma								
J						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/250 (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

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 107

	Male		Female	
#Uterus: Hemangiosarcoma				
Hemangiosarcoma		1/50 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	1700 (270)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%
			•••••	
Uterus: Leiomyoma				
		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Uterus: Polyp Stromal				
1 dip di di di		4/50 (8%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	(,
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 2.97%
Uterus: Sarcoma Stromal				
Carooma Caromai		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(0,0)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal				
Caronia Carina or ropp on onlar		4/50 (8%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	2.22 (070)
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 2.97%

<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 Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 108

			Male		Female			
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (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:** 109

Report Date: 06/29/2015

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

Length of Study: CHRONIC

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
Male										
Battelle Columbus Laboratory	059601406	09/26/06	730	50(1)	25(660)	55.9	Water Disinfection Byproducts: Bromodichloroacetic Acid			
					Female					
Battelle Columbus Laboratory	059601406	09/25/06	729	50(5)	30(680)	63.5	Water Disinfection Byproducts: Bromodichloroacetic Acid			

Strain: B6C3F1

**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:** 110

			Male				Female	
#All Organs: Benign Tumors								
		43/50 (86%)				36/50 (72%)		
Overall Incidence	Total	43/50 (86%)	Mean 86%	SD 0%	Total	36/50 (72%)	Mean 72%	SD 0%
#All Organs: Malignant Tumors		00/50 (000/)				04/50 (000)		
Overall Incidence	Total	30/50 (60%)	Maan 600/	CD 00/	Total	31/50 (62%)	Maan 600/	SD 0%
Overall incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	31/50 (62%)	Mean 62%	
#All Organs: Malignant and Benign T	umors							
		48/50 (96%)				45/50 (90%)		
Overall Incidence	Total	48/50 (96%)	Mean 96%	SD 0%	Total	45/50 (90%)	Mean 90%	SD 0%
#All Organs: Hemangioma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	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							
		5/50 (10%)				6/50 (12%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%

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

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

IOII. 3012013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Report Date: 06/29/2015

Page: 111

			Male				Female	
#All Organs: Histiocytic Sarcoma								
•		1/50 (2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Malignant Lymphoma: Histi								
manghan Lymphomai mon	.ooyo, _y	0/50 (0%)	or oriumoronilatou o	, po		6/50 (12%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS	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: Mesothelioma: Malignant		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: Osteoma		- 1						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

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

<sup>#:</sup> 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: 06/29/2015

Imor Incidence for Selected Control Anima **Route:** ORAL

Vehicle: WATER

			Male				Female	
*Adrenal Cortex: Adenoma		2/50 (4%)				0/49 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma 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%
*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: Benigr	n, Complex,	Malignant, NOS 0/50 (0%)		OD 00/	<del>-</del>	0/50 (0%)		00.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#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%
#Blood Vessel: 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

Strain: B6C3F1

\*Bone Marrow: Hemangiosarcoma

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

#Bone: Fibroma

#Bone: Osteoma

#Bone:

\*Bone Marrow: Sarcoma

\*Bone Marrow:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

**Mast Cell Tumor Malignant** 

.....

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

SD 0%

SD 0%

Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) 0/50 (0%)1/50 (2%)

Total

Total

1/50 (2%)

1/50

1/50 (2%)

(2%)

Page: 113

Mean 2%

Mean 2%

SD 0%

SD 0%

Report Date: 06/29/2015

Total

Total

Total

Total

Total

Total

0/50 (0%)

0/50

0/50 (0%)

(0%)

Mean 0%

Mean 0%

Osteosarcoma or Osteoma

<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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

ence for Selected Control Animal Route: ORAL

Page: 114

Report Date: 06/29/2015

Vehicle: WATER

			Male				Female	
#Bone: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Beni	gn							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mali	gnant, NOS	1/50 (2%)			•••••	0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Coagulating Gland: Granular 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%
Coagulating Gland: Sarcoma								
		0/50 (0%)				0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 115

			Male				Female	
#Eye: Melanoma Malignant		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: Adenoma		0/50 (4004)				5/50 (4004)		
Overall Incidence	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		6/50 (12%)				5/50 (10%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Heart: 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%
#Intestine Large: Cecum: Carcinoma		4/50 (00)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/29/2015

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

			Male				Female	
#Intestine Large: Cecum: 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%
#Intestine Large: Cecum: Leiomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: 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%
#Intestine Small: Duodenum: 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: 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 (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

Strain: B6C3F1

**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: 117

				Male				Female	
#Intestine Small: Jejunum: Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma									
			(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: Leiomyosarcoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	cified:								
		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec									
		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: Site Unspec Carcinoma or Adenoma			(60()				0/50 /00/		
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall illulation	ıvıaı	3/30 (6%)		IVICALI 070	עט עט 🗥	ıvıaı	0/30 (076)	IVIEAN U70	3D 0%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Page: 118

Mean 0%

Man -- 00/

Report Date: 06/29/2015

SD 0%

CD 00/

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total Mean 0% \*Islets, Pancreatic: Adenoma 0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0%

0/49

0/49 (0%)

Total

(0%)

*Islets,	P	ar	ıcr	eat	ic	::
0	٠					_1

**Overall Incidence** 

\*Islets, Pancreatic: Carcinoma

Carcinoma or Adenoma

.....

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

SD 0%

## \*Kidney: Pelvis and Transitional Epithelium:

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%	

## \*Kidney: Pelvis and Transitional Epithelium:

Carcinoma or Adenoma

		0/50 (0%)				0/50 (0	%)
Overell Incidence	Total	0/50 (00/)	Moon Oo/	CD 00/	Total	0/50 (09/)	

Mean 0%

Overali incidence	rotai	0/50 (0%)	iviean 0%	SD 0%	rotai	0/50 (0%)	wean 0%	SD 0%	

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

Total

0/50

0/50 (0%)

(0%)

<sup>#:</sup> 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: ORAL Vehicle: WATER **Page:** 119

			Male			Female			
*Kidney: Renal Tubule: Adenoma									
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Cholangiocarcinoma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma									
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Length of Study: CHRONIC

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

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Report Date: 06/29/2015

SD 0%

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** \*Liver: Hemangiosarcoma 1/50 (2%)2/49 (4%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 2/49 (4.08%) Mean 4.08% SD 0% \*Liver: Hepatoblastoma 4/50 (8%)0/49 (0%)**Overall Incidence** Total 4/50 (8%) Mean 8% SD 0% Total 0/49 (0%) Mean 0% SD 0% \*Liver: Hepatocellular Adenoma 39/50 (78%)33/49 (67%) **Overall Incidence** Total 39/50 (78%) Mean 78% SD 0% Total 33/49 (67.35%) Mean 67.35% SD 0% ...... \*Liver: **Hepatocellular Carcinoma** 12/50 (24%)9/49 (18%) **Overall Incidence** Total 12/50 (24%) Mean 24% SD 0% Total Mean 18.37% SD 0% 9/49 (18.37%) \*Liver: Hepatocellular Carcinoma or Hepatoblastoma 15/50 (30%)9/49 (18%) **Overall Incidence** Total 15/50 (30%) Mean 30% SD 0% Total 9/49 (18.37%) Mean 18.37% SD 0%

SD 0%

36/49

36/49 (73.47%)

Total

(73%)

Mean 73.47%

Total

42/50

42/50 (84%)

(84%)

Mean 84%

Hepatocellular Carcinoma or Hepatocellular Adenoma

\*Liver:

**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

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/29/2015

Page: 121

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female			
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma										
		42/50 (84%)				36/49 (73%)				
Overall Incidence	Total	42/50 (84%)	Mean 84%	SD 0%	Total	36/49 (73.47%)	Mean 73.47%	SD 0%		
*Liver: Hepatocholangiocarcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
*Liver: Ito Cell Tumor Benign										
		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Liver: Mast Cell Tumor Malignant		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar Adeno										
		13/50 (26%)				3/50 (6%)				
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%		
*Lung: Alveolar/Bronchiolar Carcin		7/50 (14%)				2/50 (4%)				
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
Overall incluence		` '				` '				

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

<sup>#:</sup> 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: ORAL Vehicle: WATER

Length of Study: CHRONIC

I Animal Groups Report Date: 06/29/2015

Page: 122

	Male					Female				
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 19/50 (38%) 5/50 (10%)										
Overall Incidence	Total	19/50 (38%)	Mean 38%	SD 0%	Total	5/50 (10%)	Mean 10%	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%		
#Lymph Node: Hemangiosarcoma		0/50 (00())				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Lymph Node, Mandibular: 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%		
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#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%		

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE

Page: 123

Report Date: 06/29/2015

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female			
#Lymph Node, Mesenteric: 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%		
#Mammary Gland: Carcinoma		2(-2)				(-2)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
		` ,								
#Mammary Gland: Carcinoma or Adenoma										
		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Mammary Gland: Fibroma, Fibroadenoma, C		· 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%		
#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%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
Overall incluence	ıotal	0/30 (0%)	iviean 0%	3D 0%	Total	1/30 (2%)	IVICALI 2%	3D 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: 124 Report Date: 06/29/2015

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

			Male				Female			
#Mesentery: Lipoma 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%		
#Oral Cavity (Oral Mucosa Papilloma Squamous o	a, Tongue, Phary					0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva):								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos	a, Tongue, Phary	/nx, Tooth, Gingiva): Gquamous, 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 Mucosa: Squamous Cell Carcino	oma	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 125

Report Date: 06/29/2015

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Choriocarcinoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% ..... \*Ovary: Cystadenocarcinoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% ..... \*Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Overall Incidence** SD 0% Total Mean 0% 0/50 (0%) \*Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/50 (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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 126

		Male					Female			
*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%		
*Ovary: Sarcoma										
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenoma						(201)				
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	0/49 (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

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 127

			Male			Female				
*Pancreas: Carcinoma or Adenoma										
		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Parathyroid Gland: Adenoma										
		0/44 (0%)				0/45 (0%)				
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Distali Adenoma	s or Unspeci	fied Site: 0/50 (0%)				2/49 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%		
*Pituitary Gland: Pars Distali Carcinoma	s or Unspecif	fied Site: 0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Distali Carcinoma or Adenoma										
		0/50 (0%)				2/49 (4%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%		
*Pituitary Gland: Pars Interm Adenoma										
		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 128

Report Date: 06/29/2015

Vehicle: WATER

			Male				Female		
*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma									
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma or Adenoma									
Occupation of demand	T-1-1	0/50 (0%)	Maran 00/	OD 00/	T-1-1	0/48 (0%)	M 00/	00.00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Salivary Glands: 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%	
*Salivary Glands: Myxoma									
		0/50 (0%)				0/48 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Myxosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
		0/30 (0/6)				` '			

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 06/29/2015

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female #Seminal Vesicle:** Adenoma 0/50 (0%)**Overall Incidence** 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 Rhabdomyoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 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** 

SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

SD 0%

Total

0/50

0/50 (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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 130

			Male			Female			
#Skin:	B	- T	100)						
Basai Celi Carcinoma (	or Basosquamou	s Tumor (malignant or N 0/50 (0%)	103)			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, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (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%	
		a, Basosq. Tumor (M or ratoacanthoma, Trichoel 0/50 (0%) 0/50 (0%)		ma, SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxc	oma, Myxosarcoma, or F	ibrous Histiocytoma			4/50 (8%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	
#Skin: Fibrosarcoma		0/50 (00/)				0/50 (00)			
Overell Insidence	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytom 1/50 (2%)	a			4/50 (8%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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

## **Toxicology Data Management System**

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

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Page:** 131

Report Date: 06/29/2015

Route: ORAL Vehicle: WATER

			Male				Female			
#Skin: Fibrous Histiocytoma	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 00/	Total	3/50 (6%)	Moon COV	SD 0%		
Overall Incidence	Total	1/50 (2%)	wiean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	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		4/50 (00)				4/50 (00()				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Skin: 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					•••••					
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: Liposarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

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

<sup>#:</sup> 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: ORAL Vehicle: WATER Report Date: 06/29/2015

**Page:** 132

			Male			Female			
#Skin: Melanoma Benign									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: 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%	
#Skin: Neural Crest Tumor		0/50 (00/)				0(50 (00))			
Overall Incidence	Total	0/50 (0%)	Mean 0%	CD 00/	Total	0/50 (0%)	Mean 0%	SD 0%	
		0/50 (0%)		SD 0%		0/50 (0%)			
#Skin: Neurofibrosarcoma or S	chwannoma (m					3/50 (6%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Skin: Neurofibrosarcoma, Neu						3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Skin: Sarcoma		0/50 (00)				4/50 (00()			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
Overall incluence	างเลา	0/50 (0%)	iviean 0%	3D 0%	Total	1/50 (2%)	IVIEAN 2%	SD 0%	

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 06/29/2015

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male			Female			
#Skin: Schwannoma Malignant		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Skin: Squamous Cell Carcinoma or Carcinoma	ı, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	t 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	or Papilloma	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
≴Skin: Squamous Cell Papilloma,		quamous Cell Carcinoma 0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
≴Skin: Squamous Cell Papilloma,	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%	

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

<sup>#:</sup> 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:** 134

Report Date: 06/29/2015

mor incidence for Selected Contro

Route: ORAL

Vehicle: WATER

			Male			Female			
*Spleen: Hemangiosarcoma		2/50 (4%)				0/49 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Spleen: Mast Cell Tumor Malignant		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma						0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma						1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma									
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, Glandular: Carcinoma		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%	

<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

Report Date: 06/29/2015

**Page:** 135

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

		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%)						
Total	1/50 (2%)	Mean 2%	SD 0%				
Total	0/50 (0%)	Mean 0%	SD 0%				
Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/45 /00/				0/50 /00/		
Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	Total  Total  Total	Total 0/50 (0%)  1/50 (2%)  Total 1/50 (2%)  0/50 (0%)  Total 0/50 (0%)  Total 0/45 (0%)  Total 0/45 (0%)  Total 0/45 (0%)  0/45 (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%  0/45 (0%) Total 0/45 (0%)  Total 0/45 (0%)  Mean 0%  0/45 (0%)  Mean 0%	O/50 (0%)         Mean 0%         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         0/45 (0%)         Mean 0%         SD 0%           Total         0/45 (0%)         Mean 0%         SD 0%           O/45 (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 0/50 (0%) Mean 0% SD 0%  Total 0/45 (0%) Mean 0% SD 0% Total  0/45 (0%) Mean 0% SD 0% Total  0/45 (0%) Mean 0% SD 0% Total	0/50 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           1/50 (2%)         Mean 2%         SD 0%         Total         0/50 (0%)           Total         1/50 (2%)         Mean 2%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/45 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           Total         0/45 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           Total         0/45 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)           0/45 (0%)         Mean 0%         SD 0%         Total         0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 1/50 (2%) Mean 2% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/45 (0%) Mean 0%  O/50 (0%) Mean 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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 136

			Male				Female	
*Thymus: Thymoma: Benign, Malignar	nt, NOS	0/45 (00/)				0/50 (00/)		
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

**Report Date:** 06/29/2015

Page: 137

**Species:** MICE **Strain:** B6C3F1

Vehicle: WATER

			Male				Female	
#Tongue: Squamous Cell Carcinor	ma or Papilloma					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%
#Tongue: Squamous Cell Papillom	a	0/50 (0%)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		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%
#Urethra: Hemangiosarcoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		······································			·····			GD 078
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 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 138

	Male	Female					
#Uterus: Granular Cell Tumor Benign							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Hemangioma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Hemangiosarcoma							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Uterus: Leiomyoma			0/50 (0%)				
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Polyp Stromal							
Overall Incidence		Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%		
#Uterus: Sarcoma 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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/29/2015

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

,
SD 0%
SD 0%
SD 0%

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

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