

# NTP Historical Controls Report

By Route and Vehicle

**MICE** 

August 2016

# REPORT DESCRIPTION

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

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

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

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

the data would be shown as:

	Male			Female	
M1	M2	M3	F1	F2	F3
M4	M5		F4	F5	

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

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

# **Table of Contents**

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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: 4

Report Date: 08/03/2016

### **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	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 Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					Female		
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 Ether Mixture [DE-71 (Technical Grade)]
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Page: 5

Report Date: 08/03/2016

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Benign Tumors** 33/50 (66%)30/50 (60%)38/50 (76%)17/50 (34%)24/50 (48%)22/50 (44%)**Overall Incidence** Total 101/150 (67.33%) Mean 67.33% SD 8.08% Total 63/150 (42%) Mean 42% SD 7.21% #All Organs: **Malignant Tumors** 27/50 (54%)27/50 (54%)21/50 (42%)19/50 (38%)16/50 (32%)18/50 (36%)**Overall Incidence** Total 75/150 (50%) Mean 50% SD 6.93% 53/150 (35.33%) Mean 35.33% SD 3.06% Total #All Organs: **Malignant and Benign Tumors** 48/50 (96%)40/50 (80%)47/50 (94%)30/50 (60%)34/50 (68%) 32/50 (64%)Overall Incidence Total 135/150 (90%) Mean 90% SD 8.72% Total 96/150 (64%) Mean 64% SD 4% ..... #All Organs: Hemangioma 0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% Total 3/150 (2%) Mean 2% SD 0% **#All Organs:** Hemangiosarcoma 4/50 (8%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 6/150 (4%) Mean 4% SD 3.46% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#All Organs:** Hemangiosarcoma or Hemangioma 4/50 (8%)1/50 (2%)3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)**Overall Incidence** Mean 5.33% SD 3.06% 4/150 (2.67%) Mean 2.67% SD 1.15% Total 8/150 (5.33%) Total

<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

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		2/50 (4%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 0%
All Organs: Malignant Lymphoma: Histi	ocytic, Lyn	nphocytic, Mixed, NOS, o	· Undifferentiated Cel	l Type				
5 , 1	• . •	3/50 (6%)	5/50 (10%)	3/50 (6%)		6/50 (12%)	7/50 (14%)	9/50 (18%)
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 2.31%	Total	22/150 (14.67%)	Mean 14.67%	SD 3.06%
#All Organs: Mesothelioma: Benign, Mali	gnant, NO	<b>S</b> 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant				0/50		(20)		2/22 (221)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteoma		3,100 (0.8)				0,100 (0,0)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

# **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: 7

		Male				Female	
	0/50 (0%)	0/50 (0%)	1/50 (2%)		2/49 (4%)	0/50 (0%)	0/50 (0%)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/149 (1.34%)	Mean 1.36%	SD 2.36%
ign							
	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	1/50 (2%)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%
nign, Complex		1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	1/50 (2%)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00)	0/50 (00)	0/50 /00/
Total	` '	, ,	, ,	Total	` '	` ,	0/50 (0%) SD 0%
1 Otal				10tai	0/130 (0/0)	ivicaii 070	JD 070
	(20)	2/52 (221)	0.50		2/52 (224)	2/12 (221)	2/22 (224)
	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
	nign Total nign, Complex	Total 1/150 (0.67%)  nign  O/50 (0%)  Total 1/150 (0.67%)  nign, Complex, Malignant, NOS  O/50 (0%)  Total 1/150 (0.67%)  O/50 (0%)  Total 0/150 (0%)  O/50 (0%)	0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67%  nign  0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67%  nign, Complex, Malignant, NOS  0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67%   0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%	O/50 (0%)	O/50 (0%)	O/50 (0%)	O/50 (0%)   O/50 (0%)   O/50 (0%)   1/50 (2%)   2/49 (4%)   O/50 (0%)     Total   1/150 (0.67%)   Mean 0.67%   SD 1.15%   Total   2/149 (1.34%)   Mean 1.36%     O/50 (0%)   1/50 (2%)   O/50 (0%)   O/49 (0%)   O/49 (0%)     Total   1/150 (0.67%)   Mean 0.67%   SD 1.15%   Total   1/148 (0.68%)   Mean 0.67%     Nign, Complex, Malignant, NOS   O/50 (0%)   O/50 (0%)   O/49 (0%)   O/49 (0%)     Total   1/150 (0.67%)   Mean 0.67%   SD 1.15%   Total   1/148 (0.68%)   Mean 0.67%     Total   1/150 (0.67%)   Mean 0.67%   SD 1.15%   Total   1/148 (0.68%)   Mean 0.67%     Total   O/50 (0%)   O/50 (0%)   O/50 (0%)   Total   1/150 (2%)   O/50 (0%)     Total   O/150 (0%)   Mean 0%   SD 0%   Total   1/150 (0.67%)   Mean 0.67%     Total   O/150 (0%)   Mean 0%   SD 0%   Total   O/150 (0%)   Mean 0%   Mean 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female	
Bone Marrow: Mast Cell Tumor Malignant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Bone Marrow: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page**: 9

			Male				Female	
Brain: Granular Cell Tumor Beni	ign							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mal	lignant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Coagulating Gland: Granular Cell Tumor		0/50 (0%)	0/50 (0%)	1/50 (2%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Coagulating Gland: Sarcoma								
Normall In addance	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 /00()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Trefail incluence	TULAI	0/100 (0%)	IVIEALL 070	3D 0%	TOTAL	0/130 (0%)	IVICALI 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

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Report Date: 08/03/2016

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Harderian Gland: Adenoma 6/50 (12%)5/50 (10%)7/50 (14%) 3/50 (6%)9/50 (18%) 2/50 (4%)**Overall Incidence** Total 18/150 (12%) Mean 12% SD 2% 14/150 (9.33%) Mean 9.33% SD 7.57% Total #Harderian Gland: Carcinoma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #Harderian Gland: Carcinoma or Adenoma 7/50 (14%) 6/50 (12%) 8/50 (16%) 3/50 (6%)10/50 (20%) 3/50 (6%)**Overall Incidence** 21/150 (14%) Mean 14% SD 2% 16/150 (10.67%) Mean 10.67% SD 8.08% Total Total ...... \*Heart: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) #Intestine Large: Cecum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (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%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/150 (0%) Total 0/150 (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

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

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			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma		0/50 (00/)		0(50 (00))		4/50 (000)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Intestine Small: Duodenum: Adenoma								
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Intestine Small: Duodenum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous						0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

**Page:** 12

Report Date: 08/03/2016

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
fIntestine Small: Site Unspec Adenoma	cified:							
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Intestine Small: Site Unspec Carcinoma	cified:							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspec Carcinoma or Adenoma	cified:							
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

**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:** 13

			Male				Female	
#Intestine Small: Site Unspec Leiomyosarcoma	cified:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
fintestine Small: Site Unspec Polyp Adenomatous	cified:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Islets, Pancreatic: Adenoma		4/50 (00)	4/50 /00/	0/50 (00%)		0/50 (000)	4/50 (00()	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Kidney: Pelvis and Transitio Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

**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: 14

			Male				Female	
Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		2/72 (201)	2/52 (224)	2/52 (22/)		2/22 (22)	2/52 (224)	2/22 (224)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male		Female				
Liver: Hemangiosarcoma									
	T-1-1	4/50 (8%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver: Hepatoblastoma									
		3/50 (6%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma		26/50 (52%)	23/50 (46%)	32/50 (64%)		7/50 (14%)	5/50 (10%)	13/50 (26%)	
Overall Incidence	Total	81/150 (54%)	Mean 54%	SD 9.17%	Total	25/150 (16.67%)	Mean 16.67%	SD 8.33%	
Liver: Hepatocellular Carcinoma		12/50 (24%)	18/50 (36%)	11/50 (22%)		6/50 (12%)	4/50 (8%)	2/50 (4%)	
Overall Incidence	Total	41/150 (27.33%)	Mean 27.33%	SD 7.57%	Total	12/150 (8%)	Mean 8%	SD 4%	
*Liver: Hepatocellular Carcinoma o								•••••	
pa.iooonala. oalonionia o		15/50 (30%)	18/50 (36%)	12/50 (24%)		6/50 (12%)	4/50 (8%)	2/50 (4%)	
Overall Incidence	Total	45/150 (30%)	Mean 30%	SD 6% `	Total	12/150 (8%)	Mean 8%	SD 4%	
*Liver: Hepatocellular Carcinoma o	or Hepatoc		04/50 (000)	00/50 (700)		40/50 (0.40)	0/50 (400/)	45/50 (000)	
Overell lesidence	Tatal	35/50 (70%)	31/50 (62%)	39/50 (78%)	Tatal	12/50 (24%)	8/50 (16%)	15/50 (30%)	
Overall Incidence	Total	105/150 (70%)	Mean 70%	SD 8%	Total	35/150 (23.33%)	Mean 23.33%	SD 7.02%	

<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

Length of Study: CHRONIC

Page: 16

			Male				Female	
Liver: Hepatocellular Carcino	oma. Hepatocell	lular Adenoma, or Hepatol	olastoma					
		36/50 (72%)	31/50 (62%)	39/50 (78%)		12/50 (24%)	8/50 (16%)	15/50 (30%)
Overall Incidence	Total	106/150 (70.67%)	Mean 70.67%	SD 8.08%	Total	35/150 (23.33%)	Mean 23.33%	SD 7.02%
Liver: Hepatocholangiocarcir	noma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Mast Cell Tumor Malig								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A								
Overall Incidence	Total	4/50 (8%) 15/150 (10%)	5/50 (10%) Mean 10%	6/50 (12%) SD 2%	Total	1/50 (2%) 7/150 (4.67%)	1/50 (2%) Mean 4.67%	5/50 (10%) SD 4.62%
						` ,		
Lung: Alveolar/Bronchiolar C	arcinoma							
		4/50 (8%)	5/50 (10%)	4/50 (8%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
Lung: Alveolar/Bronchiolar C	Carcinoma or Al	veolar/Bronchiolar Adeno	ma					
		8/50 (16%)	10/50 (20%)	10/50 (20%)		3/50 (6%)	1/50 (2%)	6/50 (12%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 2.31%	Total	10/150 (6.67%)	Mean 6.67%	SD 5.03%

<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: 17

			Male				Female	
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overali incidence	10tai	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)		5D 0%
Lymph Node, Mediastinal: Mast Cell Tumor Malignant		0/50 (00)	0.750 (001)	(20)		2/22 (221)	2/22 (224)	2/52 (221)
O	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 18

			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Mammary Gland: Fibroma, Fibroadenoma o								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C	Carcinoma, or	· Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Mesentery: Hemangioma		0/50 (0%)	0/50 /00/	0/50 /00/		0/50 (00/)	0/50 (00()	0/50 /00()
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female	
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Adenoma		0/00 (05)	(00)	0.50		2/22 (22.)		
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Polyp								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phary							
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Cavity (Oral Mucos Squamous Cell Carcing	sa, Tongue, Phary							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

**Page:** 20

			Male				Female	
Oral Cavity (Oral Mucosa Squamous Cell Carcino		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Oral Mucosa: Squamous Cell Carcino	oma				•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Ovary: Cystadenocarcinoma								
verall Incidence					Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
ovary: Cystadenoma								
verall Incidence					Total	1/50 (2%) 5/148 (3.38%)	2/48 (4%) Mean 3.39%	2/50 (4%) SD 1.21%
ovary: Granulosa Cell Tumor E	Benign							
verall Incidence					Total	0/50 (0%) 1/148 (0.68%)	1/48 (2%) Mean 0.69%	0/50 (0%) SD 1.2%
vary: Granulosa Cell Tumor M	Malignant							
verall Incidence					Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

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: 21

	Male		Female	
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (00)	4/40 (00%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/148 (0.68%)	1/48 (2%) Mean 0.69%	0/50 (0%) SD 1.2%
Ovary: Granulosa-Theca Tumor Malignant				
verall Incidence	Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Hemangiosarcoma				
overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Luteoma				
verall Incidence	Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
Dvary: Sarcoma				
verall Incidence	Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Tubulostromal Adenoma				
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/48 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 22 Report Date: 08/03/2016

			Male				Female	
*Ovary: Yolk Sac Carcinoma						0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
Parathyroid Gland: Adenoma		•••••						•••••
Overall Incidence	Total	0/48 (0%) 0/141 (0%)	0/48 (0%) Mean 0%	0/45 (0%) SD 0%	Total	0/43 (0%) 0/121 (0%)	0/44 (0%) Mean 0%	0/34 (0%) SD 0%
Pituitary Gland: Pars Dis	talis or Unspeci							
Adenoma			247 (224)	2/52 (221)		2/12 (22/)	<b>-</b> ( (4.004)	(201)
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	3/49 (6%) 9/149 (6.04%)	5/50 (10%) Mean 6.04%	1/50 (2%) SD 4%
Pituitary Gland: Pars Dis Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pituitary Gland: Pars Dis	talis or Unspeci							
Carcinoma or Adenoma		0/50 (0%)	0/47 (0%)	0/50 (0%)		3/49 (6%)	5/50 (10%)	1/50 (2%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	9/149 (6.04%)	Mean 6.04%	SD 4%
Pituitary Gland: Pars Inte Adenoma	rmedia:							
		0/50 (0%)	0/47 (0%)	0/50 (0%)		1/49 (2%)	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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

> Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

**Page:** 23

			Male				Female	
Pituitary Gland: Pars Interm Carcinoma	edia:							
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/50 (0%)	0/47 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
Pituitary Gland: Pars Interm Schwannoma Malignant	edia:							
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

# **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: 24

			Male				Female		
Salivary Glands: Hemangiosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (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%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/30 (0%)	0/30 (0%) Mean 0%	0/30 (0%) SD 0%					
Skeletal Muscle: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0(50 (00))		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
verali ilicidence 		` '				` '			
Skeletal Muscle: Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Skeletal Muscle: Rhabdomyosarcoma or R	Rhabdomyoma	a							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

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

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

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: CORN OIL **Page:** 25

			Male				Female	
Skeletal Muscle: Sarcoma								
Nevall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	3D 0%
Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin:		ıs Tumor (malignant or N						
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tun	nor (benign, malignar			0/50 (0%)	0/50 (0%)	1/50 (2%)
	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Overall Incidence		( . , . )				,		
Skin: Basal or Sq. Cell Carci	noma, Carcinom	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep	ithelioma	•				
Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%)	oithelioma 0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep	ithelioma	•	Total		0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Adenoma, Papilloma, S Overall Incidence #Skin:	noma, Carcinom Sq Papilloma, Ke Total	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/150 (0.67%)	ithelioma 0/50 (0%) Mean 0.67% brous Histiocytoma	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin:	noma, Carcinom Sq Papilloma, Ke Total	a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 1/150 (0.67%)	ithelioma 0/50 (0%) Mean 0.67%	1/50 (2%)	Total	0/50 (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

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Report Date: 08/03/2016

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibrosarcoma** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 2/150 (1.33%) Mean 1.33% SD 1.15% Total ...... #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15% 3/150 (2%) Mean 2% SD 0% Total #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (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%)**Overall Incidence** Total Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% 0/150 (0%) #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Skin: Keratoacanthoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.67% 0/150 (0%) Mean 0% SD 0% 1/150 (0.67%) SD 1.15% Total

<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**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Strain: B6C3F1 Length of Study: CHRONIC

Contract/Lab: All Laboratories

ed Control Animal Groups Report Date: 08/03/2016
AVAGE

Page: 27

			Male				Female	
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
≄Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor		2/22 (22)				2/22 (22)	(201)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or S	chwannoma (r	malignant or NOS) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Neurofibrosarcoma, Neu	rofibroma, or	Schwannoma (benign, ma	alignant or NOS) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/03/2016

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%	b)	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Carcinom or Carcinoma	a, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)	0/50 (0%	<b>b</b> )	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Papilloma	1	0/50 (0%)	0/50 (0%)	0/50 (0%	```	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	0/30 (0%) Mean 0%	SD 0%	o) Total	0/50 (0%)	0/30 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papilloma	or Papilloma	0/50 (0%)	0/50 (0%)	0/50 (0%	5)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, c	or Keratoacanthoma 0/50 (0%)	0/50 (0%)	1/50 (2%	5)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

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: CORN OIL Page: 29

			Male			Female				
Spleen: Hemangiosarcoma		1/50 (00/)	4/50 /00/	1/50 (20/)		0/50 (00/)	0/50 (00/)	4/50 (20/)		
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Spleen: Mast Cell Tumor Malignant										
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Stomach, Forestomach: Squamous Cell Carcinoma										
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Stomach, Forestomach: Squamous Cell Carcinoma		na Squamous								
verall Incidence	Total	2/50 (4%) 9/150 (6%)	2/50 (4%) Mean 6%	5/50 (10%) SD 3.46%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		
Stomach, Forestomach: Squamous Cell Papilloma										
verall Incidence	Total	1/50 (2%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	5/50 (10%) SD 4.16%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		
Stomach, Glandular: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

**Page:** 30

			Male			Female				
#Stomach, Glandular: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Testes: Adenoma					•••••					
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%						
*Thymus: Neoplasm NOS		0/40 /00/	0/40 /00/	0/47 (00/)	•••••	0/40 (00)	0/40 (00/)	0/50 (00/)		
Overall Incidence	Total	0/49 (0%) 0/136 (0%)	0/40 (0%) Mean 0%	0/47 (0%) SD 0%	Total	0/49 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%		
*Thymus: Thymoma Benign										
Overall Incidence	Total	1/49 (2%) 1/136 (0.74%)	0/40 (0%) Mean 0.68%	0/47 (0%) SD 1.18%	Total	0/49 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%		
*Thymus: Thymoma NOS								•••••		
Overall Incidence	Total	0/49 (0%) 0/136 (0%)	0/40 (0%) Mean 0%	0/47 (0%) SD 0%	Total	0/49 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%		
*Thymus: Thymoma: Benign, Malign	nant, NOS									
Overall Incidence	Total	1/49 (2%) 1/136 (0.74%)	0/40 (0%) Mean 0.68%	0/47 (0%) SD 1.18%	Total	0/49 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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

**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:** 31

			Male				Female	
Thyroid Gland: C-Cell: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/30 (0%) SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
		, ,				2/100 (1.00/0)		
Thyroid Gland: Follicular Ce Adenoma	II:	2/22 (221)	./=-	2/22 (224)		(J=0 (OO))	(00)	2(72 (221)
O	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous						
-	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Sele

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 32

			Male			Female				
#Tongue: Squamous Cell Papilloma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Гооth: Odontoma										
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%		
Urethra: Hemangiosarcoma										
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Jrinary Bladder: Hemangiosarcoma										
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%		
Uterus: Adenoma										
						0/50 (0%)	1/50 (2%)	0/50 (0%)		
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
Uterus: Granular Cell Tumor Benign	1									
						0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 33

	Male			Female	
#Uterus: Hemangioma			0/50 (00())	1/50 (004)	0/50 (00)
Overall Incidence		Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Polyp Stromal					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%

<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:** 34

			Male			Female			
#Zymbal's Gland: Carcinoma		2/22 (221)	(170	2(72)		2(22)	2/52 (221)	(20)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 35

Report Date: 08/03/2016

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical		
					Male				
Battelle Columbus Laboratory	052020304	07/10/07	730	50(1)	33(694)	52.6	Green Tea Extract		
Female									
Battelle Columbus Laboratory	052020304	07/09/07	729	50(5)	34(665)	62.9	Green Tea Extract		

Strain: B6C3F1

#All Organs: **Benign Tumors** 

#All Organs:

#All Organs:

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Malignant Tumors** 

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Total

Total

Total

Total

43/50

43/50 (86%)

28/50

28/50 (56%)

49/50

49/50 (98%)

2/50

2/50 (4%)

(86%)

(56%)

(98%)

(4%)

Species: MICE

Length of Study: CHRONIC

......

**Malignant and Benign Tumors** 

.....

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Male

Mean 86%

Mean 56%

Mean 98%

Mean 4%

Vehicle: WATER Female 20/50 (40%)SD 0% Total 20/50 (40%) Mean 40% SD 0% 18/50 (36%)SD 0% Total 18/50 (36%) Mean 36% SD 0%

29/50

0/50

0/50 (0%)

29/50 (58%)

Total

Total

(58%)

(0%)

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Mean 58%

Mean 0%

Report Date: 08/03/2016

SD 0%

SD 0%

#All Organs:
Hemangioma

#All Organs: Hemangiosarcoma								
_		5/50 (10%)				2/50 (4%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs:								•••••

SD 0%

SD 0%

Hemangiosarcoma or Hemangioma

7/50 (14%)2/50 (4%)

**Overall Incidence** Total 7/50 (14%) Mean 14% SD 0% Total SD 0% 2/50 (4%) Mean 4%

\*: Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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				Male			Female			
#All Organs: Histiocytic Sarcoma										
-		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs:										
Malignant Lymphoma: Histic	ocytic, Lymp	chocytic, Mixed	, NOS, or	Undifferentiated Ce	ell Type					
		4/50	(8%)				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, Mali	gnant, 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%	
#All Organs: Mesothelioma: Malignant		0/50	(224)				0/50 (00)			
		0/50	(0%)				0/50 (0%)		00.00	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50	(00()				0/50 (00)			
	<b>.</b>	0/50	(0%)		<b>OD</b> 00/	<b>T</b>	0/50 (0%)		00.007	
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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

AVAGE

**Page:** 38

		Male				Female		
	1/49 (2%)				0/49 (0%)			
Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
	0/40 (00/)				0/40 (00/)			
Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
n, Complex	0/49 (0%)				0/49 (0%)			
Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
<b>.</b>	0/50 (0%)	NA 00/	05.00/	<b>-</b>	0/50 (0%)		<b>OD</b> .00/	
ı otal	0/50 (0%)	Mean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%	
	1/50 (2%)				1/50 (2%)			
Total	, ,	Mean 2%	SD 0%	Total	` '	Mean 2%	SD 0%	
	Total n, Complex Total	Total 1/49 (2.04%)  O/49 (0%)  Total 0/49 (0%)  A, Complex, Malignant, NOS  O/49 (0%)  Total 0/49 (0%)  O/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)	1/49 (2%) Total 1/49 (2.04%) Mean 2.04%  0/49 (0%) Total 0/49 (0%) Mean 0%  1, Complex, Malignant, NOS 0/49 (0%) Total 0/49 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%  1/50 (2%)	Total 1/49 (2%) Total 1/49 (2.04%) Mean 2.04% SD 0%    O/49 (0%)	1/49 (2%) Total 1/49 (2.04%) Mean 2.04% SD 0% Total  0/49 (0%) Total 0/49 (0%) Mean 0% SD 0% Total  n, Complex, Malignant, NOS 0/49 (0%) Total 0/49 (0%) Mean 0% SD 0% Total  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total  1/50 (2%)	Total 1/49 (2%) Total 1/49 (2.04%) Mean 2.04% SD 0% Total 0/49 (0%)    O/49 (0%)	Total 1/49 (2%) Total 1/49 (2.04%) Mean 2.04% SD 0% Total 0/49 (0%)  Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  1, Complex, Malignant, NOS 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (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

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:** 39

			Male			Female			
*Bone Marrow: Mast Cell Tumor Malignant									
_		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Bone Marrow: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Fibroma		- ( )				(704)			
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/	
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteoma									
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Total	0/50 (0%)	Mana 00/	SD 0%	
	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%		
#Bone: Osteosarcoma or Osteoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma									
		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:** 40

			Male				Female					
*Brain: Granular Cell Tumor Benign												
	- · ·	0/50 (0%)		00.00/	<b>+</b>	0/50 (0%)		<b>OD</b> 207				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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, Mal	lignant, 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%				
#Coagulating Gland: Granular Cell Tumor		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Coagulating Gland: Sarcoma												
		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Eye: Melanoma Malignant		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%				
Overall incluence	rolai	, ,	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: 41

			Male			Female			
#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%	
#Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/	
	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** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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				Male			Female			
#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		0/50	(00()				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Carcinoma			(00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Adenoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Ileum: Carcinoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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			
#Intestine Small: Jejunum: Adenoma										
		,	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mea	n 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma										
			1%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mea	n 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma		2.7-2					(50)			
Overall Incidence	Tatal	•	)%) Maa	- 00/	CD 00/	Tatal	1/50 (2%)	Mana 20/	CD 00/	
Overali incidence	Total	0/50 (0%)		n 0% 	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Site Unspec Adenoma	cified:									
		•	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		n 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Carcinoma										
		2/50 (4	1%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mea	n 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Carcinoma or Adenoma										
		,	1%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mea	ո 4%	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

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 44

				Male			Female			
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:	,								
			(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Intestine Small: Site Unsp Polyp Adenomatous	ecified:									
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Adenoma		4/50	(00()				4/50 (00/)			
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
		, ,					, ,		ال سري 	
*Islets, Pancreatic: Carcinoma		4/50	(00()				0/50 (00/)			
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma										
			(4%)				1/50 (2%)			
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Kidney: Pelvis and Transit Carcinoma		m:								
			(0%)		05.00/		0/50 (0%)		00.00	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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				
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Adenoma	•••••										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma		2/22 (101)				0.50					
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma											
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Cholangiocarcinoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hemangioma											
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	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:** 46

			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

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 47

			Male				Female			
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  40/50 (80%)  14/50 (28%)  Overall heidened.										
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total	14/50 (28%)	Mean 28%	SD 0%		
*Liver: Hepatocholangiocarcir	noma	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: Mast Cell Tumor Malig										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Lung: Alveolar/Bronchiolar A Overall Incidence		12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%		
*Lung: Alveolar/Bronchiolar C		12/30 (24%)	Weall 24%	30 0%	Total	3/30 (10%)	iviean 10%	30 0%		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Lung: Alveolar/Bronchiolar C	arcinoma or Alv	eolar/Bronchiolar Adeno 14/50 (28%)	ma			6/50 (12%)				
Overall Incidence	Total	14/50 (28%)	Mean 28%	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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Page: 48

			Male			Female			
*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		•••••							
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: Hemangiosarcoma		4/50 (00/)				0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

**Page**: 49

				Male				Female	
#Mammary Gland: Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#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 or			(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%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	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 Report Date: 08/03/2016

**Page:** 50

			Male		Female    Total			
#Mesentery: Hemangiosarcoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
		0/50 (0%)	••	05 00/		` '		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	l otal	1/48 (2.08%)	Mean 2.08%	SD 0%
*Nose: Polyp								
Overall Institutes	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	` '	Mana 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	ı otal	0/48 (0%)		
#Oral Cavity (Oral Mucos Papilloma Squamous o		vnx, Tooth, Gingiva):						
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary							
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

**Page:** 51

			Male				Female	
#Oral Cavity (Oral Mucosa Squamous Cell Carcino						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	ma	- (ac)				0.50		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma						4/50 (00()		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Cystadenoma						3/50 (6%)		
Overall Incidence					Total	3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor B								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor M	lalignant							
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**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 52

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*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%

<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: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ntrol Animal Groups Report Date: 08/03/2016

**Page:** 53

			Male			0/35 (0%) 0/35 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Mean 0% SD 0%					
Overall Incidence					Total	` ,	Mean 0%	SD 0%			
*Parathyroid Gland: Adenoma											
Overall Incidence	Total	0/41 (0%) 0/41 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%			
*Pituitary Gland: Pars Dist Adenoma		fied Site:									
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)		SD 0%			
*Pituitary Gland: Pars Dist Carcinoma		fied Site:									
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%			
*Pituitary Gland: Pars Dist Carcinoma or Adenoma	alis or Unspeci	fied Site:									
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	` '	Mean 0%	SD 0%			
*Pituitary Gland: Pars Intel											
Overall Incidence	Total	0/49 (0%) 0/49 (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:** 54

			Male				0/50 (0%) 0/50 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Mean 0% SD 0%	
*Pituitary Gland: Pars Interr Carcinoma	media:							
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Schwannoma Malignant	media:	0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: 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%

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

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

**Toxicology Data Management System** 

Vehicle: WATER

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Page: 55

Report Date: 08/03/2016

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

Length of Study: CHRONIC

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD (  0/50 (0%)  Total 0/50 (0%)  Mean 0% SD (  2/50 (4%)			
*Salivary Glands: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Salivary Glands: Myxosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00/)				2/50 /40/\		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 4%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

**Page:** 56

Report Date: 08/03/2016

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female		
#Skeletal Muscle: Sarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	os)	•••••					
		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 Trichoepitheli		oma, Basosquamous Tun	nor (benign, malign	ant or		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 E ratoacanthoma, Trichoep 0/50 (0%)		ma,		0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fi	brous Histiocytoma			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
O . G. dii iiioidoiioo	iotai	3/00 (0/0)	Wicari 070	OD 070	10141	3,00 (0,70)	Widaii 070	02 070	

<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

Length of Study: CHRONIC

Vehicle: WATER

**Page:** 57

			Male			Female           0/50 (0%)         Mean 0%         SD 0%           0/50 (0%)         Mean 0%         SD 0%		
#Skin: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma,	or Fibrous Histiocytoma 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Hemangiosarcoma Overall Incidence	Total	0/50 (0%)	Maan 00/	SD 09/	Total	` '	Macr. 00/	SD 00/
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	ıotaı	0/50 (0%)	wiean 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%

<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:** 58

			Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  0/50 (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	` '	Mean 0%	SD 0%
#Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	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	` '	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S	chwannoma (m	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: Neurofibrosarcoma, Neu	ırofibroma, or S	chwannoma (benign, ma	alignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (00/)				0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

**Page:** 59

			Male			0/50 (0%) 0/50 (0%)  Mean 0%  SD 0%  0/50 (0%)  0/50 (0%)  Mean 0%  SD 0%  0/50 (0%)  0/50 (0%)  Mean 0%  SD 0%		
#Skin: Schwannoma Malignant		0/50 (00/)				0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total		Mean 0%	SD 0%
#Skin: Squamous Cell Carcinon or Carcinoma	na, Basal Cell C	•	us Tumor (malignan	it or NOS),				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	()	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a or Papilloma	0/50 (09()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom				na		0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom		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: 60

				Male				Female	
*Spleen: Hemangiosarcoma		,							
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Spleen: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	•••••	0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c		Squamous					0/50 (40/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Stomach, Glandular: Carcinoma	•••••	0/50	(00()				0/50 (00/)		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<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:** 61

#Stomach, Glandular: Carcinoma or Adenoma			Male			Female			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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%) 0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Benign		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 NOS									
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: Benign, Malig	ınant, NOS	0/44 (652)							
Overall Incidence	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 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: 62

*Thyroid Gland: C-Cell: Adenoma				Male			Female			
		,								
			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma										
			(0%)				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%)	(078)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cel Adenoma Overall Incidence	<b>I:</b> Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma										
			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma	or Papilloma	•	(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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 63

Mean 0%

Mean 0%

SD 0%

SD 0%

Report Date: 08/03/2016

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #Tongue: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% #Tooth: Odontoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Urethra: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ...... \*Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% #Uterus: Adenoma 0/50 (0%)

Total

Total

0/50 (0%)

0/50

0/50 (0%)

(0%)

**Granular Cell Tumor Benign** 

**Overall Incidence** 

**Overall Incidence** 

**#Uterus:** 

<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:** 64

Mean 4%

SD 0%

Report Date: 08/03/2016

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

Total

2/50 (4%)

<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:** 65

			Male				Female	
#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 (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: INHALATION Vehicle: AIR

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Report Date: 08/03/2016

### **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 Battelle Northwest	052060104 052072504 056031106 052051504 052052304 051047204	10/06/08 08/31/09 05/15/06 05/05/08 08/03/09 01/31/11	729 729 729 729 729 729	50(5) 50(5) 50(5) 50(5) 50(5) 50(5)	38(708) 35(697) 39(715) 39(709) 38(692) 40(705)	52.1 51.1 54.3 52.6 52.4 52.7	Antimony trioxide 2,3-Butanedione Cobalt Metal Working Fluids: CIMSTAR 3800 Metal Working Fluids: TRIM® VX p-Chloro-a,a,a-trifluorotoluene
					Female		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052060104 052072504 056031106 052051504 052052304 051047204	10/06/08 08/31/09 05/15/06 05/05/08 08/03/09 01/31/11	731 731 731 731 731 731	50(5) 50(5) 50(5) 50(5) 50(5) 50(5)	36(692) 36(697) 36(686) 39(696) 35(692) 38(700)	54.1 51.0 66.7 59.2 57.9 55.9	Antimony trioxide 2,3-Butanedione Cobalt Metal Working Fluids: CIMSTAR 3800 Metal Working Fluids: TRIM® VX p-Chloro-a,a,a-trifluorotoluene

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				Female	
#All Organs: Benign Tumors								
		37/50 (74%)	22/50 (44%)	35/50 (70%)		25/50 (50%)	15/50 (30%)	29/50 (58%)
		39/50 (78%)	32/50 (64%)	32/50 (64%)		26/50 (52%)	23/50 (46%)	24/50 (48%)
Overall Incidence	Total	197/300 (65.67%)	Mean 65.67%	SD 11.96%	Total	142/300 (47.33%)	Mean 47.33%	SD 9.44%
#All Organs: Malignant Tumors								
		25/50 (50%)	27/50 (54%)	36/50 (72%)		25/50 (50%)	24/50 (48%)	31/50 (62%)
		26/50 (52%)	32/50 (64%)	25/50 (50%)		30/50 (60%)	27/50 (54%)	24/50 (48%)
Overall Incidence	Total	171/300 (57%)	Mean 57%	SD 9.01%	Total	161/300 (53.67%)	Mean 53.67%	SD 6.12%
#All Organs:  Malignant and Benign To	<b>umors</b> Total	45/50 (90%) 46/50 (92%) 259/300 (86.33%)	37/50 (74%) 42/50 (84%) Mean 86.33%	45/50 (90%) 44/50 (88%) SD 6.62%	Total	35/50 (70%) 41/50 (82%) 226/300 (75.33%)	34/50 (68%) 38/50 (76%) Mean 75.33%	40/50 (80%) 38/50 (76%) SD 5.47%
	10tai	239/300 (00.33/6)		3D 0.02/6				
#All Organs: 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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Hemangiosarcoma								
•		2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	0/50 (0%)	3/50 (6%)
		1/50 (2%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	13/300 (4.33%)	Mean 4.33%	SD 4.97%	Total	15/300 (5%)	Mean 5%	SD 2.76%

<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

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Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Hemangiosarcoma or He	mangioma							
		2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	0/50 (0%)	3/50 (6%)
		2/50 (4%)	0/50 (0%)	2/50 (4%)		3/50 (6%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	14/300 (4.67%)	Mean 4.67%	SD 4.84%	Total	16/300 (5.33%)	Mean 5.33%	SD 2.73%
tAll Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	13/300 (4.33%)	Mean 4.33%	SD 2.34%
#All Organs: Malignant Lymphoma: Hi	istiocytic, Lym	nphocytic, Mixed, NOS, 4/50 (8%)	or Undifferentiated Cel 6/50 (12%)	I Type 4/50 (8%)		7/50 (14%)	9/50 (18%)	14/50 (28%)
	istiocytic, Lym Total				Total	7/50 (14%) 18/50 (36%) 67/300 (22.33%)	9/50 (18%) 10/50 (20%) Mean 22.33%	14/50 (28%) 9/50 (18%) SD 8.14%
Malignant Lymphoma: Hi	Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%)	6/50 (12%) 6/50 (12%)	4/50 (8%) 6/50 (12%)	Total	18/50 (36%)	10/50 (20%)	9/50 (18%)
Malignant Lymphoma: Hi  Overall Incidence  #All Organs:	Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%)	6/50 (12%) 6/50 (12%) Mean 9.67%	4/50 (8%) 6/50 (12%) SD 2.66%	Total	18/50 (36%) 67/300 (22.33%) 0/50 (0%)	10/50 (20%) Mean 22.33% 0/50 (0%)	9/50 (18%) SD 8.14% 0/50 (0%)
Malignant Lymphoma: Hi Overall Incidence #All Organs: Mesothelioma: Benign, M	Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%) 6 0/50 (0%) 0/50 (0%)	6/50 (12%) 6/50 (12%) Mean 9.67% 0/50 (0%) 0/50 (0%)	4/50 (8%) 6/50 (12%) SD 2.66% 0/50 (0%) 0/50 (0%)		18/50 (36%) 67/300 (22.33%) 0/50 (0%) 0/50 (0%)	10/50 (20%) Mean 22.33% 0/50 (0%) 0/50 (0%)	9/50 (18%) SD 8.14% 0/50 (0%) 0/50 (0%)
Malignant Lymphoma: Hi Overall Incidence #All Organs: Mesothelioma: Benign, M	Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%)	6/50 (12%) 6/50 (12%) Mean 9.67%	4/50 (8%) 6/50 (12%) SD 2.66%	Total Total	18/50 (36%) 67/300 (22.33%) 0/50 (0%)	10/50 (20%) Mean 22.33% 0/50 (0%)	9/50 (18%) SD 8.14% 0/50 (0%)
Malignant Lymphoma: Hi  Overall Incidence  #All Organs:  Mesothelioma: Benign, M  Overall Incidence	Total  Ialignant, NOS  Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%) 5 0/50 (0%) 0/300 (0%)	6/50 (12%) 6/50 (12%) Mean 9.67% 0/50 (0%) 0/50 (0%) Mean 0%	4/50 (8%) 6/50 (12%) SD 2.66% 0/50 (0%) 0/50 (0%) SD 0%		18/50 (36%) 67/300 (22.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	10/50 (20%) Mean 22.33%  0/50 (0%) 0/50 (0%) Mean 0%	9/50 (18%) SD 8.14% 0/50 (0%) 0/50 (0%) SD 0%
Malignant Lymphoma: Hi  Overall Incidence  #All Organs:     Mesothelioma: Benign, M  Overall Incidence  #All Organs:	Total  Ialignant, NOS  Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%) S 0/50 (0%) 0/300 (0%) 0/50 (0%)	6/50 (12%) 6/50 (12%) Mean 9.67% 0/50 (0%) 0/50 (0%) Mean 0%	4/50 (8%) 6/50 (12%) SD 2.66% 0/50 (0%) 0/50 (0%) SD 0%		18/50 (36%) 67/300 (22.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	10/50 (20%) Mean 22.33%  0/50 (0%) 0/50 (0%) Mean 0%	9/50 (18%) SD 8.14%  0/50 (0%) 0/50 (0%) SD 0%  0/50 (0%)
Malignant Lymphoma: Hi  Overall Incidence  #All Organs:     Mesothelioma: Benign, M  Overall Incidence  #All Organs:	Total  Ialignant, NOS  Total	4/50 (8%) 3/50 (6%) 29/300 (9.67%) 5 0/50 (0%) 0/300 (0%)	6/50 (12%) 6/50 (12%) Mean 9.67% 0/50 (0%) 0/50 (0%) Mean 0%	4/50 (8%) 6/50 (12%) SD 2.66% 0/50 (0%) 0/50 (0%) SD 0%		18/50 (36%) 67/300 (22.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	10/50 (20%) Mean 22.33%  0/50 (0%) 0/50 (0%) Mean 0%	9/50 (18%) SD 8.14% 0/50 (0%) 0/50 (0%) SD 0%

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

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

Species: MICE

Strain: B6C3F1

#### Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 08/03/2016

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #All Organs: Osteosarcoma or Osteoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Adrenal Cortex: Adenoma 4/49 (8%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)9/49 (18%)3/50 (6%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 19/298 (6.38%) Mean 6.42% SD 6.52% 2/299 (0.67%) Mean 0.67% SD 1.03% Total \*Adrenal Medulla: Pheochromocytoma Benign 0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)1/50 (2%)1/48 (2%)0/50 (0%)0/50 (0%)1/49 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.35% SD 0.85% Total 6/299 (2.01%) Mean 2.01% SD 1.27% \*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)1/48 (2%)0/50 (0%)0/50 (0%)1/49 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.35% SD 0.85% Total 6/299 (2.01%) Mean 2.01% SD 1.27%

<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				Female	
#Blood Vessel: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Bone Marrow: Hemangiosarcoma								
		0/49 (0%)	0/48 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Bone Marrow:  Mast Cell Tumor Malignant								
		0/49 (0%)	1/48 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/297 (0.67%)	Mean 0.68%	SD 1.05%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Bone Marrow: Sarcoma								
		0/49 (0%)	0/48 (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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

<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

**Overall Incidence** 

Overall Incidence

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

Osteosarcoma or Osteoma

#Bone: Fibroma

#Bone: Osteoma

#Bone:

#Bone: Sarcoma

\*Brain:

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% (0%) (0%) 0/50 0/50 (0%)0/50 (0%)0/50 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% Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

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Report Date: 08/03/2016

Total

......

0/50

0/50

0/300 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

0/50

0/50

SD 0%

(0%)

(0%)

**Granular Cell Tumor Benign** 

<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	
Brain: Meningioma Malignant								
		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%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Maliç	gnant, 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: INHALATION Vehicle: AIR

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Report Date: 08/03/2016

			Male				Female	
#Harderian Gland: Adenoma								
		6/50 (12%)	3/50 (6%)	6/50 (12%)		3/50 (6%)	3/50 (6%)	3/50 (6%)
		7/50 (14%)	4/50 (8%)	5/50 (10%)		2/50 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	31/300 (10.33%)	Mean 10.33%	SD 2.94%	Total	14/300 (4.67%)	Mean 4.67%	SD 1.63%
Harderian Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	2/50 (4%)		4/50 (8%)	1/50 (2%)	0/50 (0%)
		5/50 (10%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	11/300 (3.67%)	Mean 3.67%	SD 3.44%	Total	8/300 (2.67%)	Mean 2.67%	SD 3.5%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	3/50 (6%)	8/50 (16%)		7/50 (14%)	4/50 (8%)	3/50 (6%)
		12/50 (24%)	6/50 (12%)	6/50 (12%)		2/50 (4%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	42/300 (14%)	Mean 14%	SD 5.93%	Total	22/300 (7.33%)	Mean 7.33%	SD 3.72%
Heart: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<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				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 1.79%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<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				Female	
fIntestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Ileum: Carcinoma								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<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: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Site Uns Adenoma	specified:							
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 1.97%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Intestine Small: Site Uns Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Uns Carcinoma or Adenoma Overall Incidence		3/50 (6%) 1/50 (2%) 9/300 (3%)	0/50 (0%) 2/50 (4%) Mean 3%	2/50 (4%) 1/50 (2%) SD 2.1%	Total	0/50 (0%) 1/50 (2%) 3/300 (1%)	0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) 1/50 (2%) SD 1.1%
#Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous	specified:							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<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:** 77

			Male				Female	
*Islets, Pancreatic: Adenoma								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/296 (1.01%)	Mean 1%	SD 1.67%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
'Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/48 (0%)	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	0/296 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/296 (1.01%)	Mean 1%	SD 1.67%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Pelvis and Transit Carcinoma								
		0/50 (0%)	0/49 (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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Pelvis and Transit Carcinoma or Adenoma								
		0/50 (0%)	0/49 (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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

<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: INHALATION

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: AIR

**Page:** 78

			Male				Female	
Kidney: Renal Tubule: 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%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/49 (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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (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%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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:** 79 **Report Date:** 08/03/2016

			Male				Female	
Liver: Hemangiosarcoma		,						
		0/50 (0%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 3.27%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
Liver: Hepatoblastoma								
		2/50 (4%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 1.79%	Total	3/300 (1%)	Mean 1%	SD 1.1%
'Liver: Hepatocellular Adenoma								
		30/50 (60%)	17/50 (34%)	28/50 (56%)		11/50 (22%)	6/50 (12%)	19/50 (38%)
		24/50 (48%)	23/50 (46%)	25/50 (50%)		14/50 (28%)	9/50 (18%)	12/50 (24%)
Overall Incidence	Total	147/300 (49%)	Mean 49%	SD 9.01%	Total	71/300 (23.67%)	Mean 23.67%	SD 8.89%
Liver: Hepatocellular Carcinoma								
		15/50 (30%)	17/50 (34%)	25/50 (50%)		6/50 (12%)	5/50 (10%)	10/50 (20%)
		11/50 (22%)	21/50 (42%)	8/50 (16%)		10/50 (20%)	7/50 (14%)	7/50 (14%)
Overall Incidence	Total	97/300 (32.33%)	Mean 32.33%	SD 12.55%	Total	45/300 (15%)	Mean 15%	SD 4.15%
Liver: Hepatocellular Carcinoma o								
•	-	16/50 (32%)	18/50 (36%)	27/50 (54%)		6/50 (12%)	6/50 (12%)	10/50 (20%)
		11/50 (22%)	21/50 (42%)	9/50 (18%)		10/50 (20%)	7/50 (14%)	7/50 (14%)
Overall Incidence	Total	102/300 (34%)	Mean 34%	SD 13.21%	Total	46/300 (15.33%)	Mean 15.33%	SD 3.72%

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

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

**Toxicology Data Management System** 

Route: INHALATION

Vehicle: AIR

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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			Male				Female	
Liver: Hepatocellular Carcino	ma or Hepatoce	ellular Adenoma						
·	·	39/50 (78%) 32/50 (64%)	31/50 (62%) 34/50 (68%)	38/50 (76%) 30/50 (60%)		14/50 (28%) 20/50 (40%)	11/50 (22%) 15/50 (30%)	25/50 (50%) 18/50 (36%)
Overall Incidence	Total	204/300 (68%)	Mean 68%	SD 7.48%	Total	103/300 (34.33%)	Mean 34.33%	SD 9.91%
Liver: Hepatocellular Carcino	ma. Hepatocelli	ular Adenoma, or Hepato	blastoma				•••••	•••••
•	, <b>,</b>	39/50 (78%) 32/50 (64%)	32/50 (64%) 34/50 (68%)	39/50 (78%) 31/50 (62%)		14/50 (28%) 20/50 (40%)	12/50 (24%) 15/50 (30%)	25/50 (50%) 18/50 (36%)
Overall Incidence	Total	207/300 (69%)	Mean 69%	SD 7.24%	Total	104/300 (34.67%)	Mean 34.67%	SD 9.44%
Liver: Hepatocholangiocarcin							•••••	•••••
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	0/50 (0%) Mean 1.67%	3/50 (6%) SD 2.34%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Mast Cell Tumor Malign	nant				• • • • • • • • • • • • • • • • • • • •			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
Lung: Alveolar/Bronchiolar Ad	denoma							
		10/50 (20%)	5/50 (10%)	7/50 (14%)		1/50 (2%)	3/50 (6%)	3/49 (6%)
Overall Incidence	Total	5/50 (10%) 44/300 (14.67%)	6/50 (12%) Mean 14.67%	11/50 (22%) SD 5.16%	Total	1/50 (2%) 17/299 (5.69%)	4/50 (8%) Mean 5.69%	5/50 (10%) SD 3.21%

<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: 08/03/2016

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** \*Lung: Alveolar/Bronchiolar Carcinoma 4/50 (8%)5/50 (10%)11/50 (22%)2/50 (4%)3/50 (6%)5/49 (10%)8/50 (16%)10/50 (20%)6/50 (12%)(8%)5/50 (10%)0/50 (0%)44/300 (14.67%) 19/299 (6.35%) **Overall Incidence** Total Mean 14.67% SD 5.61% Total Mean 6.37% SD 3.92% \*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 13/50 (26%)9/50 (18%)16/50 (32%)3/50 (6%)6/50 (12%)8/49 (16%)13/50 (26%)14/50 (28%)17/50 (34%)4/50 (8%)9/50 (18%) 5/50 (10%)Mean 27.33% 35/299 (11.71%) **Overall Incidence** Total 82/300 (27.33%) SD 5.61% Total Mean 11.72% SD 4.7% \*Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% 0/299 (0%) Mean 0% SD 0% Total **#Lymph Node:** Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 2/300 (0.67%) Mean 0.67% SD 1.03% #Lymph Node, Mandibular: **Mast Cell Tumor Malignant** 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%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<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, Mediastinal: Mast Cell Tumor Malignant								
		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%

<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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Mean 0.33%

SD 0.82%

Report Date: 08/03/2016

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 5/300 (1.67%) Mean 1.67% SD 1.51% #Mammary Gland: Fibroma, Fibroadenoma or Adenoma (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% ...... **#Mammary Gland:** Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)(0%)0/50 0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% 5/300 (1.67%) Mean 1.67% SD 1.51% Total #Mesentery: Hemangioma 0/50 0/50 (0%)0/50 (0%)(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 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)

SD 0%

Total

1/300 (0.33%)

Total

0/300 (0%)

Mean 0%

**Overall Incidence** 

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

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

### **Toxicology Data Management System**

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Report Date: 08/03/2016

Contract/Lab: All Laboratories Tumor Incidence for

Species: MICE Strain: B6C3F1 Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** #Mesentery: Lipoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% \*Nose: Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Nose: Polyp 0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/298 (0.34%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

0/50

0/300 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/300 (0%)

(0%)

0/50

Mean 0%

(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**

Tumor Incidence for Selected Control Animal Groups

Page: 85

Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)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%)0/300 (0%) **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total Mean 0% SD 0% **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/300 (0%) SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Ovary: Cystadenocarcinoma 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 1/50 (2%)0/49 (0%)1/48 (2%)2/50 (4%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 7/297 (2.36%) Mean 2.35% SD 1.5% \*Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/49 (0%)0/48 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/297 (0.67%) Mean 0.67%

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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**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: **Granulosa Cell Tumor Malignant** 1/50 (2%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)0/49 (0%)0/48 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/297 (1.01%) Mean 1% SD 1.1% \*Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)1/49 (2%)0/48 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/297 (0.67%) Mean 0.67% SD 1.04% \*Ovary: Hemangiosarcoma 1/50 (2%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% \*Ovary: Luteoma 0/50 (0%)0/49 (0%)0/48 (0%)1/50 (2%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 3/297 (1.01%) Mean 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**

Tumor Incidence for Selected Control Animal Groups

**Page: 87** 

Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Sarcoma 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/297 (0%) **Overall Incidence** Total Mean 0% SD 0% \*Ovary: **Tubulostromal Adenoma** (0%) 0/50 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: **Yolk Sac Carcinoma** 0/50 (0%)0/49 (0%)1/48 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.35% SD 0.85% \*Parathyroid Gland: Adenoma 0/27 (0%)0/40 (0%)0/29 (0%)0/27 (0%)0/38 (0%)0/28 (0%)(0%) 0/34 (0%)0/28 (0%)0/36 0/26 (0%)1/35 (3%)0/36 (0%)Overall Incidence Total 0/194 (0%) Mean 0% SD 0% Total 1/190 (0.53%) Mean 0.48% SD 1.17% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 (0%)0/50 (0%)0/47 (0%)9/49 (18%)2/49 (4%)3/47 (6%)0/50 (0%)1/50 (2%)0/50 (0%)5/50 (10%)8/48 (17%)4/50 (8%) **Overall Incidence** Total 1/296 (0.34%) Mean 0.33% SD 0.82% Total 31/293 (10.58%) Mean 10.58% SD 5.74%

<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: 08/03/2016

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/49 (0%)0/50 (0%)0/47 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)3/48 (6%)0/50 (0%)**Overall Incidence** Total 0/296 (0%) Mean 0% SD 0% Total 3/293 (1.02%) Mean 1.04% SD 2.55% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma (0%) 0/490/50 (0%)0/47 (0%)9/49 (18%)2/49 (4%)(6%)(0%) 0/50 1/50 (2%)0/50 (0%)5/50 (10%)11/48 (23%)4/50 (8%)**Overall Incidence** Total 1/296 (0.34%) Mean 0.33% SD 0.82% Total 34/293 (11.6%) Mean 11.62% SD 7.39% \*Pituitary Gland: Pars Intermedia: Adenoma 0/49 (0%)0/50 (0%)0/47 (0%)0/49 (0%)0/49 (0%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/296 (0%) Mean 0% SD 0% Total 0/293 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Intermedia: Carcinoma 0/49 (0%)0/50 (0%)0/47 (0%)0/49 (0%)1/49 (2%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/296 (0%) Mean 0% SD 0% Total 1/293 (0.34%) Mean 0.34% SD 0.83% \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/47 (0%)0/49 (0%)1/49 (2%)0/47 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/296 (0%) Mean 0% SD 0% Total 1/293 (0.34%) Mean 0.34% SD 0.83%

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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**

Tumor Incidence for Selected Control Animal Groups

**Page:** 89

Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Pituitary Gland: Pars Interm Schwannoma Malignant	edia:							
		0/49 (0%)	0/50 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/293 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (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: INHALATION

**Page:** 90

Report Date: 08/03/2016

Species: MICE Strain: B6C3F1

Vehicle: AIR

			Male				Female	
Salivary Glands: Myxosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Seminal Vesicle: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
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%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
Skeletal Muscle: Rhabdomyosarcoma or Rl	nabdomyoma	a						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

<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: 08/03/2016

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

Route: INHALATION Vehicle: AIR

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or N	OS)					
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tui	mor (benign, malignan	t or				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
∜Skin: Basal or Sq. Cell Carciı	noma, Carcinom	a, Basosq. Tumor (M or I ratoacanthoma, Trichoep	3), Basal Cell Adenom					
		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%)		1/50 (2%)	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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

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Report Date: 08/03/2016

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

			Male			Female		
#Skin:	Companya Mari	M	-:					
Fibroma, Fibrosarcoma	, Sarcoma, Myx	oma, Myxosarcoma, or I	•	0/50 (00/)		0/50 (40/)	0/50 (00/)	0/50 (40/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
	<b>T</b>	0/50 (0%)	1/50 (2%)	1/50 (2%)	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%
Skin: Fibrosarcoma								
		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%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%	Total	2/50 (4%) 0/50 (0%) 5/300 (1.67%)	0/50 (0%) 0/50 (0%) Mean 1.67%	2/50 (4%) 1/50 (2%) SD 1.97%
Overall Incidence  Skin:				SD 1.03%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%
Fibrous Histiocytoma								- 4
		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%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<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:** 93

			Male		Female			
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	2/50 (4%) SD 1.63%	Total	2/50 (4%) 3/300 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.67%
Skin: Keratoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
έSkin: 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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
∜Skin: Melanoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	1/50 (2%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<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: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) (0%) 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 3/300 (1%) Mean 1% SD 1.67% Total #Skin: Schwannoma Malignant 0/50 (0%) 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

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<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: 08/03/2016

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/300 (0.33%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0.33% SD 0.82% #Skin: Squamous Cell Papilloma or Papilloma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% Total #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% \*Spleen: Hemangiosarcoma 2/49 (4%)0/48 (0%)3/50 (6%)0/50 (0%)0/50 (0%)2/49 (4%)

1/50

SD 2.54%

(2%)

1/50

4/299 (1.34%)

Total

(2%)

0/50

(0%)

Mean 1.35%

1/50

(2%)

Total

0/50

6/296 (2.03%)

(0%)

0/49

Mean 2.01%

(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: INHALATION Vehicle: AIR

**Page:** 96

			Male		Female			
Spleen: Mast Cell Tumor Malignant								
		0/49 (0%)	0/48 (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%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
	or Papillom	=	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
	or Papillom Total	=	0/50 (0%) 1/50 (2%) Mean 1%	0/50 (0%) 1/50 (2%) SD 1.1%	Total	1/50 (2%) 0/50 (0%) 4/300 (1.33%)	0/50 (0%) 1/50 (2%) Mean 1.33%	1/50 (2%) 1/50 (2%) SD 1.03%
Squamous Cell Carcinoma	-	1/50 (2%) 0/50 (0%) 3/300 (1%)	1/50 (2%) Mean 1%	1/50 (2%) SD 1.1%	Total	0/50 (0%) 4/300 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.03%
Squamous Cell Carcinoma  Overall Incidence  #Stomach, Forestomach:	-	1/50 (2%) 0/50 (0%) 3/300 (1%) 1/50 (2%)	1/50 (2%) Mean 1% 	1/50 (2%) SD 1.1% 0/50 (0%)	Total	0/50 (0%) 4/300 (1.33%) 1/50 (2%)	1/50 (2%) Mean 1.33% 0/50 (0%)	1/50 (2%) SD 1.03% 1/50 (2%)
Squamous Cell Carcinoma  Overall Incidence  #Stomach, Forestomach:	-	1/50 (2%) 0/50 (0%) 3/300 (1%)	1/50 (2%) Mean 1%	1/50 (2%) SD 1.1%	Total 	0/50 (0%) 4/300 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.03%
Squamous Cell Carcinoma  Overall Incidence  #Stomach, Forestomach: Squamous Cell Papilloma	Total	1/50 (2%) 0/50 (0%) 3/300 (1%) 1/50 (2%) 0/50 (0%)	1/50 (2%) Mean 1% 0/50 (0%) 1/50 (2%)	1/50 (2%) SD 1.1% 0/50 (0%) 1/50 (2%)		0/50 (0%) 4/300 (1.33%) 1/50 (2%) 0/50 (0%)	1/50 (2%) Mean 1.33% 0/50 (0%) 1/50 (2%)	1/50 (2%) SD 1.03% 1/50 (2%) 1/50 (2%)

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

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 97

			Male		Female			
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		0/49 (0%)	0/49 (0%)	1/50 (2%)				
Overall Incidence	Total	0/50 (0%) 1/298 (0.34%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%				
*Thymus: Neoplasm NOS								
		0/41 (0%)	0/43 (0%)	0/42 (0%)		0/47 (0%)	0/47 (0%)	1/46 (2%)
Overall Incidence	Total	0/41 (0%) 0/259 (0%)	0/44 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/44 (0%) 1/282 (0.35%)	0/48 (0%) Mean 0.36%	0/50 (0%) SD 0.89%
*Thymus: Thymoma Benign								
		0/41 (0%)	0/43 (0%)	0/42 (0%)		0/47 (0%)	0/47 (0%)	0/46 (0%)
Overall Incidence	Total	0/41 (0%) 0/259 (0%)	0/44 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/44 (0%) 0/282 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%
Thymus:					• • • • • • • • • • • • • • • • • • • •			
,		0/41 (0%)	0/43 (0%)	0/42 (0%)		1/47 (2%)	0/47 (0%)	0/46 (0%)
Overall Incidence	Total	0/41 (0%) 0/259 (0%)	0/44 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/44 (0%) 1/282 (0.35%)	0/48 (0%) Mean 0.35%	0/50 (0%) SD 0.87%
	1 Otal		IVICALI U/0		1 Otal	1/202 (0.00/0)	WIGAIT 0.3370	

<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:** 98

			Male				Female	
Thymus: Thymoma: Benign, Malign	nant, NOS							
		0/41 (0%) 0/41 (0%)	0/43 (0%) 0/44 (0%)	0/42 (0%) 0/48 (0%)		1/47 (2%) 0/44 (0%)	0/47 (0%) 0/48 (0%)	0/46 (0%) 0/50 (0%)
Overall Incidence	Total	0/259 (0%)	Mean 0%	SD 0%	Total	1/282 (0.35%)	Mean 0.35%	SD 0.87%
*Thyroid Gland: C-Cell: Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/298 (0.34%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/298 (0.34%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
						1/290 (0.5470)		
Thyroid Gland: Follicular C Adenoma	ell:							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/48 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.03%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

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Report Date: 08/03/2016

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

			Male				Female	
*Thyroid Gland: Follicular C Carcinoma or Adenoma	ell:							
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.03%
#Tongue: Squamous Cell Carcinom	a or Panillom	na Squamous						
oquamous our our onioni	a o apo	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		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%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		, ,						
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Version: Aug2016 Contract/Lab: All Laboratories

Species: MICE

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Strain: B6C3F1 Length of Study: CHRONIC Male Female

			Male				Female	
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
	<b>-</b>	1/50 (2%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Uterus: Adenoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Beniç	<b>j</b> n					1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Hemangioma								
-						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
fUterus: Hemangiosarcoma								
						1/50 (2%)	0/50 (0%)	0/50 (0%)
						1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence					Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%

<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: 101

Mean 0%

SD 0%

Report Date: 08/03/2016

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: **Polyp Stromal** (8%) 0/50 (0%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 7/300 (2.33%) Mean 2.33% SD 3.2% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal or Polyp Stromal 4/50 (8%)0/50 (0%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 7/300 (2.33%) Mean 2.33% SD 3.2% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

......

0/300 (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: INHALATION Vehicle: AIR

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		Male				Female  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 103

Report Date: 08/03/2016

## **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)

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male		Female  36/50 (72%)  Total 36/50 (72%) Mean 72% SD 0%  31/50 (62%)  Total 31/50 (62%) Mean 62% SD 0%  45/50 (90%)  Total 45/50 (90%) Mean 90% SD 0%  0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0%			
#All Organs: Benign Tumors								
Overall Incidence	Total	43/50 (86%) 43/50 (86%)	Mean 86%	SD 0%	Total	,	Mean 72%	SD 0%
#All O								
#All Organs: Malignant Tumors								
. <b>.</b>		30/50 (60%)				31/50 (62%)		
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	31/50 (62%)	Mean 62%	SD 0%
#All Organs: Malignant and Benign Tu	umors	40/50 (000()				45/50 (000()		
Overall Incidence	Total	48/50 (96%) 48/50 (96%)	Mean 96%	SD 0%	Total	,	Mean 90%	SD 0%
#All Organs: Hemangioma		0/50 (/0//)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		F/F0 (400)				0/50 (400)		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
Overell In aldeman	Tatal	5/50 (10%)	Mana 400/	CD 00/	Tatal	6/50 (12%)	Mana 400/	CD 00/
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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 105

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 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, Malignant, 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 Mean 0% SD 0% 0/50 (0%) .......... #All Organs: 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% ..... #All Organs: Osteosarcoma or Osteoma

SD 0%

1/50

1/50 (2%)

Total

(2%)

Mean 2%

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

**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:** 106

				Male		0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%)			
*Adrenal Cortex: Adenoma			(4%)				()		
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign			(0%)				` ,		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benign		Malignant, NOS					0/50 (0%)		
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%)		<b>05</b> 000
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%
#Blood Vessel: Hemangiosarcoma		0/50	(00/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
*Bone Marrow: Hemangiosarcoma			(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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 107

			Male		0/50 (0%) tal 0/50 (0%) Mean 0% SD 0%  0/50 (0%) tal 0/50 (0%) Mean 0% SD 0%			
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
*Bone Marrow: Sarcoma		0.750						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Bone: Fibroma						0/50 /00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Bone: 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%
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Bone: Sarcoma		0/50 (00/)				0/50 (004)		
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: ORAL Vehicle: WATER **Page:** 108

		Male					Female		
*Brain: Granular Cell Tumor Benign									
Overall Incidence	Total	,	(0%)	Mean 0%	SD 00/	Total	0/49 (0%)	Mean 0%	SD 0%
Overall incluence	Total	0/50 (0%)			SD 0%	Total	0/49 (0%)		שט עס 🐃
*Brain: Meningioma Malignant									
		,	(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, Mal	lignant, 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%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma									
		,	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant		4/50	(201)				0/50 /00/		
Overall Incidence	Total	,	(2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incidence	Total	1/50 (2%)					0/50 (0%)		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

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

**Page:** 109

			Male				Female	
#Harderian Gland: Adenoma		2(22)				-((100))		
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		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%
#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		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		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%
#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%

<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: 110

				Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma		•••••							
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		4/50	(00()				0/50 /00/)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50	(00()				0/50 /00/		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 111

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

			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									
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: 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 Unsp 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: Site Unsp Carcinoma			•••••						
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:					(00)			
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	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: 112

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspe Leiomyosarcoma	cified:							
•		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 Unspe Polyp Adenomatous	cified:	0/50 (00/)				0/50 (004)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		2/22 (221)				2/12 /22/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
							······································	
*Islets, Pancreatic: 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%
*Islets, Pancreatic: 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%
*Kidney: Pelvis and Transition								
		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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 113

Report Date: 08/03/2016

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** \*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*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%) Mean 0% SD 0% Total 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% ..... \*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 SD 0% 0/49 (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: 114

			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	9/49 (18.37%)	Mean 18.37%	SD 0%
*Liver: Hepatocellular Carcinoma c								
Overall Incidence	Total	15/50 (30%) 15/50 (30%)	Mean 30%	SD 0%	Total	9/49 (18%) 9/49 (18.37%)	Mean 18.37%	SD 0%
		( ,				,		02 070
*Liver: Hepatocellular Carcinoma c	or Hepatoce	Ilular Adenoma 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%

<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** 

**Page:** 115

Report Date: 08/03/2016

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

		Male				Female					
Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
, ·	42/50 (84%)				36/49 (73%)						
Total	42/50 (84%)	Mean 84%	SD 0%	Total	36/49 (73.47%)	Mean 73.47%	SD 0%				
oma	0/50 (00/)				0/40 (00/)						
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
ant											
	0/50 (0%)				0/49 (0%)						
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
lenoma											
Total	13/50 (26%)	Mean 26%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%				
rcinoma				•••••							
Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
					5/50 (10%)						
Total	19/50 (38%)	Mean 38%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%				
	Total  Total  Total  Total  Penoma  Total  Total  Total  Total  Total	42/50 (84%) Total 42/50 (84%)  Total 0/50 (0%)  Total 0/50 (0%)  ant 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Penoma 13/50 (26%)  Total 13/50 (26%)  rcinoma 7/50 (14%)  Total 7/50 (14%)  rcinoma or Alveolar/Bronchiolar Adenor 19/50 (38%)	na, Hepatocellular Adenoma, or Hepatoblastoma 42/50 (84%) Total 42/50 (84%) Mean 84%  Doma  0/50 (0%) Total 0/50 (0%) Mean 0%  ant  0/50 (0%) Total 0/50 (0%) Mean 0%  Alenoma  13/50 (26%) Total 13/50 (26%) Mean 26%  rcinoma  7/50 (14%) Total 7/50 (14%) Mean 14%  rcinoma or Alveolar/Bronchiolar Adenoma 19/50 (38%)	na, Hepatocellular Adenoma, or Hepatoblastoma 42/50 (84%) Total 42/50 (84%) Mean 84% SD 0%  Doma  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  ant  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Penoma  13/50 (26%) Total 13/50 (26%) Mean 26% SD 0%  rcinoma  7/50 (14%) Total 7/50 (14%) Mean 14% SD 0%  rcinoma or Alveolar/Bronchiolar Adenoma 19/50 (38%)	na, Hepatocellular Adenoma, or Hepatoblastoma 42/50 (84%) Total 42/50 (84%) Mean 84% SD 0% Total  Oma  O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total  ant  O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total  enoma  13/50 (26%) Total 13/50 (26%) Mean 26% SD 0% Total  rcinoma  7/50 (14%) Total 7/50 (14%) Mean 14% SD 0% Total	na, Hepatocellular Adenoma, or Hepatoblastoma 42/50 (84%) Total 42/50 (84%) Mean 84% SD 0% Total 36/49 (73.47%)  Draa  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%)  Total 13/50 (26%) Total 13/50 (26%) Mean 26% SD 0% Total 3/50 (6%)  Total 7/50 (14%) Mean 14% SD 0% Total 2/50 (4%)  Total 7/50 (14%) Mean 14% SD 0% Total 5/50 (4%)  Treinoma or Alveolar/Bronchiolar Adenoma 19/50 (38%)  Total 5/50 (10%)	na, Hepatocellular Adenoma, or Hepatoblastoma 42/50 (84%) Total 42/50 (84%) Mean 84% SD 0% Total 36/49 (73%) Mean 73.47%  Mean 73.47%  Mean 73.47%  Mean 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0%  Mean 0%  Total 13/50 (26%) Mean 26% SD 0% Total 3/50 (6%) Mean 6%  Total 13/50 (26%) Mean 4%  Total 7/50 (14%) Mean 14% SD 0% Total 2/50 (4%) Mean 4%  Treinoma or Alveolar/Bronchiolar Adenoma 19/50 (38%)  Total 19/50 (10%)				

<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: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 116

		Male			Female			
Total	,	,	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		Wear 070						
Tatal	,	,	CD 00/	Tatal	0/50 (0%)	Mary 00/	CD 004	
ı otal	0/50 (0%)	iviean 0%	SD 0%	ı otal	0/50 (0%)	Mean U%	SD 0%	
	0/50 (0%	,)			0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50 (0%	·)	OD 004	T-1-1	0/50 (0%)	M 00/	00.00	
	` '		SD 0%	ı otal	0/50 (0%)	Mean U%	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	0/50 (0%)	Mean 0%	SD 0%	
	Total  Total  Total	Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)	O/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%           O/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%	O/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         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%         Total	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (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%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%	

<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: 117

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: 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%
#Mammary Gland: Carcinoma			•••••					
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								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma		Adenoma				1/50 (20/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#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%

<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

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 118

			Male				Female	
#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%
#Mesentery: Lipoma						0/50		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Nose: Polyp		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos		/nx, Tooth, Gingiva):		•••••	•••••			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino								
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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

**Page:** 119

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)											
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Mucosa: Squamous Cell Carcinom	a	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Cystadenocarcinoma						0/50 (0%)					
Overall Incidence					Total	0/50 (0%) 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 Bei	nign					0/50 (0%)					
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa Cell Tumor Ma	lignant					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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

**Page:** 120

Male			Female				
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Granulosa-Theca Tumor Malignant							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Hemangiosarcoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Luteoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Sarcoma							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Ovary: Tubulostromal Adenoma		•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			

<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

Page: 121

			Male				Female	
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dist Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%
*Pituitary Gland: Pars Dist Carcinoma		fied Site:						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dist Carcinoma or Adenoma	talis or Unspecif							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%
*Pituitary Gland: Pars Inte Adenoma	rmedia:							
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

**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: 122

				Male				Female		
*Pituitary Gland: Pars Interm Carcinoma	nedia:									
			(0%)		05.00/		0/49 (0%)		05.00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:									
Overell Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/49 (0%)	Maan 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Interm Schwannoma Malignant	nedia:									
			(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		0/50	(0%)				0/48 (0%)			
Overall Incidence	Total	0/50 (0%)	(078)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma										
		0/50	(0%)				0/48 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma or Adenoma		0/50	(00()				0/40 (00/)			
Overall Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/48 (0%)	Maan 00/	CD 00/	
Overali incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	

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

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

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

ups **Report Date**: 08/03/2016

Page: 123

			Male			Female			
*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: Myxosarcoma		0/50 (00/)				0/40 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
#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	•								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma or F									
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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

for Selected Control Animal Groups

Page: 124

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male	Female				
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or N	os)			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%
	10lai	0/50 (0%)		3D 0%	10lal	0/50 (0%)		SD 0%
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli		oma, Basosquamous Tur	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%
#Skin: Basal or Sq. Cell Carcin	noma, Carcinoma	a, Basosq. Tumor (M or I ratoacanthoma, Trichoep 0/50 (0%)	3), Basal Cell Adeno			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:		oma, Myxosarcoma, or F 1/50 (2%)				4/50 (8%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
		1/50 (2%)				, ,		30 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** 

Page: 125

Report Date: 08/03/2016

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 4/50 (8%) **Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 4/50 (8%) Mean 8% SD 0% #Skin: **Fibrous Histiocytoma** 1/50 (2%)3/50 (6%)**Overall Incidence** Total 1/50 (2%) Mean 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 Mean 0% SD 0% 0/50 (0%) #Skin: 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% #Skin: Keratoacanthoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total SD 0% 0/50 (0%) Mean 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 126

			Male		Female			
#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: 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: 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 Overall Incidence	chwannoma (m	alignant or NOS) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
#Skin: Neurofibrosarcoma, Neu	urofibroma, or S	chwannoma (benign, ma 0/50 (0%)	lignant or NOS)			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 (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** 

Tumor Incidence for Selected Control Animal Groups

Page: 127

Report Date: 08/03/2016

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%) 3/50 (6%)	Mean 6%	SD 0%				
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignan	nt 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 Papillo	ma	0/50 (0%)	•••••			0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	ma or Papilloma	0/50 (00()				0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo		quamous Cell Carcinom		na		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma 0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

<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: 128

				Male				Female		
*Spleen: Hemangiosarcoma										
			(4%)		25. 22/		0/49 (0%)		00.00	
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Spleen: Mast Cell Tumor Malignant										
			(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%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0 %)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Carcinoma of		a Squamous	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma		0/50	(00/)				4/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Stomach, Glandular: Carcinoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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:** 129

Report Date: 08/03/2016

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male			Female			
#Stomach, Glandular: Carcinoma or Adenoma		2/20 (201)				2(22)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma		4/50 (00)							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%					
*Thymus: Neoplasm NOS		0/45 (00/)				0/50 (0%)			
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Benign		0/45 (0%)				0/50 (0%)			
Overall Incidence	Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma NOS									
Overall Incidence	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Malign	ant, NOS	0/45 (0%)				0/50 (0%)			
Overall Incidence	Total	0/45 (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: 130

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*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 1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 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% ..... #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total SD 0% 0/50 (0%) Mean 0%

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

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Page: 131 Report Date: 08/03/2016

			Male			Female			
#Tongue: 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%	
#Tooth: Odontoma									
Overell Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Urethra: Hemangiosarcoma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma						(00)			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Granular Cell Tumor Benig	ın								
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**

Tumor Incidence for Selected Control Animal Groups

Page: 132

Report Date: 08/03/2016

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Hemangioma 0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% #Uterus: Hemangiosarcoma 1/50 (2%)**Overall Incidence** Total 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** 4/50 (8%) SD 0% **Overall Incidence** Total 4/50 (8%) Mean 8% #Uterus: Sarcoma Stromal 0/50 (0%)**Overall Incidence** SD 0% Total 0/50 (0%) Mean 0% **#Uterus:** Sarcoma Stromal or Polyp Stromal 4/50 (8%) **Overall Incidence** Total Mean 8% SD 0% 4/50 (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: ORAL Vehicle: WATER Page: 133

			Male			Female				
#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 (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