

# NTP Historical Controls Report

By Route and Vehicle

**MICE** 

November 2014

## 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.

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**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903104	03/17/05	726	50(1)	34(687)	54.6	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/24/04	730	50(1)	34(689)	56.4	Kava kava extract
Battelle Columbus Laboratory	052010704	10/26/04	730	50(1)	34(665)	55.7	N,N-Dimethyl-p-toluidine
Southern Research Institute	052020904	02/25/08	729	50(1)	29(657)	55.3	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					Female		
Battelle Columbus Laboratory	059903104	03/18/05	727	50(5)	31(628)	64.5	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/23/04	729	50(5)	38(695)	66.2	Kava kava extract
Battelle Columbus Laboratory	052010704	10/25/04	729	50(5)	43(715)	66.6	N,N-Dimethyl-p-toluidine
Southern Research Institute	052020904	02/25/08	731	50(5)	33(679)	57.7	Pentabromodiphenyl oxide (technical) (DE 71)
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

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

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Mean 1.33%

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #All Organs: **Benign Tumors** 38/50 (76%)33/50 (66%)34/50 (68%)25/50 (50%)17/50 (34%)26/50 (52%)36/50 (72%)30/50 (60%)38/50 (76%)24/50 (48%)24/50 (48%)22/50 (44%)Overall Incidence Total 209/300 (69.67%) Mean 69.67% SD 6.25% Total 138/300 (46%) Mean 46% SD 6.45% #All Organs: **Malignant Tumors** 35/50 (70%)27/50 (54%)32/50 (64%)28/50 (56%)19/50 (38%)19/50 (38%)29/50 (58%)27/50 (54%)21/50 (42%)21/50 (42%)16/50 (32%)18/50 (36%)Mean 57% **Overall Incidence** Total 171/300 (57%) SD 9.61% Total 121/300 (40.33%) Mean 40.33% SD 8.33% ...... #All Organs: **Malignant and Benign Tumors** 44/50 (88%)48/50 (96%)47/50 (94%)35/50 (70%)30/50 (60%)39/50 (78%)32/50 45/50 (90%)40/50 (80%)47/50 (94%)35/50 (70%)34/50 (68%)(64%)**Overall Incidence** Total 271/300 (90.33%) Mean 90.33% SD 5.85% 205/300 (68.33%) Mean 68.33% SD 6.12% Total **#All Organs:** Hemangioma 2/50 0/50 (0%)0/50 (0%)(4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/300 (1.33%) Mean 1.33% SD 2.07% Total 4/300 (1.33%) Mean 1.33% SD 1.03% #All Organs: Hemangiosarcoma 9/50 (18%)4/50 (8%)6/50 (12%)2/50 (4%)0/50 (0%)1/50 (2%)8/50 (16%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)

SD 6.86%

Total

4/300 (1.33%)

Total

29/300 (9.67%)

.....

Mean 9.67%

<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: 11/11/2014

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 9/50 (18%)4/50 (8%)8/50 (16%)2/50 (4%)1/50 (2%)1/50 (2%)8/50 (16%)1/50 (2%)3/50 (6%)1/50 (2%)1/50 (2%)2/50 (4%)8/300 (2.67%) **Overall Incidence** Total 33/300 (11%) Mean 11% SD 6.54% Total Mean 2.67% SD 1.03% #All Organs: **Histiocytic Sarcoma** (2%)0/50 (0%)2/50 (4%)0/50 (0%)1/50 1/50 (2%)3/50 (6%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% Total 7/300 (2.33%) Mean 2.33% SD 1.97% ...... #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 1/50 (2%)3/50 (6%)2/50 (4%)11/50 (22%)6/50 (12%)6/50 (12%)3/50 9/50 4/50 (8%)5/50 (10%)(6%)15/50 (30%)7/50 (14%)(18%)**Overall Incidence** Total 18/300 (6%) Mean 6% SD 2.83% Total 54/300 (18%) Mean 18% SD 7.04% **#All Organs:** Mesothelioma: Benign 0/50 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%)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% **#All Organs:** Mesothelioma: Benign, Malignant, NOS

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

0/300 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(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: 7

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		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%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/49 (4%)	0/50 (0%)
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	2/299 (0.67%)	Mean 0.68%	SD 1.67%

<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

Report Date: 11/11/2014

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			Male				Female	
Adrenal Medulla: Pheochromocytoma B	enign							
		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%)		2/50 (4%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/298 (1.01%)	Mean 1%	SD 1.67%
Adrenal Medulla: Pheochromocytoma M	alignant							
		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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Pheochromocytoma: E	Benign, Complex		- / / / / / / / / / /					
·	Benign, Complex  Total	x, Malignant, NOS 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 2/50 (4%) 3/298 (1.01%)	0/49 (0%) 0/49 (0%) Mean 1%	0/50 (0%) 1/50 (2%) SD 1.67%
Pheochromocytoma: E Overall Incidence #Blood Vessel: Hemangioma		0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33%	0/50 (0%)		2/50 (4%) 3/298 (1.01%)	0/49 (0%)	1/50 (2%)
Overall Incidence #Blood Vessel:		0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%)	1/50 (2%) SD 1.67% 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma		0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%)	1/50 (2%) SD 1.67% 0/50 (0%)
Overall Incidence #Blood Vessel:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%)
Overall Incidence #Blood Vessel: Hemangioma Overall Incidence *Bone Marrow:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33%  0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%)		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%)	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%) SD 0.82%
Overall Incidence #Blood Vessel: Hemangioma Overall Incidence *Bone Marrow:	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) Mean 0.33%  0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/50 (0%) 0/50 (0%) SD 0%		2/50 (4%) 3/298 (1.01%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/49 (0%) Mean 1% 1/50 (2%) 0/50 (0%) Mean 0.33%	1/50 (2%) SD 1.67% 0/50 (0%) 0/50 (0%) SD 0.82%

<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** 

Page: 9

Mean 0%

SD 0%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** \*Bone Marrow: Hemangiosarcoma 0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 0/50 (0%)0/299 (0%) **Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% Total Mean 0% SD 0% \*Bone Marrow: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% \*Bone Marrow: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% #Bone: **Fibroma** 0/50 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%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Bone: 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%)

SD 0%

Total

0/300 (0%)

Total

0/300 (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:** 10

			Male				Female	
#Bone: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		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%
#Bone: Osteosarcoma or Osteo	oma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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: Granular Cell Tumor Be	nign							
	•	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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%
Brain: Meningioma: Benign, W	lalignant, 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%
*Brain: Oligodendroglioma Mal								
		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%
*Brain: Oligodendroglioma, Gli	oma, or Astrocy	rtoma						
		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%
*Clitoral/Preputial Gland: Hemangioma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/297 (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

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 12 Report Date: 11/11/2014

			Male				Female	
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/297 (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%)	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%
#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%
#Harderian Gland: Adenoma								
		4/50 (8%)	6/50 (12%)	5/50 (10%)		5/50 (10%)	3/50 (6%)	5/50 (10%)
		11/50 (22%)	5/50 (10%)	7/50 (14%)		1/50 (2%)	9/50 (18%)	2/50 (4%)
Overall Incidence	Total	38/300 (12.67%)	Mean 12.67%	SD 5.01%	Total	25/300 (8.33%)	Mean 8.33%	SD 5.72%

<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

Control Animal Groups /AGE **Page:** 13

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma								
		3/50 (6%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 2.19%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	7/50 (14%)	5/50 (10%)		6/50 (12%)	3/50 (6%)	5/50 (10%)
		11/50 (22%)	6/50 (12%)	8/50 (16%)		1/50 (2%)	10/50 (20%)	3/50 (6%)
Overall Incidence	Total	44/300 (14.67%)	Mean 14.67%	SD 4.13%	Total	28/300 (9.33%)	Mean 9.33%	SD 6.28%
Heart: Hemangiosarcoma								
		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%)	0/50 (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%
Intestine Large: Cecum: 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: 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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			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%
Intestine Large: Cecum: Leiomyosarcoma								
		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%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#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: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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** 

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Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Intestine Small: Ileum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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% #Intestine Small: Jejunum: Adenoma (0%)0/50 1/50 (2%)1/50 (2%)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 3/300 (1%) Mean 1% SD 1.1% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Intestine Small: Jejunum: Carcinoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%) 0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.1% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 0/50 (0%)0/50 (0%)(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% #Intestine Small: Site Unspecified: Adenoma 2/50 0/50 (0%)3/50 (6%)(4%)0/50 (0%)0/50 (0%)2/50 (4%)

1/50

SD 2.53%

(2%)

0/50

3/300 (1%)

Total

(0%)

0/50

(0%)

Mean 1%

1/50

(2%)

Total

0/50

6/300 (2%)

(0%)

0/50

Mean 2%

(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

Control Animal Groups Report Date: 11/11/2014 AGE

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			Male				Female	
Intestine Small: Site Uns Carcinoma	pecified:							
		1/50 (2%)	0/50 (0%)	1/50 (2%)		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	3/300 (1%)	Mean 1%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Carcinoma or Adenoma	pecified:							
		1/50 (2%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	9/300 (3%)	Mean 3%	SD 2.76%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Intestine Small: Site Uns Leiomyosarcoma								
		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%
Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)	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%)	0/50 (0%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
'Islets, Pancreatic: Carcinoma								
		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%)	0/50 (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

Contract/Lab: All Laboratories

Toxicology Data Manaç

Species: MICE Strain: B6C3F1

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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** \*Islets, Pancreatic: Carcinoma or Adenoma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/300 (0.67%) **Overall Incidence** Total 5/300 (1.67%) Mean 1.67% SD 1.51% Total Mean 0.67% SD 1.03% \*Kidney: Pelvis and Transitional Epithelium: Carcinoma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%) 0/50 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% \*Kidney: Pelvis and Transitional Epithelium: 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% \*Kidney: Renal Tubule: Adenoma 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%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% \*Kidney: Renal Tubule: 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%)

<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: 11/11/2014

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2/300 (0.67%)			10tai	0/300 (0%)		3D 0%
Kidney: Renal Tubule: Hemangioma								
		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%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%
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%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hemangiosarcoma								
		9/50 (18%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		6/50 (12%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	24/300 (8%)	Mean 8%	SD 7.04%	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: GAVAGE Vehicle: CORN OIL

d Control Animal Groups Report Date: 11/11/2014
AVAGE

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			Male				Female	
*Liver: Hepatoblastoma								
		3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	10/300 (3.33%)	Mean 3.33%	SD 2.42%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hepatocellular Adenom	ıa							
		31/50 (62%)	26/50 (52%)	27/50 (54%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
		29/50 (58%)	23/50 (46%)	32/50 (64%)		17/50 (34%)	5/50 (10%)	13/50 (26%)
Overall Incidence	Total	168/300 (56%)	Mean 56%	SD 6.69%	Total	67/300 (22.33%)	Mean 22.33%	SD 10.46%
Liver: Hepatocellular Carcino								
		22/50 (44%)	12/50 (24%)	20/50 (40%)		9/50 (18%)	6/50 (12%)	3/50 (6%)
		22/50 (44%)	18/50 (36%)	11/50 (22%)		6/50 (12%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	105/300 (35%)	Mean 35%	SD 9.78%	Total	30/300 (10%)	Mean 10%	SD 5.06%
Liver: Hepatocellular Carcino	ma or Hepatob	lastoma						
•	-	24/50 (48%)	15/50 (30%)	20/50 (40%)		10/50 (20%)	6/50 (12%)	3/50 (6%)
		22/50 (44%)	18/50 (36%)	12/50 (24%)		6/50 (12%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	111/300 (37%)	Mean 37%	SD 8.92%	Total	31/300 (10.33%)	Mean 10.33%	SD 5.72%
Liver: Hepatocellular Carcino	ma or Hepatoc	ellular Adenoma						
		39/50 (78%)	35/50 (70%)	38/50 (76%)		20/50 (40%)	12/50 (24%)	10/50 (20%)
		38/50 (76%)	31/50 (62%)	39/50 (78%)		20/50 (40%)	8/50 (16%)	15/50 (30%)
Overall Incidence	Total	220/300 (73.33%)	Mean 73.33%	SD 6.28%	Total	85/300 (28.33%)	Mean 28.33%	SD 10.15%

<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** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

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Report Date: 11/11/2014

Length of Study: CHRONIC

			Male				Female	
Liver:								
Hepatocellular Carcinor	ma, Hepatocel	lular Adenoma, or Hepato	blastoma					
		39/50 (78%)	36/50 (72%)	38/50 (76%)		20/50 (40%)	12/50 (24%)	10/50 (20%)
		38/50 (76%)	31/50 (62%)	39/50 (78%)		20/50 (40%)	8/50 (16%)	15/50 (30%)
Overall Incidence	Total	221/300 (73.67%)	Mean 73.67%	SD 6.12%	Total	85/300 (28.33%)	Mean 28.33%	SD 10.15%
Liver: Hepatocholangiocarcine	oma							
ricpatoonolarigioodiom	Oma	0/50 (0%)	0/50 (0%)	4/50 (8%)		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	4/300 (1.33%)	Mean 1.33%	SD 3.27%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign			•••••					
•		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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:  Mast Cell Tumor Malign	ant							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%
Liver: Sarcoma								
		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

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	
Lung: Alveolar/Bronchiolar Ad	denoma							
		8/50 (16%)	4/50 (8%)	9/50 (18%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		11/50 (22%)	5/50 (10%)	6/50 (12%)		2/50 (4%)	1/50 (2%)	5/50 (10%)
Overall Incidence	Total	43/300 (14.33%)	Mean 14.33%	SD 5.28%	Total	11/300 (3.67%)	Mean 3.67%	SD 3.44%
Lung: Alveolar/Bronchiolar Ca	arcinoma							
		11/50 (22%)	4/50 (8%)	2/50 (4%)		1/50 (2%)	2/50 (4%)	2/50 (4%)
		2/50 (4%)	5/50 (10%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	28/300 (9.33%)	Mean 9.33%	SD 6.65%	Total	6/300 (2%)	Mean 2%	SD 1.79%
Overall Incidence	Total	17/50 (34%) 13/50 (26%) 69/300 (23%)	8/50 (16%) 10/50 (20%) Mean 23%	11/50 (22%) 10/50 (20%) SD 6.29%	Total	1/50 (2%) 2/50 (4%) 17/300 (5.67%)	3/50 (6%) 1/50 (2%) Mean 5.67%	4/50 (8%) 6/50 (12%) SD 3.88%
*Lung: Hemangiosarcoma								
_		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma  Overall Incidence	Total	1/50 (2%) 2/300 (0.67%)	\ /	` '	Total	` ,	` '	` ,
Hemangiosarcoma  Overall Incidence	r:	1/50 (2%) 2/300 (0.67%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Hemangiosarcoma  Overall Incidence  #Lymph Node, Mandibula	r:	1/50 (2%) 2/300 (0.67%) 0/50 (0%)	0/50 (0%) Mean 0.67% 0/50 (0%)	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)
Hemangiosarcoma  Overall Incidence  #Lymph Node, Mandibula	r:	1/50 (2%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total Total	0/50 (0%) 0/300 (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** 

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Mean 1%

SD 1.1%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female #Lymph Node, Mediastinal: Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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% #Lymph Node, Mesenteric: Hemangiosarcoma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 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% **#Mammary Gland:** 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%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 3/300 (1%) Mean 1% SD 1.1% Total **#Mammary Gland:** Carcinoma or Adenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 3/300 (1%) Mean 1% SD 1.1% #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)

SD 0%

Total

3/300 (1%)

Total

0/300 (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: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

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			Male				Female	
#Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%
#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%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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%
#Mesentery: 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%
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (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: GAVAGE Vehicle: CORN OIL

Report Date: 11/11/2014

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			Male				Female	
Nose: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous		ynx, Tooth, Gingiva):						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
Oral Cavity (Oral Mucos) Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma						
		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%)	2/50 (4%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Oral Mucosa: Squamous Cell Carcin	oma							
		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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (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

\*Ovary:

\*Ovary:

\*Ovary:

\*Ovary:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Choriocarcinoma

Cystadenocarcinoma

**Overall Incidence** 

**Overall Incidence** 

Cystadenoma

**Overall Incidence** 

**Overall Incidence** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL Male **Female** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Total 1/297 (0.34%) Mean 0.33% SD 0.82% 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Total 0/297 (0%) Mean 0% SD 0% ..... 2/50 (4%)1/50 (2%)5/49 (10%)(2%)1/50 2/48 (4%)2/50 (4%)Total 13/297 (4.38%) Mean 4.4% SD 3.02%

0/50

0/50

1/297 (0.34%)

Total

(0%)

(0%)

0/50

1/48

(0%)

(2%)

Mean 0.35%

0/49

0/50

SD 0.85%

(0%)

(0%)

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Report Date: 11/11/2014

*Ovary:					
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)	1/48 (2%)	0/50 (0%)	
Overall Incidence	Total	1/297 (0.34%)	Mean 0.35%	SD 0.85%	

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

**Granulosa Cell Tumor Benign** 

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

Species: MICE

Strain: B6C3F1

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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: Hemangiosarcoma (0%) 1/50 (2%)0/50 0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% \*Ovary: Luteoma 0/50 (0%)0/50 (0%)1/49 (2%)(0%) 0/50 (0%)0/48 0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.34% SD 0.83% \*Ovary: Sarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: **Tubulostromal Adenoma** 0/50 (0%)1/50 0/49 (0%)1/50 (2%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 2/297 (0.67%) Mean 0.67%

<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

Tumor Incidence for Selected Control Animal Groups

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Mean 5.02%

SD 3.75%

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** \*Ovary: **Yolk Sac Carcinoma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/297 (0%) **Overall Incidence** Total Mean 0% SD 0% \*Pancreas: Carcinoma (0%) (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/49 (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% \*Pancreas: Carcinoma or Adenoma 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%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 0/49 (0%)0/50 (0%)(0%)4/50 (8%)3/49 (6%)2/50 (4%)0/50 (0%)0/47 (0%)0/50 (0%)0/48 (0%)5/50 (10%)1/50 (2%)**Overall Incidence** Total 0/295 (0%) Mean 0% SD 0% Total 15/297 (5.05%) Mean 5.02% SD 3.75% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/49 (0%)4/50 (8%)3/49 (6%)2/50 (4%)0/50 (0%)0/47 (0%)0/50 (0%)(0%)5/50 (10%)1/50 (2%)

SD 0%

Total

15/297 (5.05%)

Total

......

0/295 (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: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
Pituitary Gland: Pars Interm Adenoma	edia:							
		0/49 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/49 (2%)	1/50 (2%)
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.34%	SD 0.83%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
Pituitary Gland: Pars Interm Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/49 (2%)	1/50 (2%)
		0/50 (0%)	0/47 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/295 (0.34%)	Mean 0.34%	SD 0.83%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
Salivary Glands: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		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%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		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%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	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

Species: MICE

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: B6C3F1 Vehicle: CORN OIL

			Male				Female	
Salivary Glands:								
-		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%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		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	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skeletal Muscle: Rhabdomyosarcoma or F								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
		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	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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

ontrol Animal Groups GE **Page:** 30

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Skin:								,
Basal Cell Carcinoma			- / / / /				- / / /	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin: Basal Cell Carcinoma (	or Basosquamou	us Tumor (malignant or N	OS)					
Buoui oui oui oiiioiiia (	or Baccoquanie	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%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Skin:	Danal Call Adam	oma Basosauamous Tur	nor (honian maliana	nt or				
, ,	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	1/50 (2%) 0/50 (0%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
verall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.03%
verall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom bithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 2/300 (0.67%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.03% 
verall Incidence  Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli everall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or E eratoacanthoma, Trichoep 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom bithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0%	Total Total	0/50 (0%) 2/300 (0.67%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%)	1/50 (2%) SD 1.03% 
NOS), or Trichoepithelicoverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, Soverall Incidence	Total  Total  noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli  overall Incidence  Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, Soverall Incidence	Total  Total  noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%)		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%)
NOS), or Trichoepitheli  overall Incidence  Skin: Basal or Sq. Cell Carcii Adenoma, Papilloma, Soverall Incidence	Total  Total  noma, Carcinom Sq Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%)  aa, Basosq. Tumor (M or Estatoacanthoma, Trichoep 0/50 (0%) 0/50 (0%) 1/300 (0.33%)  oma, Myxosarcoma, or Fi	0/50 (0%) 0/50 (0%) Mean 0%  B), Basal Cell Adenomithelioma 0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0% na, 0/50 (0%) 1/50 (2%) SD 0.82%		0/50 (0%) 2/300 (0.67%) 1/50 (2%) 1/50 (2%) 3/300 (1%)	0/50 (0%) Mean 0.67%  0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%) SD 1.1%

<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: 11/11/2014

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Skin: **Fibrosarcoma** 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%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 4/300 (1.33%) Mean 1.33% SD 1.63% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (0%)0/50 1/50 (2%)0/50 (0%)3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)1/50 (2%)Mean 0.67% **Overall Incidence** Total 2/300 (0.67%) SD 1.03% Total 8/300 (2.67%) Mean 2.67% SD 2.07% #Skin: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin: **Granular Cell Tumor Benign** (0%) 0/50 (0%)0/50 (0%)1/50 (2%)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 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 0%

(0%)

Total

0/50

1/300 (0.33%)

(0%)

0/50

(0%)

Mean 0.33%

1/50

SD 0.82%

(2%)

Total

0/50

0/300 (0%)

(0%)

0/50

Mean 0%

(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** 

**Page:** 32

Mean 0%

SD 0%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Skin:								
Hemangiosarcoma		0/50 (00/)	0/50 (00/)	4/50 (00	<b>//</b>	0/50 (00/)	0/50 (00/)	0/50 (00/)
		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%) 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%
#Skin: 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%)	1/50 (29	<u>(</u>	1/50 (2%)	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%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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: Mast Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

0/300 (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:** 33

			Male				Female	
#Skin: Mast Cell Tumor Malignan	t							
		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%)
		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 Malignant								
		1/50 (2%)	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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Neural Crest Tumor								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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: Neurofibroma or Schwann	noma benign							
	3	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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

for Selected Control Animal Groups

Route: GAVAGE

**Page:** 34

Report Date: 11/11/2014

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: CORN OIL

			Male				Female	
#Skin:								
Neurofibrosarcoma or \$	Schwannoma (n	nalignant or NOS)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin:								
Neurofibrosarcoma, Ne	urofibroma, or	Schwannoma (benign, ma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Osteosarcoma								
		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%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Sarcoma		•••••		•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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**

Tumor Incidence for Selected Control Animal Groups

**Page:** 35

Report Date: 11/11/2014

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%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell	Carcinoma, Basosquamo	ous Tumor (malignant o	or NOS),				
		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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Skin: Squamous Cell Papilloma	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%)	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: Squamous Cell Papilloma	a 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%)	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: Squamous Cell Papilloma	a, Papilloma, S	Squamous Cell Carcinom	a 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%)	1/50 (2%)		1/50 (2%)	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** 

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

ontrol Animal Groups

**Page:** 36

Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Squamous Cell Papilloma, F	Papilloma,	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%)	1/50 (2%)		1/50 (2%)	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%
Spinal Cord: 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%
*Spleen: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/49 (0%)
		3/48 (6%)	1/50 (2%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	8/298 (2.68%)	Mean 2.71%	SD 2.15%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.03%
Spleen: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		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%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/11/2014

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon	na Squamous						
		0/50 (0%) 1/50 (2%)	2/50 (4%) 2/50 (4%)	9/50 (18%) 5/50 (10%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)
Overall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 6.62%	Total	7/300 (2.33%)	Mean 2.33%	SD 2.34%
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 2/50 (4%)	8/50 (16%) 5/50 (10%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)
Overall Incidence	Total	17/300 (5.67%)	Mean 5.67%	SD 6.12%	Total	7/300 (2.33%)	Mean 2.33%	0/50 (0%) SD 2.34%
#Stomach, Glandular: Adenoma								
		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%
Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/300 (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%
						` ,		

<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: 11/11/2014

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** \*Testes: Adenoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** Total 4/300 (1.33%) Mean 1.33% SD 1.63% \*Testes: Hemangioma (0%) 0/50 (0%)0/50 0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% \*Thymus: **Neoplasm NOS** 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/48 (0%)0/40 0/47 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/282 (0%) Mean 0% SD 0% Total 0/297 (0%) Mean 0% SD 0% \*Thymus: Thymoma Benign 0/48 0/50 (0%)1/49 (2%)(0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/40 (0%)0/47 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 1/282 (0.35%) Mean 0.34% SD 0.83% Total 0/297 (0%) Mean 0% SD 0% \*Thymus: **Thymoma Malignant** 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/48 (0%)0/40 (0%)0/47 (0%)0/50 (0%)0/48 (0%)0/50 (0%)**Overall Incidence** Total 0/282 (0%) Mean 0% SD 0% Total 0/297 (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: CORN OIL

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			Male				Female	
Thymus: Thymoma: Benign, Maligna	nnt, NOS							
		0/50 (0%) 0/48 (0%)	1/49 (2%) 0/40 (0%)	0/48 (0%) 0/47 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/282 (0.35%)	Mean 0.34%	SD 0.83%	Total	0/297 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/299 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
		0/299 (0%)				` '		SD 0.82%
*Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Thyroid Gland: Follicular Ce Adenoma	II:							
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	2/299 (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

Strain: B6C3F1

**Toxicology Data Management System** 

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Mean 0.33%

SD 0.82%

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** \*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)2/299 (0.67%) **Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total Mean 0.67% SD 1.03% **#Tissue NOS: Fibrosarcoma** (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% **#Tissue NOS:** 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% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 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%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Tongue: Squamous Cell Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 11/11/2014

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male			Female			
Tooth: Odontoma									
		0/50 (0%) 5/50 (10%)	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%) 0/50 (0%)	
verall Incidence	Total	7/300 (2.33%)	Mean 2.33%	SD 4.08%	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%)	
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
Irinary Bladder: 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%)	0/49 (0%)	0/50 (0%)	
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%	
Uterus: Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence					Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
Uterus: Carcinoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	0/50 (0%)	

Total

0/300 (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

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Report Date: 11/11/2014

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female
#Uterus: Hemangioma			
			0/50 (0%) 0/50 (0%)
		` '	1/50 (2%) 0/50 (0%)
Overall Incidence	Tota	` '	Mean 0.33% SD 0.82%
#Uterus: Hemangiosarcoma			
•		` ,	0/50 (0%) 0/50 (0%)
		` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	` '	Mean 0% SD 0%
#Uterus: Leiomyoma			
			0/50 (0%) 0/50 (0%)
		` '	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	ıl 0/300 (0%)	Mean 0% SD 0%
#Uterus: Polyp Stromal			
		1/50 (2%) 0	0/50 (0%) 2/50 (4%)
		0/50 (0%) 0	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota		Mean 1% SD 1.67%
#Uterus: Sarcoma			
		0/50 (0%) 0	0/50 (0%) 0/50 (0%)
		0/50 (0%) 0	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	o/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

#Zymbal's Gland:

**Overall Incidence** 

Carcinoma or Adenoma

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

Length of Study: CHRONIC

Male **Female #Uterus:** Sarcoma Stromal 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 3/300 (1%) Mean 1% SD 1.67% #Uterus: Sarcoma Stromal or Polyp Stromal 2/50 (4%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 6/300 (2%) Mean 2% SD 2.19% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)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%

0/50

0/50

SD 1.03%

(0%)

(0%)

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%)

Total

0/50

1/50

2/300 (0.67%)

(0%)

(2%)

0/50

1/50

Mean 0.67%

(0%)

(2%)

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<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: 44

Report Date: 11/11/2014

#### **Study Summary**

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#All Organs: Benign Tumors								
		43/50 (86%)				20/50 (40%)		
Overall Incidence	Total	43/50 (86%)	Mean 86%	SD 0%	Total	20/50 (40%)	Mean 40%	SD 0%
#All Organs: Malignant Tumors		20/50 /500/				40/50 /00%		
Overell Incidence	Total	28/50 (56%)	Maan EGO/	CD 00/	Total	18/50 (36%)	Maan 260/	CD 00/
Overall Incidence	Total	28/50 (56%)	Mean 56%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
#All Organs: Malignant and Benign T	umors							
		49/50 (98%)				29/50 (58%)		
Overall Incidence	Total	49/50 (98%)	Mean 98%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%
#All Organs: Hemangioma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		2/30 (4%)				` ,		
#All Organs: Hemangiosarcoma								
		5/50 (10%)				2/50 (4%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Hemangiosarcoma or H	emangioma							
		7/50 (14%)				2/50 (4%)		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 46

Report Date: 11/11/2014

Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Histiocytic Sarcoma								
•		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:								
Malignant Lymphoma: Histi	iocytic, Lym	phocytic, Mixed, NOS, o 4/50 (8%)	r Undifferentiated Ce	ell Type		7/50 (14%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
#All Organs: Mesothelioma: Benign		•••••		•••••		•••••		
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Mal						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall incluence		0/30 (0/0)	IVICALI U/0	0 / 0 ط		0/30 (0/0)	ivicail U/0	3D 070

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

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

Species: MICE Strain: B6C3F1

Vehicle: WATER

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

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 48

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Route: GAVAGE Vehicle: WATER

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

<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:** 49

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

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

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

<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:** 51

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

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 52

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

<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: 53

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

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

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

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

Species: MICE

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

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

Route: GAVAGE

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: WATER

**Page:** 55

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

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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

0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
0/50 (0%		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
`	<i>(</i> )					
`	/ \					
0/50 (0%)		22.00/		0/50 (0%)		05 00/
	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
2/50 (49)	<b>(1)</b>			0/50 (0%)		
*	Mean 4%	SD 0%	Total	` '	Mean 0%	SD 0%
, ,						
2/50 (60)	<b>/</b> }			4/50 (20/)		
3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
,	,			0/50 (0%)		
2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
05/50 /700	0			10/50 (0.10()		
		SD 0%	Total		Moon 24%	SD 0%
	2/50 (4%)  3/50 (6%)  3/50 (6%)  2/50 (4%)  2/50 (4%)  35/50 (70%)	2/50 (4%) 2/50 (4%) Mean 4%  3/50 (6%) 3/50 (6%) Mean 6%  2/50 (4%) 2/50 (4%) Mean 4%  35/50 (70%) 35/50 (70%) Mean 70%	2/50 (4%) 2/50 (4%)  Mean 4%  SD 0%  3/50 (6%)  Mean 6%  SD 0%  2/50 (4%)  2/50 (4%)  Mean 4%  SD 0%  35/50 (70%)  35/50 (70%)  Mean 70%  SD 0%	2/50 (4%)  2/50 (4%)  Mean 4%  SD 0%  Total  3/50 (6%)  3/50 (6%)  Mean 6%  SD 0%  Total  2/50 (4%)  2/50 (4%)  Mean 4%  SD 0%  Total	2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%)  3/50 (6%) 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%)  1/50 (24%)  1/50 (24%)  1/50 (24%)	2/50 (4%) 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0%  3/50 (6%) 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) 1/50 (2%) Mean 2%  2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0%  35/50 (70%)  12/50 (24%)

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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

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

<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: 58

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

<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:** 59

				Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		1/50	(20/)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma							0/50 (00()		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Ca	rcinoma, or	Adenoma 0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(370)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

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

<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:** 62

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

<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:** 63

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

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma											
		1/49 (2%)				0/50 (0%)					
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Intern Adenoma	nedia:										
		0/49 (0%)				0/50 (0%)					
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Intern Carcinoma or Adenoma											
		0/49 (0%)				0/50 (0%)					
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Adenoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Carcinoma or Adenoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Hemangiosarcoma		0/50 (0%)				0/50 (09/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
Overall illiciating	IUIAI	0/30 (0%)	IVIEAN U70	OD 070	ıvıaı	U/3U (U70)	IVICALI U70	3D 0%			

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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

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

<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: 66

	Male						Female	Female				
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant 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: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tu	mor (benign, maligna	ant or								
Overell Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	SD 00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
	ou ravilivilla. Nei	ratoacanthoma, Trichoe	pitii <del>c</del> iiUllia									
	• •	0/50 (0%)				0/50 (0%)						
Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%)			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%)			Total	` '	Mean 0%	SD 0%				
Overall Incidence #Skin: Fibroma, Fibrosarcom	Total	0/50 (0%) 0/50 (0%) oma, Myxosarcoma, or F			Total Total	0/50 (0%)	Mean 0%  Mean 0%	SD 0%				
Overall Incidence #Skin: Fibroma, Fibrosarcom Overall Incidence	Total a, Sarcoma, Myxo	0/50 (0%) 0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma			0/50 (0%) 0/50 (0%) 0/50 (0%)						
Overall Incidence  #Skin: Fibroma, Fibrosarcom  Overall Incidence  #Skin: Fibrosarcoma	Total a, Sarcoma, Myxo	0/50 (0%) 0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	Fibrous Histiocytoma  Mean 0%	SD 0%	Total	0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	Mean 0%	SD 0%				
Overall Incidence  #Skin: Fibroma, Fibrosarcom  Overall Incidence  #Skin:	Total a, Sarcoma, Myxo	0/50 (0%) 0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	ibrous Histiocytoma			0/50 (0%) 0/50 (0%) 0/50 (0%)						
Overall Incidence  #Skin: Fibroma, Fibrosarcom  Overall Incidence  #Skin: Fibrosarcoma  Overall Incidence	Total  a, Sarcoma, Myxo  Total  Total	0/50 (0%) 0/50 (0%)  oma, Myxosarcoma, or F 0/50 (0%)  0/50 (0%)	Fibrous Histiocytoma  Mean 0%  Mean 0%	SD 0%	Total	0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	Mean 0%	SD 0%				
Overall Incidence  #Skin: Fibroma, Fibrosarcom  Overall Incidence  #Skin: Fibrosarcoma  Overall Incidence	Total  a, Sarcoma, Myxo  Total  Total	0/50 (0%) 0/50 (0%) oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	Fibrous Histiocytoma  Mean 0%  Mean 0%	SD 0%	Total	0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	Mean 0%	SD 0%				

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

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

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

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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

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

<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:** 69

<b>eport Date:</b> 11/11/2014
-------------------------------

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

<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:** 70

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

<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

Control Animal Groups Report Date: 11/11/2014

**Page:** 71

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

<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 Animal Groups Report Date: 11/11/2014

**Page:** 72

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

<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:** 73

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

<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:** 74

				Male				Female	
*Thyroid Gland: Follicular Ce Adenoma	II:								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		a Squamous	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma			(224)						
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:** 75

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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

**Page:** 76

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

<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: 77
Report Date: 11/11/2014

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

<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**

**Page:** 78

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

# Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	056031106	05/15/06	729	50(5)	39(715)	54.3	Cobalt
Battelle Northwest	052051504	05/05/08	729	50(5)	39(709)	52.6	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052030306	06/20/05	729	50(5)	29(680)	53.1	Vinylidene chloride
					Female		
Battelle Northwest	056031106	05/15/06	731	50(5)	36(686)	66.7	Cobalt
Battelle Northwest	052051504	05/05/08	731	50(5)	39(696)	59.2	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	052030306	06/20/05	731	50(5)	36(687)	66.0	Vinylidene chloride

**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

			Male				Female	
#All Organs: Benign Tumors								
		35/50 (70%)	39/50 (78%)	43/50 (86%)		29/50 (58%)	26/50 (52%)	32/50 (64%)
Overall Incidence	Total	117/150 (78%)	Mean 78%	SD 8%	Total	87/150 (58%)	Mean 58%	SD 6%
#All Organs: Malignant Tumors								
		36/50 (72%)	26/50 (52%)	37/50 (74%)		31/50 (62%)	30/50 (60%)	33/50 (66%)
Overall Incidence	Total	99/150 (66%)	Mean 66%	SD 12.17%	Total	94/150 (62.67%)	Mean 62.67%	SD 3.06%
#All Organs: Malignant and Benign Tu	mors	45/50 (90%)	46/50 (92%)	49/50 (98%)		40/50 (80%)	41/50 (82%)	45/50 (90%)
Overall Incidence	Total	140/150 (93.33%)	Mean 93.33%	SD 4.16%	Total	126/150 (84%)	Mean 84%	SD 5.29%
All Organs: Hemangioma		0/50 (0%)	1/50 (2%)	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%
#All Organs: Hemangiosarcoma								
		7/50 (14%)	1/50 (2%)	2/50 (4%)		3/50 (6%)	3/50 (6%)	4/50 (8%)
Overall Incidence	Total	10/150 (6.67%)	Mean 6.67%	SD 6.43%	Total	10/150 (6.67%)	Mean 6.67%	SD 1.15%
#All Organs: Hemangiosarcoma or Hei	mangioma							
		7/50 (14%)	2/50 (4%)	3/50 (6%)		3/50 (6%)	3/50 (6%)	4/50 (8%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 5.29%	Total	10/150 (6.67%)	Mean 6.67%	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**

Page: 80

Report Date: 11/11/2014

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	2/50 (4%) SD 1.15%
		, ,				,		
¢All Organs: Malignant Lymphoma: Hi	stiocytic, Lyn			• •				
		4/50 (8%)	3/50 (6%)	2/50 (4%)		14/50 (28%)	18/50 (36%)	14/50 (28%)
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 2%	Total	46/150 (30.67%)	Mean 30.67%	SD 4.62%
#All Organs: Mesothelioma: Benign								
		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: Benign, M			0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: 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

**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: Osteosarcoma										
		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%		
Adrenal Cortex: Adenoma										
	<b>-</b>	1/50 (2%)	9/49 (18%)	1/50 (2%)	<b>.</b>	0/50 (0%)	0/49 (0%)	1/50 (2%)		
Overall Incidence	Total	11/149 (7.38%)	Mean 7.46%	SD 9.45%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%		
Adrenal Medulla: Pheochromocytoma Benigr	1									
		0/50 (0%)	1/48 (2%)	1/50 (2%)		1/50 (2%)	1/49 (2%)	1/50 (2%)		
Overall Incidence	Total	2/148 (1.35%)	Mean 1.36%	SD 1.18%	Total	3/149 (2.01%)	Mean 2.01%	SD 0.02%		
Adrenal Medulla: Pheochromocytoma Malign	ant									
		0/50 (0%)	0/48 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	1/50 (2%)		
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%		
Adrenal Medulla: Pheochromocytoma: Benig	n, Complex	x, Malignant, NOS								
		0/50 (0%)	1/48 (2%)	2/50 (4%)		1/50 (2%)	1/49 (2%)	2/50 (4%)		
Overall Incidence	Total	3/148 (2.03%)	Mean 2.03%	SD 2%	Total	4/149 (2.68%)	Mean 2.68%	SD 1.14%		

<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: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Blood Vessel: Hemangioma								
Overell Insidence	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%
*Bone Marrow: 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%
*Bone Marrow: Hemangiosarcoma								
		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%
*Bone Marrow: Mast Cell Tumor Malignant								
Occupation of decision	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	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%
*Bone Marrow: Sarcoma								
		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%
#Bone: Fibroma		•••••	•••••					
		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**

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

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Report Date: 11/11/2014

			Male				Female	
#Bone: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma		- (ac)	(00)	0/20		(0.00)		(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	SD 0%	0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	0%) Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
*Brain: Granular Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	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: 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%) 0/50 (0%)												
		0/50 (0%)	0/50 (0%)	,	6)	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	ignant. NOS											
	.g,	0/50 (0%)	0/50 (0%)	0/50 (0%	6)	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: Oligodendroglioma Malig	nant	0/50 (0%)	0/50 (0%)	0/50 (0%	······································	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	o) Total	0/150 (0%)	Mean 0%	SD 0%				
Brain: Oligodendroglioma, Glion	na, or Astrocy	toma										
		0/50 (0%)	0/50 (0%)	0/50 (0%	6)	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%				
Clitoral/Preputial Gland: Hemangioma												
		0/49 (0%)	0/50 (0%)	0/50 (0%	6)	0/43 (0%)	0/44 (0%)	0/45 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/132 (0%)	Mean 0%	SD 0%				
Clitoral/Preputial Gland: Hemangiosarcoma												
		0/49 (0%)	0/50 (0%)	0/50 (0%	,	0/43 (0%)	0/44 (0%)	0/45 (0%)				
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/132 (0%)	Mean 0%	SD 0%				

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Coagulating Gland: Granular Cell Tumor								
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>T</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%
Coagulating Gland:								
		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%
#Eye: Melanoma 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%
Harderian Gland: Adenoma		6/50 (12%)	7/50 (14%)	7/50 (14%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	20/150 (13.33%)	Mean 13.33%	SD 1.15%	Total	6/150 (4%)	Mean 4%	SD 2%
Harderian Gland: Carcinoma								
		2/50 (4%)	5/50 (10%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 5.03%	Total	3/150 (2%)	Mean 2%	SD 3.46%
#Harderian Gland: Carcinoma or Adenoma								
		8/50 (16%)	12/50 (24%)	7/50 (14%)		3/50 (6%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	27/150 (18%)	Mean 18%	SD 5.29%	Total	9/150 (6%)	Mean 6%	SD 2%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Heart: Hemangiosarcoma								
Overall 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%
fIntestine Large: Cecum: 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 Large: Cecum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Intestine Large: Cecum: Carcinoma or Adenoma								
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
ntestine Large: Cecum: Leiomyosarcoma								
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: 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%

<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: 11/11/2014

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Intestine Small: Duodenum: 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 Small: Ileum: Adenoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15% 1/150 (0.67%) Mean 0.67% SD 1.15% Total #Intestine Small: Ileum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% 2/150 (1.33%) Mean 1.33% SD 1.15% Total ...... #Intestine Small: Jejunum: 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% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) #Intestine Small: Jejunum: 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 Small: Jejunum: Leiomyosarcoma 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**

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Intestine Small: Site Unspecified: Adenoma 2/50 (4%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #Intestine Small: Site Unspecified: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #Intestine Small: Site Unspecified: Carcinoma or Adenoma 2/50 (4%)1/50 (2%)1/50 (2%)1/50 (2%)1/50 (2%)2/50 (4%)**Overall Incidence** 4/150 (2.67%) Mean 2.67% SD 1.15% 4/150 (2.67%) Mean 2.67% SD 1.15% Total Total ..... #Intestine Small: Site Unspecified: Leiomyosarcoma 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%) \*Islets, Pancreatic: Adenoma 0/49 (0%)2/50 (4%)2/50 (4%)0/50 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 4/149 (2.68%) Mean 2.67% SD 2.31% Total 2/150 (1.33%) Mean 1.33% SD 1.15% \*Islets, Pancreatic: Carcinoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/149 (0%) Total

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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** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 89

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/49 (0%)	2/50 (4%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	4/149 (2.68%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Kidney: Pelvis and Transitio Carcinoma	onal Epithelio	um:						
		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%
Kidney: Pelvis and Transitio Carcinoma or Adenoma	onal Epitheli	um:	•••••					
		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%
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								
		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: Carcinoma or Adenoma			(25.)	(00)				2/22
Overell In elden ee	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%

<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:** 90

			Male				Female	
Kidney: Renal Tubule: Hemangioma								
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%
		0/130 (0 /6)						
Kidney: Renal Tubule: Hemangiosarcoma		0/50 (00)	0/50 (00/)	4/50 (00/)		0/50 (00/)	0/50 /00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Liver: 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%
_iver: Hemangiosarcoma								
Overall Incidence	Total	4/50 (8%) 6/150 (4%)	0/50 (0%) Mean 4%	2/50 (4%) SD 4%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
Liver: Hepatoblastoma								
•		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Liver: Hepatocellular Adenoma		00/50 /502/	04/50 /400/	27/50 (740/)	•••••	40/50 /200/	44/50 (000()	25/50 /50%
Overall Incidence	Total	28/50 (56%) 89/150 (59.33%)	24/50 (48%) Mean 59.33%	37/50 (74%) SD 13.32%	Total	19/50 (38%) 58/150 (38.67%)	14/50 (28%) Mean 38.67%	25/50 (50%) SD 11.02%
Jverali incidence	rotai	89/150 (59.33%)	wean 59.33%	SD 13.32%	ıotai	58/150 (38.67%)	wean 38.67%	SD 11.02%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 91

			Male				Female	
Liver: Hepatocellular Carcinoma								
		25/50 (50%)	11/50 (22%)	26/50 (52%)		10/50 (20%)	10/50 (20%)	8/50 (16%)
Overall Incidence	Total	62/150 (41.33%)	Mean 41.33%	SD 16.77%	Total	28/150 (18.67%)	Mean 18.67%	SD 2.31%
Liver: Hepatocellular Carcinoma c	r Hepatob	olastoma						
·	•	27/50 (54%)	11/50 (22%)	27/50 (54%)		10/50 (20%)	10/50 (20%)	8/50 (16%)
Overall Incidence	Total	65/150 (43.33%)	Mean 43.33%	SD 18.48%	Total	28/150 (18.67%)	Mean 18.67%	SD 2.31%
Liver: Hepatocellular Carcinoma c								
		38/50 (76%)	32/50 (64%)	44/50 (88%)		25/50 (50%)	20/50 (40%)	28/50 (56%)
Overall Incidence	Total	114/150 (76%)	Mean 76%	SD 12%	Total	73/150 (48.67%)	Mean 48.67%	SD 8.08%
Liver: Hepatocellular Carcinoma, l	Hepatocel	lular Adenoma, or Hepatol 39/50 (78%)	blastoma 32/50 (64%)	45/50 (90%)		25/50 (50%)	20/50 (40%)	28/50 (56%)
Overall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 13.01%	Total	73/150 (48.67%)	Mean 48.67%	SD 8.08%
Liver: Hepatocholangiocarcinoma								
		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%
Liver: Ito Cell Tumor Benign								
		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**

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

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			Male				Female	
*Liver: Mast Cell Tumor Malignan	nt							
	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	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%
Liver: 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%
Lung: Alveolar/Bronchiolar Adei	noma	7/50 (14%)	5/50 (10%)	7/50 (14%)		3/49 (6%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 2.31%	Total	7/149 (4.7%)	Mean 4.71%	SD 2.35%
Lung: Alveolar/Bronchiolar Carc		11/50 (22%)	8/50 (16%)	9/50 (18%)		5/49 (10%)	4/50 (8%)	1/50 (2%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 3.06%	Total	10/149 (6.71%)	Mean 6.73%	SD 4.25%
Lung: Alveolar/Bronchiolar Carc		veolar/Bronchiolar Adeno	ma					
O 11 In 1 In	T-1-1	16/50 (32%)	13/50 (26%)	13/50 (26%)	T-1-1	8/49 (16%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	42/150 (28%)	Mean 28%	SD 3.46%	Total	16/149 (10.74%)	Mean 10.78%	SD 4.81%
Lung: Hemangiosarcoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	<b>+</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Toxicology Data Management System

Contract/Lab: All Laboratories

tories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Strain: B6C3F1 Length of Study: CHRONIC Route: INHALATION Vehicle: AIR

**Page:** 93

			Male				Female	
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lymph Node, Mesenteric: Hemangiosarcoma								
	<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%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Mammary Gland: Fibroma, Fibroadenoma, Ca	arcinoma, or	r Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	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: INHALATION Vehicle: AIR

**Page:** 94

			Male				Female	
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 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%
Mesentery: Hemangiosarcoma								
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%
Mesentery: Lipoma								
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%
Mesentery: Sarcoma								
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%
lose: 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%
Nose: Hemangiosarcoma								
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: INHALATION Vehicle: AIR

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			Male				Female	
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
	-	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%
Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva):						
		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%
Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma 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%
	ı Olai	0/150 (0%)			Total		Wealt 0%	
Oral Mucosa: Squamous Cell Carcin	oma							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total	0/150 (0%)		עס עס U%	Total	0/150 (0%)	wean 0%	3D 0%
Ovary: Choriocarcinoma								
						0/48 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/148 (0%)	Mean 0%	SD 0%
Ovary: Cystadenocarcinoma								
					Total	0/48 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 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

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Report Date: 11/11/2014

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Cystadenoma 1/48 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 4/148 (2.7%) Mean 2.69% SD 1.13% ..... \*Ovary: **Granulosa Cell Tumor Benign** 0/48 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/48 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% ..... \*Ovary: Hemangioma 0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% \*Ovary: Hemangiosarcoma 0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% \*Ovary: Luteoma 0/48 (0%)1/50 (2%)1/50 (2%)**Overall Incidence** 2/148 (1.35%) Mean 1.33% 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

Strain: B6C3F1

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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Sarcoma 0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% ..... \*Ovary: **Tubulostromal Adenoma** 0/50 0/48 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% \*Ovary: Yolk Sac Carcinoma 1/48 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.69% SD 1.2% ..... \*Pancreas: Carcinoma 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% \*Pancreas: Carcinoma or Adenoma 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% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma (0%)0/50 (0%)0/49 (0%)3/47 (6%)5/50 (10%) 8/50 (16%) **Overall Incidence** Total 0/146 (0%) Mean 0% SD 0% Mean 10.79% SD 4.86% Total 16/147 (10.88%)

<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	
Pituitary Gland: Pars Dista Carcinoma or Adenoma	alis or Unspec	ified Site:						
		0/47 (0%)	0/50 (0%)	0/49 (0%)		3/47 (6%)	5/50 (10%)	8/50 (16%)
verall Incidence	Total	0/146 (0%)	Mean 0%	SD 0%	Total	16/147 (10.88%)	Mean 10.79%	SD 4.86%
Pituitary Gland: Pars Inter Adenoma	media:							
		0/47 (0%)	0/50 (0%)	1/49 (2%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/146 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/147 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inter Carcinoma or Adenoma	media:	0/47 (00/)	0/50 /000	4/40 (000)		0/47 (00)	0/50 (00/)	0/50 (00/)
	Tatal	0/47 (0%)	0/50 (0%)	1/49 (2%)	Tatal	0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/146 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/147 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma								
N	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	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								
		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: 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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 99

		Male				Female	
Total	` ,	` '	` '	Total	` ,	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
	` '				` ,		
	2/22 (221)	2/52 (224)			2/22 (22()	2(22)	2/52 (224)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15% )	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
					•••••		•••••
T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
	` '				` ,		SD 0%
nabdomyoma	a						
Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	` '	0/50 (0%)	0/50 (0%) SD 0%
	` '				` '		 อบ 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
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 (0%)		0/50 /00/\	0/50 (00/)	0/50 (00/)
Total	` '	` '	` '	Total	` '	` ,	0/50 (0%) SD 0%
-	Total  Total  nabdomyoma	0/50 (0%) Total 1/150 (0.67%)  0/50 (0%) Total 0/150 (0%)  nabdomyoma 0/50 (0%) Total 0/150 (0%)  Total 0/150 (0%)  Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67%  0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%  nabdomyoma 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%  Total 0/150 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%	Total 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%   0/50 (0%) 0/50 (0%) 1/50 (2%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15%   0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%   nabdomyoma  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%   Total 0/150 (0%) Mean 0% SD 0%   Total 0/150 (0%) Mean 0% SD 0%   0/50 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total     0/50 (0%) 0/50 (0%) 1/50 (2%)	Total 0/50 (0%) 0/50 (0%) SD 0% Total 1/150 (0.67%)  Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%)  Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0%)	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67%    0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67%   Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%    0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%    0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%    0/50 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0%    0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 100 Report Date: 11/11/2014

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

Length of Study: CHRONIC

			Male				Female	
#Skin:						,		
Basal Cell Carcinoma	or Basosquamou	us Tumor (malignant or N	•					
		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: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tur	nor (benign, malignaı	nt or				
		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%
Adenoma, Papilloma, S	oq i apilioilia, ita		0/50 (00%)	4/50 (00/)		0/50 (00/)	4/50 (00/)	0/50 (00/)
Adenoma, r apmoma, c	oq r apmoma, rto	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total		Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%
Overall Incidence #Skin:	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	` '
Overall Incidence #Skin:	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	` '
Overall Incidence #Skin: Fibroma, Fibrosarcoma	Total	0/50 (0%) 1/150 (0.67%) oma, Myxosarcoma, or F	Mean 0.67%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	SD 1.15%
Overall Incidence #Skin: Fibroma, Fibrosarcoma	Total a, Sarcoma, Myx	0/50 (0%) 1/150 (0.67%) oma, Myxosarcoma, or F 0/50 (0%)	Mean 0.67% brous Histiocytoma 0/50 (0%)	SD 1.15%		1/150 (0.67%) 2/50 (4%)	Mean 0.67%  0/50 (0%)	SD 1.15% 2/50 (4%)
Overall Incidence #Skin: Fibroma, Fibrosarcoma Overall Incidence	Total a, Sarcoma, Myx	0/50 (0%) 1/150 (0.67%) oma, Myxosarcoma, or F 0/50 (0%)	Mean 0.67% brous Histiocytoma 0/50 (0%)	SD 1.15%		1/150 (0.67%) 2/50 (4%)	Mean 0.67%  0/50 (0%)	SD 1.15% 2/50 (4%)
Overall Incidence  #Skin: Fibroma, Fibrosarcoma  Overall Incidence  #Skin: Fibrosarcoma	Total  a, Sarcoma, Myx  Total  Total	0/50 (0%) 1/150 (0.67%) oma, Myxosarcoma, or Fi 0/50 (0%) 1/150 (0.67%) 0/50 (0%) 0/150 (0%)	Mean 0.67%  brous Histiocytoma 0/50 (0%) Mean 0.67%  0/50 (0%) Mean 0%	SD 1.15% (2%) SD 1.15%		1/150 (0.67%)  2/50 (4%)  4/150 (2.67%)	Mean 0.67% 0/50 (0%) Mean 2.67%	SD 1.15%  2/50 (4%) SD 2.31%
Overall Incidence  #Skin: Fibroma, Fibrosarcoma  Overall Incidence  #Skin: Fibrosarcoma  Overall Incidence	Total  a, Sarcoma, Myx  Total  Total	0/50 (0%) 1/150 (0.67%)  oma, Myxosarcoma, or Fi 0/50 (0%) 1/150 (0.67%)  0/50 (0%) 0/150 (0%)	Mean 0.67%  (brous Histiocytoma 0/50 (0%)  Mean 0.67%  0/50 (0%)  Mean 0%	SD 1.15%  1/50 (2%) SD 1.15%  0/50 (0%)	Total	1/150 (0.67%)  2/50 (4%) 4/150 (2.67%)  0/50 (0%)	Mean 0.67%  0/50 (0%)  Mean 2.67%  0/50 (0%)	SD 1.15%  2/50 (4%) SD 2.31%  1/50 (2%)
Overall Incidence  #Skin: Fibroma, Fibrosarcoma  Overall Incidence  #Skin: Fibrosarcoma  Overall Incidence	Total  a, Sarcoma, Myx  Total  Total	0/50 (0%) 1/150 (0.67%) oma, Myxosarcoma, or Fi 0/50 (0%) 1/150 (0.67%) 0/50 (0%) 0/150 (0%)	Mean 0.67%  (brous Histiocytoma 0/50 (0%)  Mean 0.67%  0/50 (0%)  Mean 0%	SD 1.15%  1/50 (2%) SD 1.15%  0/50 (0%)	Total	1/150 (0.67%)  2/50 (4%) 4/150 (2.67%)  0/50 (0%)	Mean 0.67%  0/50 (0%)  Mean 2.67%  0/50 (0%)	SD 1.15%  2/50 (4%) SD 2.31%  1/50 (2%)

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		·	Male			Female				
#Skin: Fibrous Histiocytoma		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%		
#Skin: Granular Cell Tumor Ber	nign									
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: Hemangioma			- / /				- /			
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: Hemangiosarcoma							- /			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%		
#Skin: Keratoacanthoma		0/50 (00/)	0/50 (00/)	4/50 (00)		0/50 (00/)	0/50 (004)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Skin: Lipoma	•••••									
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**

Page: 102

Report Date: 11/11/2014

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Skin: Liposarcoma 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% #Skin: Mast Cell Tumor Benign 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: **Mast Cell Tumor 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% ..... #Skin: Melanoma Benign 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% #Skin: **Melanoma 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% #Skin: **Neural Crest Tumor** 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.67% 1/150 (0.67%) Mean 0.67% SD 1.15% 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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 103

			Male				Female			
#Skin: Neurofibroma or Schwannoma benign										
		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%		
Skin: Neurofibrosarcoma or Sc	:hwannoma (ma	alignant or NOS)								
	(	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%		
Skin: Neurofibrosarcoma, Neur	rofibroma, or Se	chwannoma (benign, ma	lignant or NOS) 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%		
Skin: Osteosarcoma		(00)	(00)	0./50			(201)	0/50 (00)		
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%		
verali ilicidelice										
Skin: Sarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (09	,	2/50 (4%)	0/50 (0%)	1/50 (2%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%		
Skin: Schwannoma Benign										
		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: INHALATION Vehicle: AIR

**Page:** 104

			Male				Female				
#Skin: Schwannoma 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%			
#Skin: Squamous Cell Carcinom or Carcinoma	ıa, Basal Cell (	Carcinoma, Basosquamo	us Tumor (malignant	or 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%			
#Skin: Squamous Cell Papilloma	1										
		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%			
#Skin: Squamous Cell Papilloma	a or Papilloma										
		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%			
#Skin: Squamous Cell Papilloma	a, Papilloma, S	Squamous Cell Carcinom 0/50 (0%)	a or Keratoacanthoma	<b>a</b> 1/50 (2%)		0/50 (0%)	1/50 (2%)	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%			
#Skin: Squamous Cell Papilloma	a, Papilloma, c	or Keratoacanthoma	0/50 (0%)	1/50 (2%)	•••••	0/50 (0%)	1/50 (2%)	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

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:** 105

			Male			Female				
#Spinal Cord: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Spleen: Hemangiosarcoma		3/50 (6%)	0/50 (0%)	2/50 (4%)		2/49 (4%)	1/50 (2%)	3/50 (6%)		
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	6/149 (4.03%)	1/50 (2%) Mean 4.03%	SD 2%		
*Spleen: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%		
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	na Squamous	•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	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										
Overall Incidence	Total	1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (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

**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				
#Stomach, Glandular: 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%		
#Stomach, Glandular: Carcinoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00/)	4/50 (00)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Testes: Adenoma										
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%						
Testes: Hemangioma	•••••		•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%						
*Thymus: Neoplasm NOS		0/40 /(00/)	0/44 (00/)	0/00 (00/)		4/40 (00)	0/44 (00/)	0/47 (00/)		
Overall Incidence	Total	0/42 (0%) 0/122 (0%)	0/41 (0%) Mean 0%	0/39 (0%) SD 0%	Total	1/46 (2%) 1/137 (0.73%)	0/44 (0%) Mean 0.72%	0/47 (0%) SD 1.26%		

<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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Mean 0%

SD 0%

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Thymus: **Thymoma Benign** 0/42 (0%)0/41 (0%)0/39 (0%)0/46 (0%)0/44 (0%)0/47 (0%)SD 0% Overall Incidence Total 0/122 (0%) Mean 0% SD 0% Total 0/137 (0%) Mean 0% \*Thymus: **Thymoma Malignant** 0/42 (0%)0/41 (0%)0/39 (0%)0/46 (0%)0/44 (0%)0/47 (0%)**Overall Incidence** Total 0/122 (0%) Mean 0% SD 0% Total 0/137 (0%) Mean 0% SD 0% \*Thymus: Thymoma: Benign, Malignant, NOS 0/42 (0%)0/41 (0%)0/39 (0%)0/46 (0%)0/44 (0%)0/47 (0%)**Overall Incidence** Total 0/122 (0%) Mean 0% SD 0% Total 0/137 (0%) Mean 0% SD 0% ..... \*Thyroid Gland: C-Cell: Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Thyroid Gland: C-Cell: Carcinoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Thyroid Gland: C-Cell: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/150 (0%)

Total

Mean 0%

Total

0/149 (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:** 108

			Male			Female				
Гhyroid Gland: Follicular Cell: Adenoma										
		0/49 (0%)	0/50 (0%)	0/50	(0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
		0/49 (0%)	0/50 (0%)	0/50	(0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Tissue NOS: Fibrosarcoma										
		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%	
Tissue NOS: 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%	(070)	Total	0/150 (0%)	Mean 0%	SD 0%	
Tongue: Squamous Cell Carcinoma o	r Papilloma	a <b>Squamous</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%	
Tongue: Squamous Cell Papilloma						••••				
		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: INHALATION Vehicle: AIR

**Page:** 109

			Male			Female			
Tooth: Odontoma									
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%	
Urethra: Hemangiosarcoma									
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%	
Jrinary Bladder: Hemangiosarcoma			(100)	2/22					
verall Incidence	Total	0/48 (0%) 1/148 (0.68%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
Iterus: Adenoma									
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
terus: Carcinoma									
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Jterus: Hemangioma									
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

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

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

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	Male		Female	
#Uterus: Hemangiosarcoma				
Overall Incidence	Tot	` ,	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
Uterus: Leiomyoma				
Overall Incidence	Tot	, ,	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Uterus: Polyp Stromal				
Overall Incidence	Tot	` ,	0/50 (0%) Mean 2.67%	2/50 (4%) SD 2.31%
Uterus: Sarcoma				
Overall Incidence	Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Sarcoma Stromal				
Overall Incidence	Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal				
Overall Incidence	Tot	2/50 (4%) al 4/150 (2.67%)	0/50 (0%) Mean 2.67%	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

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			
#Zymbal's Gland: 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%	
#Zymbal's Gland: Carcinoma or 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%	

<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

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Report Date: 11/11/2014

Route: ORAL Vehicle: WATER

# **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	052000904	11/09/04	730	50(1)	24(645)	57.1	beta-Picoline
Battelle Columbus Laboratory	059601406	09/26/06	730	50(1)	25(660)	55.9	Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Columbus Laboratory	052000904	11/08/04	729	50(5)	38(702)	67.4	beta-Picoline
Battelle Columbus Laboratory	059601406	09/25/06	729	50(5)	30(680)	63.5	Water disinfection byproducts (Bromodichloroacetic acid)

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 113

			Male				Female	
#All Organs: Benign Tumors								
		36/50 (72%)	43/50 (86%)			40/50 (80%)	36/50 (72%)	
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 9.9%	Total	76/100 (76%)	Mean 76%	SD 5.66%
#All Organs: Malignant Tumors								
		36/50 (72%)	30/50 (60%)			29/50 (58%)	31/50 (62%)	
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 8.49%	Total	60/100 (60%)	Mean 60%	SD 2.83%
#All Organs: Malignant and Benign T	umors	48/50 (96%)	48/50 (96%)			43/50 (86%)	45/50 (90%)	
Overall Incidence	Total	96/100 (96%)	Mean 96%	SD 0%	Total	88/100 (88%)	Mean 88%	SD 2.83%
#All Organs: Hemangioma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								•••••
		6/50 (12%)	5/50 (10%)			3/50 (6%)	6/50 (12%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	9/100 (9%)	Mean 9%	SD 4.24%
#All Organs: Hemangiosarcoma or He	emangioma							
		7/50 (14%)	5/50 (10%)		_	3/50 (6%)	6/50 (12%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	9/100 (9%)	Mean 9%	SD 4.24%

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

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

#All Organs:

#All Organs:

#All Organs:

**Overall Incidence** 

**Overall Incidence** 

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Histiocytic Sarcoma** 

.....

Mesothelioma: Benign

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER Male **Female** 1/50 (2%)1/50 (2%)2/50 (4%)Mean 1% SD 1.41% Total 3/100 (3%) Mean 3% SD 1.41% Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)14/50 (28%)6/50 (12%) Mean 0% SD 0% Total 20/100 (20%) Mean 20% SD 11.31%

O/EO

(00/)

Page: 114

O/EO

O/EO

(00/)

(00/)

SD 1.41%

Report Date: 11/11/2014

		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs:

Mesothelioma: Benign, Malignant, NOS

		1/30 (2%)	1/30 (2%)			0/30 (0%)	0/30 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs:

Mesothelioma: Malignant

		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

#All Organs: Osteoma

		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (19/.)	Moon 19/

(00/)

(20/)

1 /EO

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

Total

Total

0/50

1/100 (1%)

0/50

0/100 (0%)

1/E0

(0%)

(0%)

(20/)

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/11/2014

**Page:** 115

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

			Male			·	Female	
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Adrenal Cortex: Adenoma								
		2/49 (4%)	2/50 (4%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign						4/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
*Adrenal Medulla: Pheochromocytoma Maligna	ant							
_		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benig	n, Complex	x, <b>Malignant, NOS</b> 0/49 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 116

Report Date: 11/11/2014

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

			Male				Female	
#Blood Vessel: Hemangioma		0/50 (0%)	0/50 (05)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Bone Marrow: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Bone Marrow: Hemangiosarcoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
Bone Marrow: Mast Cell Tumor Malignant		, ,	0/50 (0%)			` '	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Bone Marrow: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Bone: Fibroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

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

**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: 117

			Male				Female	
#Bone: Hemangiosarcoma		0(50 (00))	0/50 (00/)			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

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

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

**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:** 118

			Male	Female				
*Brain: Meningioma Malignant	Total	0/50 (0%)	1/50 (2%)	CD 4 449/	Total	0/50 (0%)	0/49 (0%) Mean 0%	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)		SD 0%
*Brain: Meningioma: Benign, Ma	lignant, NOS	-4						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Malig		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glio			0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (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: ORAL Vehicle: WATER **Page:** 119

	Male Female					0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0  2/50 (4%) 5/50 (10%) Total 7/100 (7%) Mean 7% SD 4.2		
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	1/50 (2%)			` '	` ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%		0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		5/50 (10%)	6/50 (12%)	00 4 4404		, ,	, ,	00 10101
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	ı otal	7/100 (7%)	Mean 7%	SD 4.24%
#Harderian Gland: Carcinoma								
		2/50 (4%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma or Adenoma		7/50 (149/)	6/50 /429/\			A/50 (89/\	5/50 (10%)	
Overall Incidence	Total	7/50 (14%) 13/100 (13%)	6/50 (12%) Mean 13%	SD 1.41%	Total	4/50 (8%) 9/100 (9%)	5/50 (10%) Mean 9%	SD 1.41%
Overall illiciation	ıvıaı	13/100 (13/6)	IVICALI 13/0	JD 1.41/0	ıvıaı	ا (۵/۵)	IVICALI 3/0	3D 1.4170

<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: 120

	Male Female					0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD (0%)			
*Heart: Hemangiosarcoma									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` '	()	SD 0%	
#Intestine Large: Cecum: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%	
#Intestine Large: Cecum: Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	` ,	` '	SD 0%	
#Intestine Large: Cecum: Carcinoma or Adenoma						0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		0/100 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Intestine Small: Duodenum: Adenoma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<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: 121

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 04  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 04  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 04			
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	1/50 (2%)			` ,	, ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	, ,	` '	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		
#Intestine Small: Jejunum: Adenoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	, ,	` '	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		` '		
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%)	1/50 (2%)			` ,	` ,	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 122

			Male				Female	
#Intestine Small: Site Un	specified:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Una Carcinoma	specified:							
		2/50 (4%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Un Carcinoma or Adenom	•	- 1						
		2/50 (4%)	3/50 (6%)	00		0/50 (0%)	0/50 (0%)	<b>25 20</b> /
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Una Leiomyosarcoma	specified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/49 (2%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/97 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (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: 123

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma			0.50				242 (224)	
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition	onal Epitheliu	ım:						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition Carcinoma or Adenoma		ım:						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma	•••••		2/50 /40/			0/40 /00/	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 124

Report Date: 11/11/2014

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

			Male			Female				
*Kidney: Renal Tubule: Hemangioma										
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Hemangiosarcoma										
Overell Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/49 (0%)	0/50 (0%)	CD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Liver: Hemangioma		0/50 (00/)	0(50 (00))			0/40 (00/)	0/40 /00/)			
Overell Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/49 (0%)	CD 00/		
Overall Incidence	Total	0/100 (0%)	iviean 0%	3D 0%	ı olal	0/98 (0%)	Mean 0%	SD 0%		
*Liver: Hemangiosarcoma		5/50 (10%)	1/50 (2%)			2/49 (4%)	2/49 (4%)			
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	4/98 (4.08%)	Mean 4.08%	SD 0%		
*Liver: Hepatoblastoma										
		6/50 (12%)	4/50 (8%)			1/49 (2%)	0/49 (0%)			
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 2.83%	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%		
*Liver: Hepatocellular Adenoma										
-		33/50 (66%)	39/50 (78%)			38/49 (78%)	33/49 (67%)			
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	71/98 (72.45%)	Mean 72.45%	SD 7.22%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 11/11/2014

Page: 125

Species: MICE Strain: B6C3F1

Vehicle: WATER

			Male				Female	
*Liver: Hepatocellular Carcinor	ma							
		26/50 (52%)	12/50 (24%)			11/49 (22%)	9/49 (18%)	
Overall Incidence	Total	38/100 (38%)	Mean 38%	SD 19.8%	Total	20/98 (20.41%)	Mean 20.41%	SD 2.89%
*Liver: Hepatocellular Carcinor	na or Hepatobla	astoma						
-	-	26/50 (52%)	15/50 (30%)			12/49 (24%)	9/49 (18%)	
Overall Incidence	Total	41/100 (41%)	Mean 41%	SD 15.56%	Total	21/98 (21.43%)	Mean 21.43%	SD 4.33%
*Liver: Hepatocellular Carcinor	na or Hepatoce	ellular Adenoma 45/50 (90%)	42/50 (84%)			40/49 (82%)	36/49 (73%)	
Overall Incidence	Total	87/100 (87%)	Mean 87%	SD 4.24%	Total	76/98 (77.55%)	Mean 77.55%	SD 5.77%
*Liver:		ular Adenoma, or Hepatob 45/50 (90%) 87/100 (87%)		SD 4.24%	Total	40/49 (82%) 76/98 (77.55%)	36/49 (73%) Mean 77.55%	SD 5.77%
*Liver: Hepatocholangiocarcin		2/50 (4%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/98 (0%)	Mean 0%	SD 0%
			•••••			•••••		
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/11/2014

Page: 126

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

			Male			0/49 (0%) 0/49 (0%) Total 0/98 (0%) Mean 0% SD 0%  5/50 (10%) 3/50 (6%) Total 8/100 (8%) Mean 8% SD 2.83%  7/50 (14%) 2/50 (4%) Total 9/100 (9%) Mean 9% SD 7.07%  11/50 (22%) 5/50 (10%)			Female				
*Liver: Mast Cell Tumor Malignant													
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	()	` ,	SD 0%					
*Liver: Sarcoma													
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%					
*Lung: Alveolar/Bronchiolar Adend													
Overall Incidence	Total	6/50 (12%) 19/100 (19%)	13/50 (26%) Mean 19%	SD 9.9%	Total	8/100 (8%)	Mean 8%						
*Lung: Alveolar/Bronchiolar Carcir													
Overall Incidence	Total	9/50 (18%) 16/100 (16%)	7/50 (14%) Mean 16%	SD 2.83%	Total	9/100 (9%)	` '	SD 7.07%					
*Lung: Alveolar/Bronchiolar Carcir		/eolar/Bronchiolar Adenor 14/50 (28%)					5/50 (10%)						
Overall Incidence	Total	33/100 (33%)	Mean 33%	SD 7.07%	Total	` '	, ,	SD 8.49%					
*Lung: Hemangiosarcoma													
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 127

			Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant			0/50 (0%)       0/50 (0%)       0/5         Mean 0%       SD 0%       Total       0/100 (0%)       1         0/50 (0%)       0/50 (0%)       0/5       0/					
_		0/50 (0%)	0/50 (0%)			` '	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%)	, ,			` ,	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	, ,			` '	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	` '			, ,	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenoma, Ca	rcinoma, oı							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<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

i umor incide

Length of Study: CHRONIC

Page: 128

		Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE  0/49 (0%) 0/50 (0%)		
#Mesentery: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 1.41%
#Mesentery: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	, ,	` ,	SD 0%
*Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
*Nose: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/49 (0%) 0/99 (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

**Overall Incidence** 

**Overall Incidence** 

Cystadenocarcinoma

**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: 129

Report Date: 11/11/2014

			Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Papilloma Squamous or Papilloma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Oral Mucosa: Squamous Cell Carcin	oma	•••••								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Ovary: Choriocarcinoma										
						0/40 (00/)	0 (= 0 (0 0 ()			

Total

Total

0/49

0/49

0/99 (0%)

0/99 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0%

SD 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: 11/11/2014

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Cystadenoma 3/49 (6%)1/50 (2%)**Overall Incidence** Total 4/99 (4.04%) Mean 4.06% SD 2.92% \*Ovary: **Granulosa Cell Tumor Benign** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% ..... \*Ovary: Hemangioma 0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/99 (0%) Mean 0% \*Ovary: Hemangiosarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Luteoma

0/49

0/99 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

**Overall Incidence** 

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 131

			Male				Female	
*Ovary: Sarcoma						0/40 (00%)	0/50 (00/)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		•••••						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma								
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	4/50 (8%) 6/99 (6.06%)	2/49 (4%) Mean 6.04%	SD 2.77%

<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: 132

			Male				Female	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		fied Site:						
		0/47 (0%)	0/50 (0%)			4/50 (8%)	2/49 (4%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	6/99 (6.06%)	Mean 6.04%	SD 2.77%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inte Carcinoma or Adenoma	ermedia:							
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma	1							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

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

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

Mean 0%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
*Salivary Glands: Myxoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma		0/50 (0%)	0/50 /02/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma		0/50 (00/)	0/50 (0%)			0/50 (09/)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

SD 0%

0/100 (0%)

Total

Mean 0%

SD 0%

Total

0/100 (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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date: 11/11/2014

**Page:** 134

Species: MICE Strain: B6C3F1

Vehicle: WATER

			Male				Female	
#Skin:		T	201					
Basai Celi Carcinoma (	or Basosquamou	us Tumor (malignant or NC 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tum	or (benign, malignan	t or				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 0/50 (0%) 0/100 (0%)		<b>a</b> , SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		oma, Myxosarcoma, or Fil	1/50 (2%)			2/50 (4%)	4/50 (8%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytoma				0/50 /40/	4/50 (00/)	
Occupation of demand	T-1-1	1/50 (2%)	1/50 (2%)	00.00/	T-1-1	2/50 (4%)	4/50 (8%)	OD 0.000/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 135

Report Date: 11/11/2014

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

			Male				Female	
#Skin: Fibrous Histiocytoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Granular Cell Tumor Benig								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma		1/50 (2%)	1/50 (2%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 136

			Male				Female	
#Skin: Liposarcoma								SD 0%  SD 1.41%  SD 0%  SD 0%
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Mast Cell Tumor Maligna	ınt	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						, ,		
#Skin: Melanoma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor			0/50 (00)					
Overall Incidence	Total	` '	` ,	SD 0%	Total	` '	, ,	SD 0%
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (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: ORAL Vehicle: WATER Page: 137

			Male				Female				
#Skin: Neurofibroma or Schwannoma benign											
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Neurofibrosarcoma or \$	Schwannoma (m	alignant or NOS)									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%			
		6chwannoma (benign, mai	0/50 (0%)	<b>OD</b> 007	Total	0/50 (0%)	3/50 (6%)	CD 4.040/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%			
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
#Skin: Osteosarcoma	Total	······	0/50 (0%) Mean 0%	SD 0%	Total			SD 4.24%			
#Skin:	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%				
#Skin: Osteosarcoma  Overall Incidence  #Skin: Sarcoma	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%)				
#Skin: Osteosarcoma  Overall Incidence  #Skin: Sarcoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% 1/50 (2%)	SD 0%			
#Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%) 0/100 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%	Total	0/50 (0%) 0/100 (0%) 2/50 (4%)	0/50 (0%) Mean 0% 1/50 (2%)	SD 0%			

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

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

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

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

Page: 138

Report Date: 11/11/2014

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Schwannoma Malignan	nt							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell (	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma	0/50 (09/)	0/50 (0%)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma or Papilloma		0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	ı olal		wiean 0%			0/100 (0%)	wean 0%	
#Skin: Squamous Cell Papillo	ma, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma	a				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	ma, Papilloma, o	r Keratoacanthoma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	` '	( ,	SD 0%	Total	, ,	` '	SD 0%
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 139

			Male			Female           Total         0/50 (0%) (0%) (0%) (0%) (0%) (0%)           Total         1/46 (2%) (2%) (0/49 (0%) (0%)           Total         1/95 (1.05%) (0%) (0%) (0%) (0%) (0%)           Total         0/46 (0%) (0%) (0%) (0%) (0%) (0%) (0%) (0%)					
#Spinal Cord: Hemangiosarcoma											
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Spleen: Hemangiosarcoma											
		1/46 (2%)	2/50 (4%)			` ,	0/49 (0%)				
Overall Incidence	Total	3/96 (3.12%)	Mean 3.09%	SD 1.29%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%			
*Spleen: Mast Cell Tumor Malignant		0/46 (0%)	0/50 (0%)			0/46 (00/)	0/40 (09/)				
Overall Incidence	Total	0/46 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%			
		, ,									
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Carcinoma o			0/50 (0%)								
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Stomach, Forestomach: Squamous Cell Papilloma		(65)	(0.1)			(00)	(-2)				
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/50 (0%)	1/50 (2%)	05 4 440/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			

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

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

**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:** 140

			Male				Female	
#Stomach, Glandular: Adenoma					Female           Total         0/50 (0%) 0/50 (0%) 0/50 (0%)         SD 0%           0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         SD 0%           Total         0/100 (0%) 0/50 (0%) 0/50 (0%)         SD 0%           Total         0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)         SD 0%			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		2/22 (221)	(20)			2/-2 (221)	(201)	
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	, ,	CD 00/
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	wiean 0%	SD 0%
*Testes: Adenoma		0/50 (001)	(00)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Testes: Hemangioma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS		0/44 (00/)	0/45 /00/			0/45 (00)	0/50 (00)	
Overell Incidence	Total	0/41 (0%)	0/45 (0%)	CD 00/	Total	0/45 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/95 (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: 141

			Male				Female	
*Thymus: Thymoma Benign							15 (0%) 0/50 (0%) 5 (0%) Mean 0% SD 0% 15 (0%) 0/50 (0%) 5 (0%) Mean 0% SD 0% 15 (0%) 0/50 (0%) 5 (0%) Mean 0% SD 0% 18 (0%) 0/49 (0%) 7 (0%) Mean 0% SD 0%	
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	()	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	` '	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/41 (0%)	0/45 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	` '	SD 0%
*Thyroid Gland: C-Cell: Adenoma						0/40 (00/)	0/40 (09/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	` ,	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								•••••
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	` '	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/40 (00)	0/50 (0%)			0/40 (00/)	0/40 (09/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell Adenoma	:							
		1/49 (2%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
		1/49 (2%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/97 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma c		na Squamous						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

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

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

Control Animal Groups Report Date: 11/11/2014
RAL

Page: 143

	Male				Female			
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Urethra: Hemangiosarcoma								
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
	<b>-</b>	0/45 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/44 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma						1/50 (2%)	0/50 (0%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma								
• " ' '					<b>-</b>	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

Sarcoma Stromal

#Uterus:

**#Uterus:** 

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

Tumor Incidence for Selected Control Animal Groups

Page: 144

Mean 0%

Mean 0%

Mean 6%

(0%)

(8%)

0/50

4/50

SD 0%

SD 0%

SD 2.83%

Report Date: 11/11/2014

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus:** Hemangiosarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 2/50 (4%)4/50 (8%) **Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% ..... **#Uterus:** Sarcoma 0/50 (0%)0/50 (0%)

Total

Total

Total

0/100 (0%)

0/50

2/50

6/100 (6%)

0/100 (0%)

(0%)

(4%)

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

#: Denominator is number of animals necropsied

Sarcoma Stromal or Polyp Stromal

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: 145

			Male			Female				
#Zymbal's Gland: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Zymbal's Gland: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

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Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

# **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		
Southern Research Institute	058813308	12/13/04	729	50(1)	30(665)	54.9	Trimethylolpropane triacrylate
					Female		
Southern Research Institute	058813308	12/13/04	732	50(1)	39(712)	66.6	Trimethylolpropane triacrylate

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 147

			Male			Female				
#All Organs: Benign Tumors										
		37/50 (74%)				41/50 (82%)				
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%		
#All Organs: Malignant Tumors										
		38/50 (76%)				38/50 (76%)				
Overall Incidence	Total	38/50 (76%)	Mean 76%	SD 0%	Total	38/50 (76%)	Mean 76%	SD 0%		
#All Organs: Malignant and Benign T										
		46/50 (92%)				47/50 (94%)				
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%		
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma	•••••									
		6/50 (12%)				2/50 (4%)				
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#All Organs: Hemangiosarcoma or He	emangioma									
-	-	6/50 (12%)				2/50 (4%)				
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 148

				Male				Female			
#All Organs: Histiocytic Sarcoma		0/50	(0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#All Organs: Malignant Lymphoma: Histioc	ytic, Lymp			Undifferentiated Ce	ell Type						
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	20/50 (40%) 20/50 (40%)	Mean 40%	SD 0%		
		, ,					20/30 (40/0)				
#All Organs: Mesothelioma: Benign		0/50	(0%)				0/50 (0%)				
	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, Malign		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignant		0/50	(00()				0/50 (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%		
						1 Ulai					
#All Organs: Osteoma		0/50	(00()				0/50 /00/				
Overall Institutes	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%		

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 149

Report Date: 11/11/2014

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

			Male			Female			
#All Organs: Osteosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma									
		6/50 (12%)				0/50 (0%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benig									
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Maligr									
		0/49 (0%)				2/50 (4%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benig	ın, Complex,	Malignant, NOS 0/49 (0%)				2/50 (4%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 150

			Male				Female	
#Blood Vessel: 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%
*Bone Marrow: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma  Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		1/30 (2/6)			·····		iviean 076	
*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								
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

Page: 151

Report Date: 11/11/2014

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Bone: Osteoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Bone: Osteosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Bone: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (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% \*Brain: **Granular Cell Tumor Benign** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 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: SKIN Vehicle: ACETONE Page: 152

			Male				Female	
*Brain: Meningioma Malignant		0/50 (0	)%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Mal	ignant, NOS							
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Malig	nant	1/50 (2	2%)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glior		toma	2%)			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0	)%)			0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<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: SKIN

Page: 153

Report Date: 11/11/2014

Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female	
#Coagulating Gland: Granular Cell Tumor		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma		8/50 (16%)				5/50 (10%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
#Harderian Gland: Carcinoma								
Occupation of decises	T-1-1	3/50 (6%)	Mara 2007	00.00/	Taral	2/50 (4%)	NA 40/	00.00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		11/50 (22%)				7/50 (14%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 154

			Male				Female	
*Heart: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma		0/50 (0%	<i>'</i>			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		1/50 (29				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma		0/50 (0%	/)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 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: SKIN Vehicle: ACETONE **Page:** 155

				Male				Female	
Intestine Small: Duodenum: Carcinoma									
		0/50 (0	%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean	- / -	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Ileum: Adenoma									
		0/50 (0	,				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma									
		0/50 (0	,		25 22/		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma									
		0/50 (0	,				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma									
		2/50 (4	%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean	4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma	••••								
		0/50 (0	,				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean		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: SKIN Vehicle: ACETONE Page: 156

			Male				Female	
#Intestine Small: Site Uns	specified:							
Overall Incidence	Total	0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma	specified:							
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	%) Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Uns Carcinoma or Adenoma	specified:	2/50 (49	ν.)			1/50 (2%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Uns Leiomyosarcoma		0/50 (09				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
Overall Incidence	Total	0/50 (09 0/50 (0%)	%) Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%
*Islets, Pancreatic: Carcinoma		0/50 /00	····			0/40 /00/		
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: SKIN Vehicle: ACETONE **Page:** 157

			Male				Female				
*Islets, Pancreatic: Carcinoma or Adenoma											
		0/50 (0%)				2/49 (4%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%			
*Kidney: Pelvis and Transitio Carcinoma	nal Epitheliu	ım:									
		0/48 (0%)				0/49 (0%)					
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheliu	um: 0/48 (0%)				0/49 (0%)					
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Adenoma						2(12 (22)					
Overall Incidence	Total	2/48 (4%) 2/48 (4.17%)	Mean 4.17%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma											
		0/48 (0%)				0/49 (0%)					
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma											
		2/48 (4%)				0/49 (0%)					
Overall Incidence	Total	2/48 (4.17%)	Mean 4.17%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 158

Report Date: 11/11/2014

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female           Mean 0%         SD 0%           Mean 0%         SD 0%           Mean 0%         SD 0%           Mean 0%         SD 0%		
*Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)		SD 0%
*Liver: 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%
*Liver: Hemangiosarcoma  Overall Incidence	Total	2/50 (4%)	Moon 49/	SD 00/	Total	0/50 (0%) 0/50 (0%)	Moon 09/	SD 09/
Overall incidence		2/50 (4%)	Mean 4%	SD 0%		0/50 (0%)	wean 0%	2D 0%
*Liver: Hepatoblastoma		5/50 (400V)				0/50 (00/)		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		34/50 (68%)				34/50 (68%)		
Overall Incidence	Total	34/50 (68%)	Mean 68%	SD 0%	Total	34/50 (68%)	Mean 68%	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: SKIN Vehicle: ACETONE **Page:** 159

			Male		37/50 (74%) Total 37/50 (74%) Mean 74% SD 0% 37/50 (74%)				
*Liver: Hepatocellular Carcino	ma								
Overall Incidence	Total	22/50 (44%) 22/50 (44%)	Mean 44%	SD 0%	Total		Moon 249/	SD 09/	
	ı olal	22/50 (44%)	iviean 44%			12/50 (24%)	Wiean 24%		
*Liver: Hepatocellular Carcino	ma or Hepatobla	ustoma							
•	•	26/50 (52%)				12/50 (24%)			
Overall Incidence	Total	26/50 (52%)	Mean 52%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%	
*Liver: Hepatocellular Carcino	-	37/50 (74%)		00.00		` '	M 740/	00.00	
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	37/50 (74%)	Mean 74%	SD 0%	
*Liver: Hepatocellular Carcino	ma, Hepatocellu	lar Adenoma, or Hepatob 38/50 (76%)	lastoma						
Overall Incidence	Total	38/50 (76%)	Mean 76%	SD 0%	Total	37/50 (74%) 37/50 (74%)	Mean 74%	SD 0%	
*Liver: Hepatocholangiocarcin		38/50 (76%)				37/50 (74%)			
*Liver:		38/50 (76%)				37/50 (74%)			
*Liver: Hepatocholangiocarcin	noma	38/50 (76%) 2/50 (4%)				37/50 (74%) 0/50 (0%)			

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

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

## **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 160

			Male				Female	
*Liver: Mast Cell Tumor Malignant	:							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Aden						2/50 (60/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Lung: Alveolar/Bronchiolar Carci		12/50 (24%)				2/50 (4%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Carci	noma or Alve	eolar/Bronchiolar Adeno 13/50 (26%)	ma			5/50 (10%)		
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Lung: Hemangiosarcoma		0/50 (05)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page**: 161

				Male			Female           0/50 (0%)         Mean 0%         SD 0%           0/50 (0%)         Mean 0%         SD 0%			Female			
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		,											
_			(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%)				` '						
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Lymph Node, Mesenteric: Hemangiosarcoma		4/50	(00()				0/50 (00/)						
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	` '	Mean 0%	SD 0%				
#Mammary Gland: Carcinoma		0/50	(00()				0/50 (00/)						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%				
#Mammary Gland: Carcinoma or Adenoma													
			(0%)				` '						
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Fibroma, Fibroadenoma, Cal	rcinoma, or		(00()				0/50 (00/)						
Overall Incidence	Total		(0%)	Moon 0%	SD 0%	Total	0/50 (0%)	Moon 0%	SD 00/				
Overali 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: 162

Report Date: 11/11/2014

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female			
#Mesentery: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incidence		0/50 (0%)				0/50 (0%)	wean 0%	5D 0%
*Nose: Adenoma		2/22 (221)				2/52 (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%
*Nose: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 163

			Male			Female				
#Oral Cavity (Oral Mucosa, T Papilloma Squamous or Pa		/nx, Tooth, Gingiva):								
Overell lesidence	Tatal	0/50 (0%)	Maan 00/	CD 00/	Tatal	0/50 (0%)	Maan 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucosa, T Squamous Cell Carcinoma		ynx, Tooth, Gingiva):								
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Cavity (Oral Mucosa, T Squamous Cell Carcinoma	•	Squamous, or Papilloma 0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Oral Mucosa: Squamous Cell Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Ovary: Choriocarcinoma										
						0/47 (0%)				
Overall Incidence					Total	0/47 (0%)	Mean 0%	SD 0%		
*Ovary: Cystadenocarcinoma						4/47 (20/)				
Overall Incidence					Total	1/47 (2%) 1/47 (2.13%)	Mean 2.13%	SD 0%		
Overall incluence					Total	1/47 (2.13%)		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**

**Page:** 164

Report Date: 11/11/2014

Contract/Lab: All Laboratories Tu

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

	Male			Female	
*Ovary: Cystadenoma			1/47 (2%)		
Overall Incidence		Total	1/47 (2.13%)	Mean 2.13%	SD 0%
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			0/47 (0%)		
Overall Incidence		Total	0/47 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma			0/47 (0%)		
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma			0/47 (00/)		
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		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

Species: MICE

Strain: B6C3F1

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

Page: 165

Report Date: 11/11/2014

SD 0%

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Male **Female** \*Ovary: Sarcoma 0/47 (0%)**Overall Incidence** Total 0/47 (0%) Mean 0% SD 0% \*Ovary: **Tubulostromal Adenoma** 0/47 (0%)**Overall Incidence** Total 0/47 (0%) Mean 0% SD 0% \*Ovary: Yolk Sac Carcinoma 0/47 (0%)**Overall Incidence** Total 0/47 (0%) Mean 0% SD 0% ..... \*Pancreas: Carcinoma 1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/49 (0%) Mean 0% SD 0% \*Pancreas: 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% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma

SD 0%

7/49

Total

7/49 (14.29%)

(14%)

Mean 14.29%

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: SKIN Vehicle: ACETONE Page: 166

				Male				Female	
*Pituitary Gland: Pars Dist Carcinoma or Adenoma		ied Site:							
	<b>T</b>		(0%)		00.007	<b>+</b>	7/49 (14%)		<b>OD</b> 004
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	7/49 (14.29%)	Mean 14.29%	SD 0%
*Pituitary Gland: Pars Inte 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%
*Pituitary Gland: Pars Inte Carcinoma or Adenoma	rmedia:								
			(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%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<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: SKIN Vehicle: ACETONE Page: 167

			Male		0/50 (0%)  Mean 0% SD 0%  0/50 (0%)  0/50 (0%)  Mean 0% SD 0%  0/50 (0%)  Mean 0% SD 0%  2/50 (4%)			
*Salivary Glands: Myxoma								
		0/50 (0%	,			` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%	,			` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00	0			0(50 (00))		
	<b>-</b>	0/50 (0%	,	00.007	<b>-</b>	` '		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,		SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma	2/72 /22				(20)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%	6)			2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Basal Cell Carcinoma		0/50 (0%	٠٠٠٠٠ د			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

Tumor Incidence for Selected Control Animal Groups

Report Date: 11/11/2014

Page: 168

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

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal Cell Carcinoma	or Basosquamou	us Tumor (malignant or N 0/50 (0%)	NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:	Basal Cell Adend	oma, Basosquamous Tu						
,,		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Adenoma, Papilloma, S	Sq Papilloma, Ke	a, Basosq. Tumor (M or ratoacanthoma, Trichoe 1/50 (2%)	pithelioma		Tatal	1/50 (2%)	M 20/	CD 00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibroma, Fibrosarcom Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or F 0/50 (0%) 0/50 (0%)	Fibrous Histiocytoma	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%
#Skin: Fibrosarcoma		0/50 (0%)				3/50 (6%)		
		,	Marana 00/	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
Overall Incidence	Total	0/50 (0%)	Mean 0%	3D 0%	iotai	0/00 (0/0)	Modif 070	
#Skin:		0/50 (0%) a, or Fibrous Histiocytom 0/50 (0%)		30 0%	·····	4/50 (8%)	indan 070	

<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: SKIN Vehicle: ACETONE Report Date: 11/11/2014

Page: 169

				Male		Female           Total         0/50 (0%) 0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%) 0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%) 0/50 (0%)         Mean 0%         SD 0%           Total         2/50 (4%) 2/50 (4%)         Mean 4%         SD 0%			
#Skin: Fibrous Histiocytoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%		0/50 (0%)		
#Skin: Granular Cell Tumor Benign									
Grandial Gen Tullion Beiligh		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%		0/50 (0%)		
#Skin: Hemangioma		0/50	(0%)						
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%		0/50 (0%)		
#Skin: Hemangiosarcoma			(4%)						
Overall Incidence	Total	2/50 (4%)	` ,	Mean 4%	SD 0%		2/50 (4%)		
#Skin: Keratoacanthoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma									
Overall Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<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: SKIN Vehicle: ACETONE

d Control Animal Groups Report Date: 11/11/2014

**Page:** 170

			Male			(0%) %) Mean 0% SD 0%  (0%) %) Mean 0% SD 0%  (2%) %) Mean 2% SD 0%		
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)		
#Skin: Melanoma Benign		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)		
#Skin: Melanoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 171

			Male				Female				
#Skin: Neurofibroma or Schwannoma 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:											
Neurofibrosarcoma or So	chwannoma (ma	alignant or NOS) 0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin:											
Neurofibrosarcoma, Neu	rofibroma, or S		lignant or NOS)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Skin:											
Osteosarcoma		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:											
Sarcoma											
Occupation of demand	T-1-1	0/50 (0%)	Maran 00/	00.00/	T-1-1	1/50 (2%)	M 00/	OD 00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Schwannoma Benign											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<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: SKIN

Length of Study: CHRONIC

Vehicle: ACETONE

Page: 172

		Male				Female	
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
a	1/50 (2%)				1/50 (2%)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
a or Papilloma	4/50 (20/)				4/50 (20/)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
a, Papilloma, S		a or Keratoacanthor	ma		1/50 (2%)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
a, Papilloma, o	r Keratoacanthoma 1/50 (2%)				1/50 (2%)		
Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
	Total  Total	Total 0/50 (0%)  na, Basal Cell Carcinoma, Basosquamo  0/50 (0%)  Total 0/50 (0%)  a 1/50 (2%)  Total 1/50 (2%)	0/50 (0%) Total 0/50 (0%) Mean 0%  na, Basal Cell Carcinoma, Basosquamous Tumor (malignar 0/50 (0%)) Total 0/50 (0%) Mean 0%  a 1/50 (2%) Total 1/50 (2%) Mean 2%  a or Papilloma 1/50 (2%) Mean 2%  a, Papilloma, Squamous Cell Carcinoma or Keratoacanthor 1/50 (2%) Total 1/50 (2%) Mean 2%  a, Papilloma, or Keratoacanthoma 1/50 (2%) Total 1/50 (2%) Mean 2%  Total 1/50 (2%) Mean 2%	O/50 (0%)   Mean 0%   SD 0%	Total   0/50   (0%)   Mean 0%   SD 0%   Total	O/50 (0%)   Mean 0%   SD 0%   Total   O/50 (0%)	Total   0/50 (0%)   Mean 0%   SD 0%   Total   0/50 (0%)   Mean 0%   Mean 0%   SD 0%   Total   0/50 (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**

**Page:** 173

Report Date: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ACETONE

			Male				Female	
#Spinal Cord: 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%
*Spleen: Hemangiosarcoma		4/49 (8%)				0/49 (0%)		
Overall Incidence	Total	4/49 (8.16%)	Mean 8.16%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Spleen: Mast Cell Tumor Malignant		•••••						
		0/49 (0%)				0/49 (0%)		
Overall Incidence	Total	0/49 (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%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papillom	a Squamous 3/50 (6%)				2/50 (4%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma						0/50 (40/)		
	<b>-</b>	3/50 (6%)		OD 00/	<b>-</b>	2/50 (4%)	14 40/	OD 00/
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 174

			Male			Female			
#Stomach, Glandular: Adenoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (004)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	Maan 00/	SD 0%	Total	0/50 (0%)	Maan 00/	SD 0%	
		0/50 (0%)	Mean 0%			0/50 (0%)	Mean 0%	0% עכ	
*Testes: Adenoma		4/50 (00/)							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%					
*Testes: Hemangioma									
		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Neoplasm NOS		0/40 (00%)				0/47 (00/)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
Overall incluence	Total	0/48 (0%)	ivican 0%	SD 0%	Total	0/47 (0%)	ivicari 0%	3D 0%	

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 175 Report Date: 11/11/2014

				Male				Female	
*Thymus: Thymoma Benign		0/40 //	20()				0/47 (00%)		
Overall Incidence	Total	0/48 (0%)		ın 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/48 ((	)%)				1/47 (2%)		
Overall Incidence	Total	0/48 (0%)	,	ın 0%	SD 0%	Total	1/47 (2.13%)	Mean 2.13%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/48 ((	)%)				1/47 (2%)		
Overall Incidence	Total	0/48 (0%)	,	ın 0%	SD 0%	Total	1/47 (2.13%)	Mean 2.13%	SD 0%
*Thyroid Gland: C-Cell: Adenoma Overall Incidence	Total		0%) Mea	ın 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 ((	)%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	,	ın 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 ((	)%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	,	ın 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

KIN

Page: 176

			Male				Female	
*Thyroid Gland: Follicular 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: Follicular 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%
#Tissue NOS: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
	10tai	0/50 (0%)		3D 0%	10tai	1/50 (276)	VIEdII 270	3D 0%
#Tissue NOS: Hemangiosarcoma		0/50 (09	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o								
		0/50 (0%	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` ,				( ,		

<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: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

nimal Groups Report Date: 11/11/2014

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Mean 0%

SD 0%

Male **Female** #Tooth: Odontoma 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total Mean 0% Total 0/50 (0%) Mean 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 0/47 (0%)0/48 (0%)SD 0% **Overall Incidence** Total 0/47 (0%) Mean 0% Total 0/48 (0%) Mean 0% SD 0% ..... **#Uterus:** Adenoma 0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% #Uterus: Carcinoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **#Uterus:** Hemangioma 0/50 (0%)

Total

0/50 (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

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 11/11/2014

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

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE **Page:** 179

			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: SKIN Vehicle: ETHANOL Page: 180

Report Date: 11/11/2014

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical	
	Male							
Battelle Columbus Laboratory	059903204	09/21/04	729	50(1)	37(698)	56.4	Pyrogallol	
Female								
Battelle Columbus Laboratory	059903204	09/20/04	729	50(1)	33(675)	69.3	Pyrogallol	

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 181

Report Date: 11/11/2014

Length of Study: CHRONIC

Vehicle: ETHANOL

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

<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: SKIN Vehicle: ETHANOL Page: 182

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

<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: SKIN Vehicle: ETHANOL **Page:** 183

			Male			Female			
#All Organs: Osteosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0(50 (00))				0/50 (00)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	10tai 	0/50 (0%)		3D 0%	ı otal	0/50 (0%)	wiean 0%	טע עצ 👊	
*Adrenal Cortex: Adenoma									
		9/50 (18%)				1/50 (2%)			
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Benign									
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Maligna									
-		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Benigi		Malignant, NOS 0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Male Female

Page: 184

			Male		remaie				
#Blood Vessel: Hemangioma		0/50 (00/)				0(50 (00))			
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Bone Marrow: Hemangioma		2/72 (221)				2(72)			
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Bone Marrow: Hemangiosarcoma		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
		` '				` '			
*Bone Marrow: Mast Cell Tumor Malignant		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									•••••
Overell lesidence	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%	

<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: SKIN Vehicle: ETHANOL

Control Animal Groups Report Date: 11/11/2014

Page: 185

			Male			Female			
#Bone: Hemangiosarcoma		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Bone: Osteoma		(00)				(201)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Bone: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benigr		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<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: SKIN Vehicle: ETHANOL Page: 186

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

<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: SKIN

Vehicle: ETHANOL

Page: 187

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

<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: SKIN Vehicle: ETHANOL Report Date: 11/11/2014

Page: 188

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

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

ute: SKIN

**Page:** 189

			Male				Female			
#Intestine Small: Duodenum: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Carcinoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Adenoma	Total	0/50 (0%)	iviean 0%	30 0%	Total	0/50 (0%)	iviean 0%	3D 0%		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma		1/50 (2%)				1/50 (2%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<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: 190

Report Date: 11/11/2014

SD 0%

Mean 0%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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

SD 0%

Total

0/50 (0%)

Total

1/50 (2%)

Mean 2%

**Overall Incidence** 

<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: SKIN Vehicle: ETHANOL Page: 191

(0%)

Mean 0%

0/50

0/50 (0%)

Total

Report Date: 11/11/2014

SD 0%

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

SD 0%

Total

(0%)

Mean 0%

0/50

0/50 (0%)

**Overall Incidence** 

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 192

			Male				Female	
*Kidney: Renal Tubule: 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%
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Liver: Hemangioma	•••••	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		3/50 (6%)				1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Liver: Hepatoblastoma		4/50 (8%)				1/50 (2%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Liver: Hepatocellular Adenoma		39/50 (78%)				30/50 (60%)		
Overall Incidence	Total	39/50 (78%)	Mean 78%	SD 0%	Total	30/50 (60%)	Mean 60%	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: SKIN

Page: 193

Report Date: 11/11/2014

SD 0%

Mean 0%

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

**Overall Incidence** 

<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: SKIN

Report Date: 11/11/2014

**Page:** 194

Species: MICE Strain: B6C3F1

Vehicle: ETHANOL

Length of Study: CHRONIC

		Male				Female					
*Liver:  Mast Cell Tumor Malignant  0/50 (0%)  0/50 (0%)											
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
	0/50 (00/)				0/50 (00/)						
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
noma											
Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
cinoma											
Total	4/50 (8%)	Mean 8%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
	eolar/Bronchiolar Adenor										
Total	15/50 (30%)	Mean 30%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%				
	0/50 (00/)				0/50 (00/)						
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
	Total  Total  Total  Sinoma  Total  Sinoma or Alve	0/50 (0%) Total 0/50 (0%)  0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  noma  12/50 (24%)  Total 12/50 (24%)  sinoma  4/50 (8%)  Total 4/50 (8%)  Total 4/50 (8%)  Total 15/50 (30%)  Total 15/50 (30%)	10tal 0/50 (0%)  Total 0/50 (0%)  Mean 0%  0/50 (0%)  Total 0/50 (0%)  Mean 0%  12/50 (24%)  Total 12/50 (24%)  Mean 24%  Sinoma  4/50 (8%)  Total 4/50 (8%)  Mean 8%  Sinoma or Alveolar/Bronchiolar Adenoma 15/50 (30%)  Total 15/50 (30%)  Mean 30%	10	Total 0/50 (0%) Mean 0% SD 0% Total    Total 0/50 (0%)	12/50 (24%) Total 0/50 (8%) 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 12/50 (24%)  Total 12/50 (24%)  Total 12/50 (8%)  Total 12/50 (8%)  Total 4/50 (8%)  Mean 8% SD 0%  Total 2/50 (4%)  Sinoma  4/50 (8%)  Total 4/50 (8%)  Total 15/50 (30%)  Mean 30%  SD 0%  Total 2/50 (4%)  A/50 (8%)  Total 4/50 (8%)  Total 4/50 (8%)  Total 15/50 (30%)  Mean 30%  SD 0%  Total 4/50 (8%)  Total 4/50 (8%)  O/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%    0/50 (0%)				

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 195

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

**Page:** 196

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

Length of Study: CHRONIC

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

<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: 197

Report Date: 11/11/2014

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Animal Groups Report Date: 11/11/2014

Page: 198

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

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

**Page:** 199

			Male				Female	
*Ovary: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	a							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%

<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

Vehicle: ETHANOL

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 200

			Male				Female	
*Pituitary Gland: Pars Distal Carcinoma or Adenoma	lis or Unspecif	fied Site:						
		0/50 (0%)				4/50 (8%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%
*Pituitary Gland: Pars Intern Adenoma	nedia:	2/ ()				(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%
*Pituitary Gland: Pars Intern Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma								
		0/50 (0%)		25. 22/		0/50 (0%)		05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<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: SKIN Vehicle: ETHANOL Page: 201

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

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 202

Report Date: 11/11/2014

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

Length of Study: CHRONIC

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

<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: SKIN Vehicle: ETHANOL Page: 203

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Page: 204

Report Date: 11/11/2014

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

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			O/50 (0%) O/50 (0%) Mean 0% SD 0%  O/50 (0%) Mean 0% SD 0%  O/50 (0%) Mean 0% SD 0%			
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Skin: Mast Cell Tumor Benign Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Skin: Mast Cell Tumor Malignant Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	` ,	Mean 0%	SD 0%	
#Skin: Melanoma Benign Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Melanoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<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: 205

Report Date: 11/11/2014

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male			Female       1/50 (2%)     Mean 2%     SD 0%       0/50 (0%)     0/50 (0%)     Mean 0%     SD 0%       1/50 (2%)     Mean 2%     SD 0%       1/50 (2%)     Mean 2%     SD 0%       0/50 (0%)     Mean 0%     SD 0%			
#Skin: Neurofibroma or Schwar	nnoma benign	0/50 (0%)				( /			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Neurofibrosarcoma or S	chwannoma (m	alignant or NOS)							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%	
#Skin: Neurofibrosarcoma, Neu	rofibroma, or S	chwannoma (benign, ma 0/50 (0%)	lignant or NOS)			1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%	
#Skin: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Schwannoma Benign		0/50 (00/)				4/50 (00)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

<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: 206

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

r Incidence for Selected Control Animal Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

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

<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

Contract/Lab: All Laboratori
Species: MICE

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

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

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

<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: 208

Report Date: 11/11/2014

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				` ,		
#Stomach, Glandular: Carcinoma								
Garomonia		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Testes: Hemangioma		0/50 (09/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
Overall Institutes	Tatal	0/48 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male			Female				
*Thymus: Thymoma Benign Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma Malignant		0/48 (0%)				0/50 (0%)				
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/48 (0%)				0/50 (0%)				
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

R

Report Date: 11/11/2014

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			Male					
*Thyroid Gland: Follicular Cell Adenoma	l:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	l:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma		0/50 (00/)				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/30 (0%)			ı Olai	0/30 (0%)	iviean 0%	ال طق U%
#Tissue NOS: Hemangiosarcoma		0/50 (00/)				1/50 (20/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Tongue: Squamous Cell Carcinoma o						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 /00/				0/50 /00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overali incidence	Total	0/50 (0%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<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: 11/11/2014

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

<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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 11/11/2014

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

<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: SKIN Vehicle: ETHANOL

Report Date: 11/11/2014

Page: 213

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

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

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