# NTP Historical Controls Report

By Route And Vehicle

**MICE** 

November 2008

### 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
	М2
	М3
	Μ4
	М5
Fema	ale
	F1
	F2
	F3
	F4
	F5

the data would be shown as:

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

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

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

## **Table of Contents**

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GAVAGE	CORN OIL	4
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Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

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

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Report Date:11/19/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

### Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				М	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 059902304 059902006 058814807	05/09/02 04/11/02 04/15/03 02/04/03	728 728 730 728	50 (1) 50 (1) 50 (1) 50 (1)	39(688) 34(692) 38(691) 35(702)	56.7 56.2 56.6 52.7	Isoeugenol beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene
				Fer	male		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 059902304 059902006 058814807	05/08/02 04/10/02 04/14/03 02/03/03	727 727 729 731	49 (5) 50 (5) 49 (5) 50 (5)	34(679) 39(705) 35(705) 35(675)	65.0 64.1 64.9 63.2	Isoeugenol beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene

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: 5

			Male				Female	
#All Organs: Benign Tumors								
-		33/50 (66%) 30/50 (60%)	33/50 (66%)	30/50 (60%)		20/49 (41%) 24/50 (48%)	21/50 (42%)	27/49 (55%)
Overall Incidence	Total	126/200 (63%)	Mean 63%	SD 3.46%	Total	92/198 (46.46%)	Mean 46.48%	SD 6.55%
#All Organs: Malignant Tumors			•••••			•••••		
		20/50 (40%) 28/50 (56%)	30/50 (60%)	19/50 (38%)		21/49 (43%) 13/50 (26%)	14/50 (28%)	20/49 (41%)
Overall Incidence	Total	97/200 (48.5%)	Mean 48.5%	SD 11.12%	Total	68/198 (34.34%)	Mean 34.42%	SD 8.65%
#All Organs: Malignant and Benign T								
		43/50 (86%) 41/50 (82%)	43/50 (86%)	38/50 (76%)		34/49 (69%) 29/50 (58%)	30/50 (60%)	40/49 (82%)
Overall Incidence	Total	165/200 (82.5%)	Mean 82.5%	SD 4.73%	Total	133/198 (67.17%)	Mean 67.26%	SD 10.79%
All Organs: Hemangioma			•••••			•••••		
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	2/50 (4%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/198 (2.02%)	Mean 2.01%	SD 1.63%
All Organs: Hemangiosarcoma								
•		3/50 (6%) 3/50 (6%)	7/50 (14%)	3/50 (6%)		1/49 (2%) 0/50 (0%)	1/50 (2%)	3/49 (6%)
Overall Incidence	Total	16/200 (8%)	Mean 8%	SD 4%	Total	5/198 (2.53%)	Mean 2.54%	SD 2.57%

<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: 6
Report Date:11/19/2008

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

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
All Organs: Hemangiosarcoma or He	emangioma							
rioman <b>g</b> iodardoma di rio	, mangioma	3/50 (6% 3/50 (6%		3/50 (6%)		1/49 (2%) 1/50 (2%)	3/50 (6%)	4/49 (8%)
verall Incidence	Total	16/200 (8%)	Mean 8%	SD 4%	Total	9/198 (4.55%)	Mean 4.55%	SD 3.05%
All Organs: Histiocytic Sarcoma								
		0/50 (0% 0/50 (0%		0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	3/49 (6%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/198 (2.02%)	Mean 2.03%	SD 2.89%
or Undifferentiated Cell 1	туре	0/50 (0%		1/50 (2%)		11/49 (22%)	7/50 (14%)	6/49 (12%)
	Total	1/50 (2% 3/200 (1.5%)	Mean 1.5%	SD 1%	Total	2/50 (4%) 26/198 (13.13%)	Mean 13.17%	SD 7.57%
		3/200 (1.5%)	Mean 1.5%			26/198 (13.13%)		
All Organs: Mesothelioma: Benign, M		3/200 (1.5%)	Mean 1.5% ) 0/50 (0%)	0/50 (0%)		26/198 (13.13%)		0/49 (0%)
All Organs: Mesothelioma: Benign, M		3/200 (1.5%)s 0/50 (0%	Mean 1.5% ) 0/50 (0%)			26/198 (13.13%)		
All Organs: Mesothelioma: Benign, N	Malignant, NO:	3/200 (1.5%)  S  0/50 (0% 0/50 (0%	Mean 1.5% ) 0/50 (0%) )	0/50 (0%)		26/198 (13.13%) 0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Malignant, NO:	3/200 (1.5%)  S  0/50 (0% 0/50 (0%	Mean 1.5% ) 0/50 (0%) ) Mean 0% ) 0/50 (0%)	0/50 (0%)		26/198 (13.13%) 0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Adrenal Cortex: Adenoma								
		3/50 (6%) 3/50 (6%)	2/50 (4%)	1/50 (2%)		0/48 (0%) 0/49 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 1.91%	Total	2/196 (1.02%)	Mean 1.01%	SD 1.17%
*Adrenal Cortex: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (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: 8

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	onian							
rneocmomocytoma Be	enign	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%
Adrenal Medulla: Pheochromocytoma Co	omplex		•••••			•••••	•••••	
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Ma	alignant						•••••	
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%
Adrenal Medulla: Pheochromocytoma: B							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/48 (0%) 1/49 (2%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/196 (1.02%)	Mean 1.02%	SD 1.18%
Bone Marrow: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

			Male				Female	
Bone Marrow: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Bone: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Bone: Osteoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Bone: Osteosarcoma or Osteoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/197 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mal								
	.g,	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/197 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
<b></b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

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

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	
Clitoral/Preputial Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/47 (0%)
		0/50 (0%)	(-,-)	()		0/49 (0%)	(5.5)	(-,0)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 1/49 (2%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/192 (0.52%)	Mean 0.51%	SD 1.02%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 1/49 (2%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/192 (0.52%)	Mean 0.51%	SD 1.02%
Clitoral/Preputial Gland: Hemangioma								
<b>3</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/192 (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** 

Vehicle: CORN OIL

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: GAVAGE

Length of Study: CHRONIC

Page: 12

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%				
#Esophagus: Squamous Cell Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/50 (0%) 0/198 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
#Eye:		0,200 (0,6)						
Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/44 (0%)	0/49 (0%)	0/49 (0%)		0/42 (0%)	0/47 (0%)	0/48 (0%)
Overall Incidence	Total	0/49 (0%) 0/191 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/186 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
Harderian Gland: Adenoma								
		8/50 (16%) 6/50 (12%)	9/50 (18%)	6/50 (12%)		3/49 (6%) 14/50 (28%)	4/50 (8%)	7/49 (14%)
verall Incidence	Total	29/200 (14.5%)	Mean 14.5%	SD 3%	Total	28/198 (14.14%)	Mean 14.1%	SD 9.9%
Harderian Gland: Carcinoma								
		4/50 (8%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 3.46%	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%
Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%) 6/50 (12%)	9/50 (18%)	7/50 (14%)		4/49 (8%) 14/50 (28%)	4/50 (8%)	8/49 (16%)
Overall Incidence	Total	34/200 (17%)	Mean 17%	SD 5.29%	Total	30/198 (15.15%)	Mean 15.12%	SD 9.42%
Harderian Gland: Sarcoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Heart: Hemangioma								
<b>3</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

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

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	
Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Heart: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

7.5.61.1.10.7.2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 15

			Male				Female	
Intestine Large: Cecum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
ntestine Large: Colon/Rectum Leiomyosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 16

			Male				Female	
fintestine Small: Duodenum: Polyp Adenomatous		0/50 (00/)	0/50 (00/)	0(50 (00))		0/40 /00/	0/50 (00/)	0/40 (00%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Hemangiosarcoma								
<b>.</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Polyp Adenomatous								
r diyp Adenomatous		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Intestine Small: Jejunum: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Leiomyosarcoma	•••••							
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspeci Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 18

			Male				Female	
Intestine Small: Site Uns	pecified:							
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Intestine Small: Site Uns Carcinoma or Adenom	pecified:		•••••					•••••
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Intestine Small: Site Uns Hemangiosarcoma	pecified:							•••••
•		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns			•••••					•••••
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 19

			Male				Female	
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Islets, Pancreatic: Carcinoma								•••••
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
'Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 2/49 (4%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	2/195 (1.03%)	Mean 1.02%	SD 2.04%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/195 (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: 20 Report Date:11/19/2008

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

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
(idney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/195 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
iver: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
.iver: Hemangioma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 21

				Ma	ile					Fema	le		
Liver: Hemangiosarcoma													
		1/50 1/50	(2%) (2%)	5/50	(10%)	0/50 (0%)		0/49 0/49	(0%) (0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	7/200 (3	,		3.5%	SD 4.43%	Total	0/197	` '	Mean		SD	
Liver: Hepatoblastoma													
		3/50 2/50	(6%) (4%)	4/50	(8%)	1/50 (2%)		0/49 0/49	(0%) (0%)	0/50	(0%)	0/49	(0%)
Overall Incidence	Total	10/200	(5%)	Mean	5%	SD 2.58%	Total	0/197	(0%)	Mean	0%	SD	0%
Liver: Hepatocellular Adenoma					•••••		•••••			• • • • • • • • • • • • • • • • • • • •			•••••
•		24/50 22/50	(48%) (44%)	26/50	(52%)	22/50 (44%)		11/49 3/49	(22%) (6%)	6/50	(12%)	13/49	(27%)
Overall Incidence	Total	94/200	(47%)	Mean	47%	SD 3.83%	Total	33/197	(16.75%)	Mean	16.78%	SD	9.37%
Liver: Hepatocellular Carcinoma					•••••		•••••			• • • • • • • • • • • • • • • • • • • •			•••••
.,		8/50 17/50	(16%) (34%)	14/50	(28%)	13/50 (26%)		3/49 2/49	(6%) (4%)	1/50	(2%)	5/49	(10%)
Overall Incidence	Total	52/200	(26%)	Mean	26%	SD 7.48%	Total	11/197	(5.58%)	Mean	5.6%	SD	3.5%
*Liver: Hepatocellular Carcinoma o												•••••	
		11/50 19/50	(22%) (38%)	16/50	(32%)	13/50 (26%)		3/49 2/49	(6%) (4%)	1/50	(2%)	5/49	(10%)
Overall Incidence	Total		(29.5%)	Mean	29.5%	SD 7%	Total	11/197	(5.58%)	Mean	5.6%	SD	3.5%

<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:11/19/2008

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

Route: GAVAGE Vehicle: CORN OIL

				Ma	ale					Fema	ale		
Liver: Hepatocellular Carcinoma (	or Hepatoce	ellular Aden	oma										
		28/50 34/50	(56%) (68%)	33/50	(66%)	29/50 (58%)		13/49 4/49	(27%) (8%)	7/50	(14%)	17/49	(35%)
verall Incidence	Total	124/200	` ,	Mean		SD 5.89%	Total	41/197	(20.81%)		n 20.85%	_	12%
.iver: Hepatocellular Carcinoma, Hepatoblastoma													
riepatobiastoma		30/50 34/50	(60%) (68%)	34/50	(68%)	29/50 (58%)		13/49 4/49	(27%) (8%)	7/50	(14%)	17/49	(35%)
verall Incidence	Total	127/200	(63.5%)	Mean	63.5%	SD 5.26%	Total	41/197	(20.81%)	Mea	n 20.85%	SD	12%
iver: Hepatocholangiocarcinoma		2/50	(4%)		(0%)	0/50 (0%)	•••••	0/49	(0%)	0/50	(0%)	0/49	(0%)
		1/50	(2%)	0/50	(0%)	0/30 (0%)		0/49	(0%)	0/30	(0%)		,
verall Incidence	Total	3/200 (	1.5%)	Mean	1.5%	SD 1.91%	Total	0/197	(0%)	Mea	n 0%	SD	0%
iver: Ito Cell Tumor Benign													
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50 (0%)		0/49 0/49	(0%) (0%)	0/50	(0%)	0/49	(0%)
verall Incidence	Total	0/200 (	0%)	Mean	0%	SD 0%	Total	0/197	(0%)	Mea	n 0%	SD	0%
iver: Ito Cell Tumor Malignant									•••••				
3		0/50 0/50	(0%) (0%)	2/50	(4%)	0/50 (0%)		0/49 0/49	(0%) (0%)	0/50	(0%)	0/49	(0%)
verall Incidence	Total		1%)	Mean	1%	SD 2%	Total		(0%)	Mea	า 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:11/19/2008

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

			Male				Female	
Liver: Sarcoma								
Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Lung: Adenoma							•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A					•••••			
		6/50 (12%) 5/50 (10%)	8/50 (16%)	6/50 (12%)		4/48 (8%) 3/49 (6%)	4/50 (8%)	1/49 (2%)
verall Incidence	Total	25/200 (12.5%)	Mean 12.5%	SD 2.52%	Total	12/196 (6.12%)	Mean 6.12%	SD 2.89%
.ung:								
Alveolar/Bronchiolar C	arcinoma	2/50 (4%) 3/50 (6%)	5/50 (10%)	3/50 (6%)		0/48 (0%) 0/49 (0%)	2/50 (4%)	2/49 (4%)
verall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 2.52%	Total	4/196 (2.04%)	Mean 2.02%	SD 2.33%
Lung: Alveolar/Bronchiolar C Adenoma	Carcinoma or Alv	/eolar/Bronchiolar					•••••	
Addioma		7/50 (14%) 7/50 (14%)	13/50 (26%)	9/50 (18%)		4/48 (8%) 3/49 (6%)	6/50 (12%)	3/49 (6%)
Overall Incidence	Total	36/200 (18%)	Mean 18%	SD 5.66%	Total	16/196 (8.16%)	Mean 8.14%	SD 2.77%

<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: 24

			Male				Female	
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
_ung: Fibrous Histiocytoma				•••••		•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Lung:								
Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Lymph Node: Fibrous Histiocytoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 25

			Male				Female	
Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
⊁Lymph Node: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma	•••••							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 26

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 27

			Male				Female	
#Mammary Gland: Adenoacanthoma		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/40 (00/)	0/50 (00/)	4/40 (20/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#Mammary Gland: Fibroadenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Mammary Gland:								
Fibroma, Fibroadenoma	a, Carcinoma, c	or Adenoma 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#Mesentery: Fibrosarcoma					••••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
#Mesentery: Hemangiosarcoma					•••••			
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 29

			Male				Female	
fMesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Nose: Hemangioma							•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malign	ant							
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary	nx, Tooth, Gingiva):						
	·	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary						•••••	
- <b>-</b>		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date:11/19/2008

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

Vehicle: CORN OIL

			Male				Female	
#Oral Cavity (Oral Mucosa, T Squamous Cell Carcinon Papilloma	ongue, Phary na, Papilloma	nx, Tooth, Gingiva): Squamous, or						
. upu		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcinon	na		•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma			•••••			(201)	0.50	(20)
						0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma	•		•••••	•••••				
Cystadenoma						3/48 (6%)	2/50 (4%)	1/49 (2%)
Overall Incidence					Total	2/49 (4%) 8/196 (4.08%)	Mean 4.09%	SD 1.72%
*Ovary:	•••••							
Fibrous Histiocytoma						0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/49 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Report Date:**11/19/2008

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

Ma	ale		Female	
*Ovary:				
Granulosa Cell Tumor Benign		0/48 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%
***************************************				
*Ovary: Granulosa Cell Tumor Malignant				
<u>-</u>		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Granulosa Celi Tunior. Benign, Manghant, NOS		0/48 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%
*Ovary: Hemangioma				
Telliangiona		0/48 (0%) 1/49 (2%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	2/196 (1.02%)	Mean 1.02%	SD 1.18%
*Ovary: Hemangiosarcoma				
-		0/48 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%

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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

Tumor Incidence for Selected Control Animal Groups

Page: 32 Report Date:11/19/2008

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

Route: GAVAGE Vehicle: CORN OIL

	Male			Female	
Ovary:					
Leiomyosarcoma			0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary:		•••••			
Luteoma			0/48 (0%) 0/49 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence		Total	1/196 (0.51%)	Mean 0.5%	SD 1%
Ovary: Teratoma Benign					
Totalonia Bongii			0/48 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%
Ovary:					•••••
Teratoma Malignant			0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary:		•••••		•••••	•••••
Tubulostromal Adenoma			0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		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: CORN OIL Page: 33

			Male				Female	
*Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distal Adenoma					•••••			
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		4/47 (9%) 1/49 (2%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	8/195 (4.1%)	Mean 4.16%	SD 3.06%
Pituitary Gland: Pars Distal								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 34 Report Date:11/19/2008

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

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Pituitary Gland: Pars Dista Carcinoma or Adenom		fied Site:						
Outcinoma of Adenom	u	0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		4/47 (9%) 1/49 (2%)	1/50 (2%)	2/49 (4%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	8/195 (4.1%)	Mean 4.16%	SD 3.06%
Pituitary Gland: Pars Inter Adenoma			•••••			•••••	•••••	
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Inter Carcinoma or Adenom	media:							
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Prostate: Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenom								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				

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

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

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

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL Page: 35

			Male				Female	
*Prostate: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma	•••••		•••••			•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Salivary Glands: Mast Cell Tumor Malignant	•••••							
v		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC **Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 36

			Male				Female	
Skeletal Muscle: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Myxosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma						•••••	•••••	
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 2/50 (4%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/198 (1.01%)	Mean 1%	SD 2%
Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyom	a				•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 2/50 (4%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/198 (1.01%)	Mean 1%	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: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma o				•••••		••••••	•••••	
Basar Gen Adenoma G	i Basosquamou	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
#Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous '	Tumor Benign, or 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0.5%	SD 1%
		0/200 (0%)				1/198 (0.51%)		
#Skin: Basal Cell Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/40 /00/	0/50 (00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma NOS)	or Basosquamo	us Tumor (malignant o	r					
1103)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Skin: Basal Cell Carcinoma, E Tumor (benign, maligna		Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/198 (0.51%)	Mean 0.5%	SD 1%
Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma,	Papilloma, Sq pithelioma						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/198 (1.01%)	Mean 1%	SD 1.15%
Skin: Basosquamous Tumor verall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/50 (0%) 1/198 (0.51%)	1/50 (2%) Mean 0.5%	0/49 (0%) SD 1%
Skin: Fibroma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	, Sarcoma, Myx	coma, Myxosarcoma, or						
-		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		3/49 (6%) 1/50 (2%)	2/50 (4%)	2/49 (4%)
Verall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	8/198 (4.04%)	Mean 4.05%	SD 1.68%

<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

			Male			Female
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	1/50 (2%) 1/49 (2%)
Overall Incidence	Total	1/50 (2%) 1/200 (0.5%)	Mean 0.5%	SD 1%	1/50 (2%) Total 3/198 (1.52%)	Mean 1.51% SD 1.01%
·····	····				10tal 3/130 (1.3270)	
#Skin: Fibrosarcoma, Sarcoma Histiocytoma	ı, Myxosarcoma	a, or Fibrous				
riistiocytonia		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)	3/49 (6%) 1/50 (2%)	2/50 (4%) 2/49 (4%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total 8/198 (4.04%)	Mean 4.05% SD 1.68%
#Skin: Fibrous Histiocytoma		•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 1/198 (0.51%)	Mean 0.51% SD 1.02%
#Skin: Hemangioma						
Tiemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total 1/198 (0.51%)	Mean 0.5% SD 1%
#Skin: Hemangiosarcoma		•••••				
		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)	1/49 (2%) 0/50 (0%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total 2/198 (1.01%)	Mean 1.01% SD 1.17%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 40

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
‡Skin: Myxosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
skin:					•••••			
Neurofibrosarcoma or \$	Schwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	2/49 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/198 (1.52%)	Mean 1.52%	SD 1.95%
#Skin: Neurofibrosarcoma, Ne malignant or NOS)	urofibroma, or	Schwannoma (benign,						
manghant of 1400)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	2/49 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/198 (1.52%)	Mean 1.52%	SD 1.95%

<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

ed Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
≄Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		3/49 (6%) 0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	4/198 (2.02%)	Mean 2.03%	SD 2.89%
≇Skin: Schwannoma Malignant			•••••				•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	2/49 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/198 (1.52%)	Mean 1.52%	SD 1.95%
Skin: Squamous Cell Carcinoma	•••••		•••••				•••••	
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinoma, Basosquamous Tumor (mal								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 42

			Male				Female	
#Skin: Squamous Cell Papillon	na							
oquamous con r apmon		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Skin: Squamous Cell Papillon	na or Papilloma	a		•••••				
	·	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Squamous Cell Papillon Carcinoma or Keratoaca Overall Incidence		9/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 1/50 (2%) 1/198 (0.51%)	0/50 (0%) Mean 0.5%	0/49 (0%) SD 1%
Skin: Squamous Cell Papillon	na, Papilloma,	or Keratoacanthoma 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Skin: Trichoepithelioma				•••••			•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 43

			Male				Female	
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Spinal Cord: Meningioma Malignant			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma					••••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/195 (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: 44

			Male				Female	
Spleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma					•••••		•••••	
		0/50 (0%) 2/50 (4%)	1/49 (2%)	2/50 (4%)		1/48 (2%) 0/49 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 1.91%	Total	2/195 (1.03%)	Mean 1.03%	SD 1.19%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c								
- <b>-</b>		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		1/49 (2%) 2/50 (4%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	6/198 (3.03%)	Mean 3.03%	SD 1.17%

<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:11/19/2008

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

			Male				Female	
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 2/50 (4%)	1/50 (2%)	2/49 (4%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	6/198 (3.03%)	Mean 3.03%	SD 1.17%
Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Stomach, Glandular: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Festes: Adenoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/200 (1%)	Mean 1%	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: GAVAGE Vehicle: CORN OIL Page: 46

			Male				Female	
*Testes: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign								
		0/48 (0%) 0/41 (0%)	0/47 (0%)	0/49 (0%)		0/47 (0%) 1/48 (2%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/185 (0%)	Mean 0%	SD 0%	Total	1/192 (0.52%)	Mean 0.52%	SD 1.04%
*Thymus: Thymoma Malignant								
,		0/48 (0%) 0/41 (0%)	0/47 (0%)	0/49 (0%)		0/47 (0%) 0/48 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/185 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Mali							•••••	•••••
, , , , , , , , , , , , , , , , , , , ,	<b>3</b> ,	0/48 (0%) 0/41 (0%)	0/47 (0%)	0/49 (0%)		0/47 (0%) 1/48 (2%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/185 (0%)	Mean 0%	SD 0%	Total	1/192 (0.52%)	Mean 0.52%	SD 1.04%
*Thyroid Gland: Adenoma							•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/196 (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: 47

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/196 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma							•••••	
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/196 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Adenoma	• • • • • • • • • • • • • • • • • • • •							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/196 (1.02%)	Mean 1.01%	SD 1.17%
Thyroid Gland: Follicular Cell: Carcinoma			•••••					
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/48 (0%) 2/49 (4%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	3/196 (1.53%)	Mean 1.53%	SD 1.95%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/48 (0%) 2/49 (4%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	5/196 (2.55%)	Mean 2.54%	SD 1.96%

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

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

Strain: B6C3F1

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Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 48

			Male				Female	
Tissue NOS: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma	•••••							
·		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma c								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

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: 49

			Male				Female	
fTongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/198 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
-		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Urinary Bladder: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/195 (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: 50 Report Date:11/19/2008

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

	Male			Female	
Jterus:					
Adenoma					
			0/49 (0%)	0/50 (0%)	0/49 (0%)
		<b>T</b>	0/50 (0%)		00.00/
rerall Incidence		Total	0/198 (0%)	Mean 0%	SD 0%
terus:			•••••		
Carcinoma					
Garcinoma			0/49 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	(***)	(0,10)
verall Incidence		Total	0/198 (0%)	Mean 0%	SD 0%
Jterus:					
Hemangioma					
			0/49 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	,	,
verall Incidence		Total	0/198 (0%)	Mean 0%	SD 0%
Jterus:					
Hemangiosarcoma			0/40 (00/)	0/50 (00/)	0/40 (00/)
			0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence		Total	` '	Moon 09/	SD 00/
			0/198 (0%)	Mean 0%	SD 0%
terus:					
terus: Leiomyoma					
Loiomyonia			0/49 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	3/00 (0/0)	3/10 (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

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date:11/19/2008

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

Vehicle: CORN OIL

	Male		Female	
#Uterus:				
Leiomyosarcoma		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/00 (0/0)	0/40 (0/0)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				
,		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal				
		1/49 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#Uterus:				
Sarcoma Stromal or Polyp Stromal		1/49 (2%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	. ,	. ,
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
			•••••	
#Uterus: Schwannoma Malignant				
Communication and managination		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 52 Report Date:11/19/2008

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

0/40 /00/
0/49 (0%)
SD 0%
0/49 (0%)
SD 0%
0/49 (0%)
SD 0%
0/49 (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: METHYLCELLULOSE

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Report Date:11/19/2008

### **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			
				M	ale					
Southern Research Institute Southern Research Institute	059902408 059100508	12/16/02 07/10/00	729 729	50 (1) 50 (1)	36(687) 35(693)	53.8 53.6	Androstenedione Methylene blue trihydrate			
Female										
Southern Research Institute Southern Research Institute	059902408 059100508	12/16/02 07/10/00	733 732	50 (5) 50 (5)	35(690) 29(695)	65.3 63.5	Androstenedione Methylene blue trihydrate			

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Benign Tumors								_
•		38/50 (76%)	37/50 (74%)			27/50 (54%)	25/50 (50%)	
Overall Incidence	Total	75/100 (75%)	Mean 75%	SD 1.41%	Total	52/100 (52%)	Mean 52%	SD 2.83%
#All Organs: Malignant Tumors		07/50 (740/)	00/50 (500)			07/50 /540()	00/50 (50%)	
Overall Incidence	Total	37/50 (74%) 63/100 (63%)	26/50 (52%) Mean 63%	SD 15.56%	Total	27/50 (54%) 53/100 (53%)	26/50 (52%) Mean 53%	SD 1.41%
#All Organs: Malignant and Benign Tu	umors							
Overall Incidence	Total	47/50 (94%) 93/100 (93%)	46/50 (92%) Mean 93%	SD 1.41%	Total	40/50 (80%) 79/100 (79%)	39/50 (78%) Mean 79%	SD 1.41%
	ı olal				10161	13/100 (13/0)		
#All Organs: Hemangioma		1/50 (20/)	0/50 (09/)			4/50 (20/)	4/50 (20/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	5/50 (10%) 11/100 (11%)	6/50 (12%) Mean 11%	SD 1.41%	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%
Overall molacine	rotai	11/100 (11/0)	Wican 1170	OD 1.4170	10101	4/100 (4/0)	Wicum 470	OD 2.0070
#All Organs: Hemangiosarcoma or He	emangioma							
Overell In aldeman	Tatal	5/50 (10%)	6/50 (12%)	CD 4 440/	Tatal	2/50 (4%)	4/50 (8%)	CD 0.000/
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 2.83%

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

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<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

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Report Date:11/19/2008

Vehicle: METHYLCELLULOSE

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 (00/)	0/50 (00/)			0/50 /40/	0/50 /40/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
#All Organs: Malignant Lymphoma: I or Undifferentiated Cell								
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	14/50 (28%) 20/100 (20%)	6/50 (12%) Mean 20%	SD 11.31%
#All Organs: Mesothelioma: Benign,		S 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%
#All Organs: Mesothelioma: Maligna	nt	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%
#All Organs: Osteoma								
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%
#All Organs: Osteosarcoma		0/50 (0%)	0/50 (09/)			1/50 (2%)	1/50 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/100 (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: METHYLCELLULOSE

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			Male				Female			
#All Organs: Osteosarcoma or Osteoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%		
*Adrenal Cortex: Adenoma			E/AD (400()							
Overall Incidence	Total	1/50 (2%) 6/98 (6.12%)	5/48 (10%) Mean 6.21%	SD 5.95%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Adrenal Cortex: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Beniq		0/49 (0%)	0/48 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
Adrenal Medulla: Pheochromocytoma Com	plex	0/49 (0%)	0/48 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Malig	ınant	0/40 /00/				0/50 (00)	0/50 (00/)			
Overall Incidence	Total	0/49 (0%) 0/97 (0%)	0/48 (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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma: Benig	ın, Complex	x, Malignant, NOS 0/49 (0%)	0/48 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Bone Marrow: Hemangiosarcoma		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%
*Bone Marrow: Mast Cell Tumor Malignant		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%
#Bone: 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%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 /09/	0/50 (00/)			4/50 (00()	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

			Male				Female	
#Bone: Osteosarcoma or Osteom		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Bone: Sarcoma		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%
*Brain: Meningioma 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%
*Brain: Meningioma Malignant		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%
*Brain: Meningioma: Benign, Mali	ignant, NOS	2/22 (22/)	(201)				(201)	
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: Schwannoma Malignant		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%

<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:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/95 (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	0/47 (0%) 0/95 (0%)	0/48 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	0/50 (00/)		•••••	0/47 (00/)	0/40 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/95 (0%)	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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

Page: 60

Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

			Male				Female	
*Epididymis: Sarcoma		0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Esophagus: 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%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/45 (0%)	0/40 (0%)			0/44 (0%)	0/42 (0%)	
Overall Incidence	Total	0/45 (0%)	Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma			•••••					
Overall Incidence	Total	7/50 (14%) 15/100 (15%)	8/50 (16%) Mean 15%	SD 1.41%	Total	9/50 (18%) 13/100 (13%)	4/50 (8%) Mean 13%	SD 7.07%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) 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

Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	9/50 (18%) 20/100 (20%)	11/50 (22%) Mean 20%	SD 2.83%	Total	10/50 (20%) 14/100 (14%)	4/50 (8%) Mean 14%	SD 8.49%
#Harderian Gland: Sarcoma		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%
*Heart: Hemangioma		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%
*Heart: 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%
*Heart: 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%
#Intestine Large: Cecum: Carcinoma		0/50 (00()	4/50 (00()			0/50 (00/)	0/50 (00()	
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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma		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 Large: Cecum: Leiomyoma		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%
#Intestine Large: Cecum: Polyp Adenomatous		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%
#Intestine Large: Colon/Rectun 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%
#Intestine Small: Duodenum: Adenoma								
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: Carcinoma					•••••			
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) 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**

Tumor Incidence for Selected Control Animal Groups

Page: 63

Report Date:11/19/2008

# Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: 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%
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 /00/\	0/50 /00/)			0/50 (0%)	0/50 (0%)	
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: Ileum: Carcinoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
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%
#Intestine Small: Ileum: 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%
#Intestine Small: Ileum: Polyp Adenomatous			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%
#Intestine Small: Jejunum: Adenoma		0/50 (00/)	4/50 (00)			0/50 /00/	0/50 (00/)	
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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

## Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:11/19/2008

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			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		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%
#Intestine Small: Jejunum: Hemangiosarcoma		(00)	2(72 (224)				(00)	
Occasional descriptions of	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: 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%
Overall includince	Total	0/100 (0/0)	WCall 070	OD 070	Total	0/100 (0/0)	Wican 070	00 070
#Intestine Small: Jejunum: Polyp Adenomatous		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%
Overall incidence	TOLAI	0/100 (0%)	Wearr 0%	30 0%	I Ulai	0/100 (0%)	ivieari 0%	3D 0%
#Intestine Small: Site Unspec Adenoma	ified:							
	<b>-</b>	0/50 (0%)	1/50 (2%)	05 4 440/	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	ified:			•••••			•••••	
		3/50 (6%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspec	cified:	2/52 (224)				(00)		
		3/50 (6%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspe			•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••		
Hemangiosarcoma	cillea.							
		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%
#Intestine Small: Site Unspe			•••••			•••••		
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%
#Intestine Small: Site Unsper				•••••			•••••	
1 ciyp Additomatods		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%
tiolete Demonstrie			•••••			•••••		
*Islets, Pancreatic: Adenoma								
		2/50 (4%)	0/50 (0%)			0/49 (0%)	1/46 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%
*Islets, Pancreatic:	•••••				•••••			
Carcinoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/46 (0%)	
Overall Incidence	Total	0/100 (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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Islets, Pancreatic: Carcinoma or Adenoma		2/50 (4%)	0/50 (0%)	00.000		0/49 (0%)	1/46 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%
*Kidney: Renal Tubule: Adenoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)	1/49 (2%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/98 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)	1/49 (2%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	0/98 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)	0/40 (00/)			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Liver: Cholangiocarcinoma					•••••			
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

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: METHYLCELLULOSE

Page: 67

			Male				Female	
*Liver: Fibrous Histiocytoma 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%
*Liver: Hemangioma		4/50 (00())	0/50 (0%)			0/50 (00()	0/50 (00()	
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%
*Liver: Hemangiosarcoma		3/50 (6%)	2/50 (4%)	CD 4 440V	Tatal	0/50 (0%)	0/50 (0%)	CD oov
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma		3/50 (6%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	32/50 (64%) 60/100 (60%)	28/50 (56%) Mean 60%	SD 5.66%	Total	14/50 (28%) 29/100 (29%)	15/50 (30%) Mean 29%	SD 1.41%
*Liver: Hepatocellular Carcinoma					•••••			
Overall Incidence	Total	26/50 (52%) 39/100 (39%)	13/50 (26%) Mean 39%	SD 18.38%	Total	5/50 (10%) 10/100 (10%)	5/50 (10%) Mean 10%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

	Male					Female			
*Liver: Hepatocellular Carcino	ma or Hepatob		45/50 (200())			F/F0 /400/\	E/E0 /400/)		
Overall Incidence	Total	27/50 (54%) 42/100 (42%)	15/50 (30%) Mean 42%	SD 16.97%	Total	5/50 (10%) 10/100 (10%)	5/50 (10%) Mean 10%	SD 0%	
*Liver: Hepatocellular Carcino	ma or Hepatoco	ellular Adenoma 41/50 (82%)	37/50 (74%)			17/50 (34%)	19/50 (38%)		
Overall Incidence	Total	78/100 (78%)	Mean 78%	SD 5.66%	Total	36/100 (36%)	Mean 36%	SD 2.83%	
*Liver: Hepatocellular Carcino Hepatoblastoma	ma, Hepatocell	ular Adenoma, or 41/50 (82%)	38/50 (76%)			17/50 (34%)	19/50 (38%)		
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 4.24%	Total	36/100 (36%)	Mean 36%	SD 2.83%	
*Liver: Hepatocholangiocarcin		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%	
*Liver: Ito Cell Tumor Benign		0/50 /09/	0/50 (0%)			0/50 (09/ \	0/50 (09/)		
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%	
*Liver: Ito Cell Tumor Maligna	nt	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

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
*Liver: Sarcoma		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%
*Lung: Adenoma			(201)					
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%
*Lung: Alveolar/Bronchiolar Ac	denoma	7/50 (440)	44/50 (000)			0/50 (00)	4/50 (00()	
Overall Incidence	Total	7/50 (14%) 18/100 (18%)	11/50 (22%) Mean 18%	SD 5.66%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca	arcinoma	44/50 (220/)	1/50 (2%)			4/50 (99/)	E/EO (400()	
Overall Incidence	Total	11/50 (22%) 12/100 (12%)	Mean 12%	SD 14.14%	Total	4/50 (8%) 9/100 (9%)	5/50 (10%) Mean 9%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca Adenoma		veolar/Bronchiolar						
Overall Incidence	Total	16/50 (32%) 28/100 (28%)	12/50 (24%) Mean 28%	SD 5.66%	Total	4/50 (8%) 10/100 (10%)	6/50 (12%) Mean 10%	SD 2.83%
*Lung: 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%

<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: 70

Report Date:11/19/2008

Species: MICE Strain: B6C3F1

Vehicle: METHYLCELLULOSE

			Male			Female           Total         0/50 (0%) 0/100 (0%)         0/50 (0%) Mean 0%         SD 0%           Total         0/50 (0%) 0/50 (0%) Mean 0%         SD 0%           Total         0/100 (0%) 0/50 (0%) Mean 0%         SD 0%           Total         0/50 (0%) 0/50 (0%) Mean 0%         SD 0%           Total         0/100 (0%) Mean 0%         SD 0%           Total         1/50 (2%) 0/50 (0%) Mean 0%         SD 0%		Female		
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			` ,	` ,			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%		
*Lung: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%		
#Lymph Node: Fibrous Histiocytoma		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%		
#Lymph Node: Hemangioma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	` '	SD 1.41%		
#Lymph Node: 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%		

<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:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Lymph Node: 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%
#Lymph Node, Bronchial: Hemangiosarcoma								
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%
#Lymph Node, Mandibular: Fibrous Histiocytoma 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%
#Lymph Node, Mandibular: Hemangiosarcoma	Total	0/50 (0%)	0/50 (0%)	OD 004	T. (-)	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, Mandibular: Mast Cell Tumor Malignant 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%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
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

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

			Male				Female	
#Lymph Node, Mesenteric: Hemangioma		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%
#Lymph Node, Mesenteric: 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%
#Mammary Gland: Adenoacanthoma						-/		
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%
#Mammary Gland: 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%
#Mammary Gland: Carcinoma		0/50 (00/)	0/50 (00/)			4/50 (004)	0/50 (404)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	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: GAVAGE

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Report Date:11/19/2008

Vehicle: METHYLCELLULOSE

			Male				Female	
#Mammary Gland: Fibroadenoma		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%
#Mammary Gland: Fibroma, Fibroadenom		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%
#Mammary Gland: Fibroma, Fibroadenom			0/50 (0%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Mesentery: 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%
#Mesentery: Hemangioma		(004)	(00)			(00)	(201)	
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%
#Mesentery: Hemangiosarcoma	•••••	0/50 (00/)	0(50 (004)			0/50 (004)	0/50 (004)	
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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories T

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
#Mesentery: Sarcoma								
		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%
*Nose: Hemangioma			•••••					
		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%
*Nose:								
Mast Cell Tumor Malig	gnant							
		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 Mucosa		nx, Tooth, Gingiva):						
Papilloma Squamous	or Papilloma	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	SD 09/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Squamous Cell Carcir		nx, Tooth, Gingiva):						
		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 Mucosa Squamous Cell Carcir Papilloma	a, 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%

<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: METHYLCELLULOSE

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			Male				Female	
#Oral Mucosa: Squamous Cell Carcino	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								
Overall Incidence					Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*0								
*Ovary: Cystadenoma						4/49 (8%)	2/47 (4%)	
Overall Incidence					Total	6/96 (6.25%)	Mean 6.21%	SD 2.76%
*Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor E	Benign					0/49 (0%)	0/47 (0%)	
Overall Incidence					Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*•								
*Ovary: Granulosa Cell Tumor N	Malignant					0/49 (0%)	0/47 (0%)	
Overall Incidence					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

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(0%)

0/96 (0%)

Total

Report Date: 11/19/2008

(0%)

SD 0%

Mean 0%

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Male Female \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS (0%)**Overall Incidence** Total 0/96 (0%) Mean 0% SD 0% Hemangioma 0/49 (0%)**Overall Incidence** SD 0% Total 0/96 (0%) Mean 0% \*Ovary: Hemangiosarcoma 0/49 (0%)1/47 (2%)**Overall Incidence** Total 1/96 (1.04%) Mean 1.06% SD 1.5% \*Ovary: Leiomyosarcoma 0/49 0/47 (0%)Mean 0% **Overall Incidence** Total 0/96 (0%) SD 0% \*Ovary: Luteoma 0/49 (0%)**Overall Incidence** Total 0/96 (0%) Mean 0% SD 0% \*Ovary: Teratoma Benign

**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: GAVAGE

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Report Date:11/19/2008

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female			
*Ovary: Teratoma Malignant						0/49 (0%)	0/47 (0%)		
Overall Incidence					Total	0/96 (0%)	Mean 0%	SD 0%	
*Ovary: Tubulostromal Adenoma						0/40 (00)	0.47 (0.4)		
Overall Incidence					Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%	
*Pancreas: Adenoma		0/50 (0%)	0/48 (0%)			0/49 (0%)	0/46 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%	
Pancreas: Carcinoma		0/50 (0%)	0/48 (0%)			0/49 (0%)	0/46 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
Pancreas: Carcinoma or Adenoma	•••••								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/95 (0%)	0/46 (0%) Mean 0%	SD 0%	
*Pituitary Gland: Pars Distalis o Adenoma		ied Site:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 2/95 (2.11%)	1/46 (2%) Mean 2.11%	SD 0.09%	

<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:11/19/2008

Species: MICE Strain: B6C3F1 Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:						
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/46 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma	or Unspecif	ied Site:						
		0/50 (0%)	0/50 (0%)			1/49 (2%)	1/46 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/95 (2.11%)	Mean 2.11%	SD 0.09%
*Pituitary Gland: Pars Interme Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/46 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)		•••••	0/49 (0%)	1/46 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/95 (1.05%)	Mean 1.09%	SD 1.54%
*Prostate: Adenoma								
		0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 /00/	0/40 (00/)					
Overell lesidence	Tatal	0/50 (0%)	0/49 (0%)	CD 00/				
Overall Incidence	Total	0/99 (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

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Report Date:11/19/2008

Vehicle: METHYLCELLULOSE

			Male		Female				
*Prostate: Hemangioma		0/50 (0%)	0/49 (0%)						
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%					
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Carcinoma or Adenoma		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%	
*Salivary Glands: Mast Cell Tumor Malignant		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%	
#Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%					
#Skeletal Muscle: Fibrosarcoma	•••••	0/50 (09/.)	0/50 (09/)			4/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) 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

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male Female **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)(0%)(0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ..... **#Skeletal Muscle:** Myxosarcoma 0/50 0/50 (0%)1/50 0/50 (0%)**Overall Incidence** SD 0% SD 1.41% Total 0/100 (0%) Mean 0% Total 1/100 (1%) Mean 1% **#Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) SD 0% **Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma (0%)(0%)(0%)0/50 0/50 SD 0% Mean 0% **Overall Incidence** Total 0/100 (0%) Mean 0% Total 0/100 (0%) SD 0% **#Skeletal Muscle:** Sarcoma 1/50 (2%)(0%)0/50 0/50 **Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** 0/100 (0%) SD 0% 0/100 (0%) SD 0% Total Mean 0% Total 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

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Trichoepithelioma	Jamous T	0/50 0/100	(0%)	0/50 Mean	(0%)			0/50 (0%)	0/50 (0%)											
Overall Incidence #Skin:	Total		` ,		` '			Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma												
#Skin:	Total	0/100	(0%)	Mean	0%			0/30 (0%)	0/30 (0%)											
					U /0	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%										
		0/50	(0%)	0/50	(0%)			0/50 (0%)	1/50 (2%)											
Overall Incidence	Total	0/100	` ,	Mean	` '	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%										
#Skin: Basal Cell Carcinoma or Baso NOS)		us Tumor	(malignant o	r																
Overall Incidence	Total	0/50 0/100	` ,	0/50 Mean	(0%) 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%										
#Skin: Basal Cell Carcinoma, Basal C Tumor (benign, malignant or N	NOS), or 1	Trichoepit 0/50	thelioma (0%)		(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%										
#Skin: Basal or Sq. Cell Carcinoma, ( or B), Basal Cell Adenoma, Ac Papilloma, Keratoacanthoma,	denoma, F	Papilloma	, Sq	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%										
≴Skin: Basosquamous Tumor Benigr	า	0/50	(00()	0/50	(00()			0/50 (00()	0/50 (00/)											
Overall Incidence	Total	0/50 0/100	(0%)	0/50 Mean	(0%) 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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibroma		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: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, Myx							
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/50 (6%) 6/100 (6%)	3/50 (6%) Mean 6%	SD 0%
#Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	a, or Fibrous						
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%
#Skin: Fibrous Histiocytoma	•••••	4/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (00)	
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: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/30 (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

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: METHYLCELLULOSE

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			Male				Female	
#Skin: Hemangiosarcoma		4/50 /20/	4/50 (20/)			4/50 /20/	4/50 (20/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
:Skin: Liposarcoma								
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: Myxosarcoma		0/50 (00)	0/50 (00/)			4/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Skin: Neural Crest Tumor		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 \$			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, Ne malignant or NOS)		Schwannoma (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%

<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:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male			Female			
#Skin: Osteosarcoma		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: Sarcoma		0/50 (0%)	1/50 (2%)		•••••	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Skin: Schwannoma Malignant		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 Carcinom	na	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 Carcinom Basosquamous Tumor (n	na, Basal Cell		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%	
#Skin: Squamous Cell Papilloma	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%	

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male			Female			
#Skin: Squamous Cell Papillo	ma or Papillom	<b>a</b> 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 Carcinoma or Keratoad									
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, Papilloma,	or Keratoacanthoma 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: Trichoepithelioma		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: Sebaceous Gland: Adenoma		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: Sebaceous Gland: Carcinoma		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%	

<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:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

						Female	
- otal	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%
	0/50 (0%)	0/50 (0%)	OD 004	Total	0/50 (0%)	0/50 (0%)	OD 00/
otal	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	Mean U%	SD 0%
<sup>-</sup> otal	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
<sup>-</sup> otal	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
otal	1/50 (2%) 3/99 (3.03%)	2/49 (4%) Mean 3.04%	SD 1.47%	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
·otal	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%
	otal otal otal	0/50 (0%)  0/50 (0%)  otal 0/100 (0%)  0/50 (0%)  otal 0/99 (0%)  0/50 (0%)  otal 0/99 (0%)  1/50 (2%)  otal 3/99 (3.03%)  0/50 (0%)	otal         0/100 (0%)         Mean 0%           0/50 (0%)         0/50 (0%)           otal         0/100 (0%)         0/49 (0%)           otal         0/99 (0%)         0/49 (4%)           otal         3/99 (3.03%)         0/50 (0%)           0/50 (0%)         0/50 (0%)	otal         0/100 (0%)         Mean 0%         SD 0%           otal         0/50 (0%)         0/50 (0%)         otal 0/100 (0%)         SD 0%           otal         0/50 (0%)         0/49 (0%)         otal 0/99 (0%)         SD 0%           otal         0/50 (0%)         0/49 (0%)         otal 0/99 (0%)         SD 0%           otal         0/99 (0%)         Mean 0%         SD 0%	otal         0/100 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         0/50 (0%)         0/50 (0%)         D 0%         Total           0/50 (0%)         0/49 (0%)         SD 0%         Total           0/50 (0%)         0/49 (0%)         SD 0%         Total           0/50 (0%)         0/49 (0%)         SD 0%         Total           0/50 (0%)         0/49 (4%)         SD 0%         Total           0/50 (2%)         2/49 (4%)         SD 1.47%         Total           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)	otal         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           o/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)           otal         0/100 (0%)         0/49 (0%)         0/50 (0%)           otal         0/99 (0%)         0/50 (0%)         0/50 (0%)           otal         3/99 (3.03%)         Mean 3.04%         SD 1.47%         Total         0/97 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)	otal         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)         Mean 0%           otal         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)           otal         0/100 (0%)         0/49 (0%)         0/50 (0%)         0/50 (0%)         0/47 (0%)           otal         0/99 (0%)         Mean 0%         SD 0%         Total         0/97 (0%)         0/47 (0%)           otal         0/99 (0%)         Mean 0%         SD 0%         Total         0/97 (0%)         0/47 (0%)           otal         0/99 (0%)         Mean 0%         SD 0%         Total         0/97 (0%)         0/47 (0%)           otal         3/99 (3.03%)         Mean 3.04%         SD 1.47%         Total         0/97 (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

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1 Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	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%
#Stomach, Forestomach: Squamous Cell Carcinoma			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma		2/50 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Glandular: 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%
#Stomach, Glandular: Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (0%)	0/50 (0%)	
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%
#Stomach, Glandular: Carcinoma or Adenoma		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%

<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:11/19/2008 Route: GAVAGE

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Species: MICE Strain: B6C3F1

Vehicle: METHYLCELLULOSE

			Male				Female	
*Testes: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign		0/45 (0%)	0/38 (0%)			0/47 (0%)	0/43 (0%)	
Overall Incidence	Total	0/83 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/45 (0%)	0/38 (0%)			0/47 (0%)	0/43 (0%)	
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	nant, NOS	0/45 (0%)	0/38 (0%)			0/47 (0%)	0/43 (0%)	
Overall Incidence	Total	0/83 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma		0/50 (00/)	0/50 (0%)			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (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 Tu

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

pups Report Date:11/19/2008

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			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/46 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma	•••••					4/50 (00)		
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	1/50 (2%) 2/96 (2.08%)	1/46 (2%) Mean 2.09%	SD 0.12%
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)				4/50 (20/)	0/46 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/96 (1.04%)	0/46 (0%) Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	2/50 (4%) 3/96 (3.12%)	1/46 (2%) Mean 3.09%	SD 1.29%
#Tissue NOS: Carcinoma	•••••	0/50 (09/)	0/50 (09/)			0/50 (00/)	0/50 (0%)	
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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Tissue NOS: 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%
#Tissue NOS: Schwannoma Malignant		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 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%
#Tongue: Squamous Cell Carcinoma			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 (00/.)	0/50 (09/)	•••••		0/50 (00/)	0/50 (0%)	
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%
#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%

<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:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Hemangioma		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/45 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)	1/48 (2%)			0/50 (0%)	0/45 (0%)	
Overall Incidence	Total	1/98 (1.02%)	Mean 1.04%	SD 1.47%	Total	0/95 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/95 (0%)	0/45 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangioma	•••••					0/50 (00)	0(50 (00))	
Overall Incidence					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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

	Male	Fema	ale
#Uterus: Hemangiosarcoma		0/50 (00/) 4/50	(20()
Overall Incidence	Total	0/50 (0%) 1/50 1/100 (1%) Mean	(2%) n 1% SD 1.41%
#Uterus: Leiomyoma		0/50 (00)	(00)
Overall Incidence	Total	0/50 (0%) 1/50 1/100 (1%) Mear	(2%) n 1% SD 1.41%
#Uterus: Leiomyosarcoma		0/50 (0%) 0/50	(0%)
Overall Incidence	Total	` ,	n 0% SD 0%
#Uterus: Polyp Stromal		2/50 (4%) 0/50	(0%)
Overall Incidence	Total	` ,	n 2% SD 2.83%
#Uterus: Sarcoma Stromal			
Overall Incidence	Total	0/50 (0%) 0/50 0/100 (0%) Mear	(0%) n 0% SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal			
Overall Incidence	Total	2/50 (4%) 0/50 2/100 (2%) Mean	(0%) n 2% SD 2.83%

<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:11/19/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male	Male Female					
#Uterus: Schwannoma Malignant						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Vagina: Squamous Cell Carcinoma									
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
#Vagina: Squamous Cell Papilloma						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#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**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:11/19/2008

### **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
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/04/01 02/10/04 08/09/01	728 730 728	50 (1) 50 (1) 50 (1)	39(698) 32(691) 40(702)	52.9 51.1 52.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/03/01 02/09/04 08/08/01	727 729 727	50 (5) 50 (5) 50 (5)	38(692) 38(711) 39(694)	64.7 63.9 64.4	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

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: 95

			Male				Female	
All Organs: Benign Tumors								
5		31/50 (62%)	38/50 (76%)	42/50 (84%)		17/50 (34%)	33/50 (66%)	26/50 (52%)
verall Incidence	Total	111/150 (74%)	Mean 74%	SD 11.14%	Total	76/150 (50.67%)	Mean 50.67%	SD 16.04%
All Organs: Malignant Tumors								
verall Incidence	Total	28/50 (56%) 80/150 (53.33%)	26/50 (52%) Mean 53.33%	26/50 (52%) SD 2.31%	Total	26/50 (52%) 57/150 (38%)	15/50 (30%) Mean 38%	16/50 (32%) SD 12.17%
All Organs:								
Malignant and Benign Tu	mors	41/50 (82%)	46/50 (92%)	49/50 (98%)		36/50 (72%)	42/50 (84%)	34/50 (68%)
verall Incidence	Total	136/150 (90.67%)	Mean 90.67%	SD 8.08%	Total	112/150 (74.67%)	Mean 74.67%	SD 8.33%
All Organs: Hemangioma		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
All Organs: Hemangiosarcoma					• • • • • • • • • • • • • • • • • • • •			
		3/50 (6%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	5/50 (10%)
verall Incidence	Total	9/150 (6%)	Mean 6%	SD 2%	Total	7/150 (4.67%)	Mean 4.67%	SD 5.03%
All Organs: Hemangiosarcoma or He								
		5/50 (10%)	5/50 (10%)	2/50 (4%)		2/50 (4%)	1/50 (2%)	7/50 (14%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 3.46%	Total	10/150 (6.67%)	Mean 6.67%	SD 6.43%

<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: 96

			Male				Female	
All Organs: Histiocytic Sarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
All Organs: Malignant Lymphoma: H or Undifferentiated Cell	istiocytic, Lyr							
	<b>-</b>	2/50 (4%)	4/50 (8%)	2/50 (4%)	<b>+</b>	10/50 (20%)	9/50 (18%)	8/50 (16%)
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%	Total	27/150 (18%)	Mean 18%	SD 2%
fAll Organs: Mesothelioma: Benign, I			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: Malignan	t	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								
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%
Torum molucitos	ı olal	0,100 (0,0)	WICAIT 070	OD 070	ı olal	0,100 (070)	INICALL 070	OD 070
All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/30 (0 %) Mean 0%	SD 0%

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

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

II. NOV2008

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: 97

			Male		Female
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%) 0/50 (0	0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	,	Mean 0% SD 0%
Adrenal Cortex: Adenoma		2/50 (4%)	1/50 (2%) 5/49 (1	10%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	8/149 (5.37%)	1/50 (2%) 5/49 (1 Mean 5.4% SD 4.2	,	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Adrenal Cortex: Sarcoma		0/50 (00/.)	0/50 (0%) 0/40 (/	000)	0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0 Mean 0% SD 0%	0%) 0/49 (0%) Total 0/149 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Adrenal Medulla: Pheochromocytoma Benign	•••••	0/50 (0%)	0/50 (0%) 0/49 (0	0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	,	Mean 0.67% SD 1.15%
Adrenal Medulla: Pheochromocytoma Complex	κ				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0 Mean 0% SD 0%	0%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Adrenal Medulla: Pheochromocytoma Malignal	nt	1/50 (29/)	0/50 (0%) 0/40 (/	0/50 (0%)	0/50 (09/) 0/50 (09/)
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) 0/49 (0 Mean 0.67% SD 1.1	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: 98

			Male				Female	
Adrenal Medulla: Pheochromocytoma: Benig	ın, Complex		0/50 (00/)	0/40 (00/)		0/50 (00/)	4/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) Mean 0.67%	0/49 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Bone Marrow: Mast Cell Tumor Malignant								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Bone: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Bone: Osteoma						•••••		
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%
Bone: Osteosarcoma								
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%

<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: 99

			Male				Female	
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Bone: Sarcoma								0/50 (0%)
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%
Brain: Meningioma Benign		0/50 (00()	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (0%)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Malig	nant, NOS							
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%
Brain: Schwannoma Malignant								
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

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: 100

			Male				Female	
Clitoral/Preputial Gland: 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%
litoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
litoral/Preputial Gland: 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%
litoral/Preputial Gland: Hemangioma		0/50 (0%)						
	T-1-1	` ,	` ,	` ,	T-1-1	` '	(/	()
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
litoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
litoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<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:11/19/2008

Page: 101

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

			Male	Female
*Epididymis: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	
#Esophagus: 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%)
#Eye: Sarcoma	•••••	0/50 (09/)	0/50 (0%) 0/50 (0%)	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Gallbladder: Adenoma				0/47 (0%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/45 (0%) 0/143 (0%)	0/49 (0%) 0/49 (0%) Mean 0% SD 0%	0/47 (0%) 0/49 (0%) 0/50 (0%)  Total 0/146 (0%) Mean 0% SD 0%
#Harderian Gland: Adenoma				
Overall Incidence	Total	6/50 (12%) 28/150 (18.67%)	11/50 (22%) 11/50 (22%) Mean 18.67% SD 5.77%	4/50 (8%) 7/50 (14%) 7/50 (14%) Total 18/150 (12%) Mean 12% SD 3.46%
#Harderian Gland: Carcinoma	•••••			4/50 (00)
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) 3/50 (6%) Mean 4% SD 2%	4/50 (8%) 0/50 (0%) 0/50 (0%) Total 4/150 (2.67%) Mean 2.67% SD 4.62%

<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: 102

Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	7/50 (14%) 32/150 (21.33%)	12/50 (24%) Mean 21.33%	13/50 (26%) SD 6.43%	Total	8/50 (16%) 22/150 (14.67%)	7/50 (14%) Mean 14.67%	7/50 (14%) SD 1.15%
#Harderian Gland: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 /00/		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Hemangioma		4/50 (004)	0/50 (00/)	0/50 (00/)		0/50 (004)	0/50 (00/)	0/50 (00/)
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%
*Heart: Hemangiosarcoma		0/50 (00/)	4/50 (00/)	0/50 /00/		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Sarcoma		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%	0/50 (0%) SD 0%	Total	0/30 (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%) 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

Tumor Incidence for Selected Control Animal Groups

Page: 103
Report Date:11/19/2008

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

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma		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%
#Intestine Large: Cecum: Leiomyoma		2/20 (201)	2/22 (22)	(00)		(201)	(201)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Large: Cecum: Polyp Adenomatous			(204)	(004)				
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: Colon/Rectun Leiomyosarcoma		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: Duodenum: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Carcinoma					•••••			
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 104

			Male				Female	
Intestine Small: Duodenum: Leiomyosarcoma								
		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%
ntestine Small: Duodenum: Polyp Adenomatous								
		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%
ntestine Small: Ileum: Carcinoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
testine Small: lleum: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	` ,	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
eran incidence	Total	0/150 (0%)	iviean 0%	SD 0%	Total	0/150 (0%)	wean 0%	SD 0%
itestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
testine Small: Jejunum: 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%

<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: 105

			Male				Female	
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Hemangiosarcoma								
verall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
veraii incidence	Total	0/150 (0%)	Mean 0%		Total	0/150 (0%)	Mean 0%	
ntestine Small: Jejunum: Leiomyosarcoma								
		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%
ntestine Small: Jejunum: Polyp Adenomatous		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%
ntestine Small: Site Unspecifi Adenoma	ed:							
		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%
ntestine Small: Site Unspecifi Carcinoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%

<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: 106

Report Date:11/19/2008

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

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:	0/50 (00/)	0/50 (00/)	0/50 (40())		0/50 /00/	0/50 (00/)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Hemangiosarcoma	cified:	0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Leiomyosarcoma								0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec	ified:				•••••			
i olyp Adelioiliatous		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%
*Islets, Pancreatic: Adenoma							•••••	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		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%
*Islets, Pancreatic: Carcinoma								
Owner Haller and James	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
Islets, Pancreatic: Carcinoma or Adenoma								
Normall Implications	Tatal	0/50 (0%)	2/50 (4%)	0/50 (0%)	Tatal	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
idney: Renal Tubule: Adenoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
idney: Renal Tubule: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
idney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)	4/50 (00/)	4/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2/150 (1.55%)	ivieari 1.33%	30 1.13%	ı Olai	0/150 (0%)	Mean 0%	30 0%
idney: Renal Tubule: Hemangiosarcoma								
		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%
iver: Cholangiocarcinoma		0(50 (00))	0/50 (00/)	0(50 (00))		0/50 (00/)	0/50 (004)	0/50 (00/)
		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%

<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: 108

			Male				Female	
Liver: Fibrous Histiocytoma		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%
Liver: Hemangioma		0/50 (0%)	0/50 (09/)	NEO (00()		0/50 (00/)	0/50 /00/	0/50 /00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0 Mean 0%	%0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
iver: Hemangiosarcoma		4/50 (00/)	0/50 (404)	(50. (60.)		0/50 (00)		
verall Incidence	Total	1/50 (2%) 4/150 (2.67%)	2/50 (4%) 1 Mean 2.67%	/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
iver: Hepatoblastoma		1/50 (2%)		/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
iver: Hepatocellular Adenoma								
verall Incidence	Total	24/50 (48%) 91/150 (60.67%)	34/50 (68%) 3 Mean 60.67%	3/50 (66%) SD 11.02%	Total	6/50 (12%) 41/150 (27.33%)	21/50 (42%) Mean 27.33%	14/50 (28%) SD 15.01%
iver: Hepatocellular Carcinoma					•••••			
Overall Incidence	Total	15/50 (30%) 40/150 (26.67%)	14/50 (28%) 1 Mean 26.67%	1/50 (22%) SD 4.16%	Total	4/50 (8%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	2/50 (4%) SD 2.31%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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

			Male				Female	
Liver: Hepatocellular Carcinoma	or Hepatob							
		16/50 (32%)	14/50 (28%)	12/50 (24%)		4/50 (8%)	2/50 (4%)	3/50 (6%)
verall Incidence	Total	42/150 (28%)	Mean 28%	SD 4%	Total	9/150 (6%)	Mean 6%	SD 2%
.iver:						• • • • • • • • • • • • • • • • • • • •		
Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma						
•	•	33/50 (66%)	39/50 (78%)	39/50 (78%)		9/50 (18%)	23/50 (46%)	14/50 (28%)
verall Incidence	Total	111/150 (74%)	Mean 74%	SD 6.93%	Total	46/150 (30.67%)	Mean 30.67%	SD 14.19%
.iver: Hepatocellular Carcinoma Hepatoblastoma	, Hepatocell	ular Adenoma, or 34/50 (68%)	39/50 (78%)	39/50 (78%)		9/50 (18%)	23/50 (46%)	15/50 (30%)
verall Incidence	Total	112/150 (74.67%)	Mean 74.67%	SD 5.77%	Total	47/150 (31.33%)	Mean 31.33%	SD 14.05%
iver: Hepatocholangiocarcinon	na	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
iver:		•••••						
Ito Cell Tumor Benign		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	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%
eran incluence	Total	0/130 (0%)	Weatt 070	3D 0%	Total	0/130 (0%)	iviedii U70	3D 0%
iver: Ito Cell Tumor Malignant		(004)	(201)	(00)		(201)	(201)	0.50
		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%

<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: 110 Report Date:11/19/2008

Contract/Lab: All Laboratories

aboratorie

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male	Fer	male
*Liver: Sarcoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 Total 0/150 (0%) Me	(0%) 0/50 (0%) an 0% SD 0%
*Lung: Adenoma		0/50 (00/)	0/50 (00)	0/50 (001) 0/50	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 Total 0/150 (0%) Me	(0%) 0/50 (0%) an 0% SD 0%
Lung: Alveolar/Bronchiolar Adend	oma	10/50 (20%)	9/50 (18%) 10/50 (20%)	4/50 (8%) 6/50	(12%) 2/50 (4%)
Overall Incidence	Total	29/150 (19.33%)	Mean 19.33% SD 1.15%	` ,	an 8% SD 4%
Lung: Alveolar/Bronchiolar Carcir	noma	0/50 (4004)	0/50 (00) 7/50 (440)	0/50 (40)	(00)
Overall Incidence	Total	6/50 (12%) 16/150 (10.67%)	3/50 (6%) 7/50 (14%) Mean 10.67% SD 4.16%	2/50 (4%) 1/50 Total 4/150 (2.67%) Me	(2%) 1/50 (2%) an 2.67% SD 1.15%
'Lung: Alveolar/Bronchiolar Carcir Adenoma	noma or Al	veolar/Bronchiolar			
Overall Incidence	Total	16/50 (32%) 44/150 (29.33%)	12/50 (24%) 16/50 (32%) Mean 29.33% SD 4.62%	5/50 (10%) 7/50 Total 15/150 (10%) Me	(14%) 3/50 (6%) an 10% SD 4%
Lung: Fibrosarcoma		0/50 (00/)	0/50 (00) 0/50 (00)	0/50 /00/) 0/50	(0)()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 Total 0/150 (0%) Me	(0%) 0/50 (0%) an 0% SD 0%

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male				Female	
*Lung: Fibrous Histiocytoma								
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%
*Lung: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (09/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Sarcoma	••••	0/50 (0%)	0/50 (00)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (09/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (00/)	0/50 (00)	0/50 /00/		0/50 (00()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<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:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#Lymph Node: 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%
#Lymph Node, Bronchial: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (00/)	0/50 /09/\ 0/50 /09/\	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma	•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (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

Tumor Incidence for Selected Control Animal Groups

Page: 113 Report Date:11/19/2008

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

			Male				Female	
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								4/50 (004)
		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%
Mammary Gland: Adenoacanthoma								
		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%
Mammary Gland: Adenoma		(00)	(00)	(20)			(00)	(00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
//ammary Gland: Carcinoma				•••••			•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
verall 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

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Report Date:11/19/2008

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

Vehicle: WATER

			Male				Female	
#Mammary Gland: Fibroadenoma								
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%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma	0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00/)	4/50 (001)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, o	r Adenoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
#Mesentery: Fibrosarcoma		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%
#Mesentery: 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%
#Mesentery: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0(50 (00))	•••••	0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<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: 115

			Male				Female	
Mesentery:								
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%
 Nose:					•••••			
Hemangioma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Nose:					•••••			
Mast Cell Tumor Malig	nant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa								
Papilloma Squamous	or Papilloma	0/50 (00/)	0/50 (00/)	0(50 (00))		0/50 (00/)	0/50 (00/)	0/50 (00/)
	<b>T</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin	, Tongue, Phary							
oquamous con caroni	- Ciria	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma	, Tongue, Phary	Squamous, or			•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Oral Mucosa: Squamous Cell Carcinoma** 0/50 (0%)(0%)(0%)(0%)0/50 (0%)(0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Choriocarcinoma 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% \*Ovary: Cystadenoma 1/50 (2%)7/50 (14%)3/50 (6%)**Overall Incidence** Total 11/150 (7.33%) Mean 7.33% SD 6.11% \*Ovary: Fibrous Histiocytoma (0%)0/50 (0%)0/50 (0%)Total Mean 0% **Overall Incidence** 0/150 (0%) SD 0% **Granulosa Cell Tumor Benign** 0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 Mean 0% SD 0% \*Ovary: **Granulosa Cell Tumor Malignant** (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (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

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Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male		Female	
	0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)
	, ,		SD 0%
			0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%
	Total  Total  Total	O/50 (0%) Total O/150 (0%)  O/50 (0%)  Total O/150 (0%)  O/50 (0%)  O/50 (0%)  O/50 (0%)	O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%  O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%  O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%  O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%  O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

			Male			Female			
Ovary: Teratoma Malignant						0/50 /00/	0/50 (09/)	0/50 (09/)	
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Ovary: Tubulostromal Adenoma						2/52 (221)	2/52 (221)	2/52 (221)	
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Pancreas: Adenoma				0/50 (0%)					
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
Pancreas: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/40 (00)	0/50 (00/)	0/40 (00/)	
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
ancreas: Carcinoma or Adenoma									
verall incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
Pituitary Gland: Pars Distalis o Adenoma									
Overall Incidence	Total	1/50 (2%) 2/148 (1.35%)	1/50 (2%) Mean 1.33%	0/48 (0%) SD 1.15%	Total	3/50 (6%) 6/149 (4.03%)	1/50 (2%) Mean 4.03%	2/49 (4%) SD 2%	
veran incluence	IUlai	2/140 (1.33/0)	IVICALI 1.33%	JD 1.1370	i Ulai	0/143 (4.03/0)	WEATT 4.03%	SD 2/0	

<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: 119

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	fied Site:						
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Carcinoma or Adenoma	or Unspecif	fied Site:				•••••		
		2/50 (4%)	1/50 (2%)	0/48 (0%)		3/50 (6%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	3/148 (2.03%)	Mean 2%	SD 2%	Total	6/149 (4.03%)	Mean 4.03%	SD 2%
Pituitary Gland: Pars Intermed Adenoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%
Pituitary Gland: Pars Intermed Carcinoma or Adenoma	dia:			•••••	•••••	•••••		
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%
Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenoma	•••••	0/50 (00/)	0/50 (00)	0/50 (00/)				
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				

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

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

**Toxicology Data Management System** 

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

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male		Female			
*Prostate: Hemangioma	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/49 (0%)	0/50 (00/)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)	0/50 (00/)		0/40 (00/)	0/50 (00)	0/40 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/148 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skeletal Muscle: Fibrosarcoma		0/50 (00()	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 /00/	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<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: 121

			Male				Female	
Skeletal Muscle: Hemangiosarcoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Skeletal Muscle: Myxosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
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%
Skeletal Muscle: Rhabdomyosarcoma or Rl	nabdomyom							
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%
Skeletal Muscle: Sarcoma								
verall 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%
Skin: Basal Cell Adenoma or Ba	sosquamou	s Tumor Benign 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/150 (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

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Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous <sup>*</sup>	Tumor Benign, or						
,		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:		•••••				•••••		
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma ( NOS)		ous Tumor (malignant o						
•		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%
Basal Cell Carcinoma, Tumor (benign, malign	ant or NOS), or	Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma	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%
	Total  Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq	` '	` ,	Total	` ,	` ,	` '
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total  Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma	Mean 0%	SD 0%	Total Total	0/150 (0%) <sup>′</sup>	Mean 0%	SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total  noma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´ 	Mean 0%	SD 0% /
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%		0/150 (0%) ´  0/50 (0%)  0/50 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / 0/50 (0%) SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan everall Incidence	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´ 	Mean 0%	SD 0% /

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
‡Skin: Fibroma		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 /00/	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, oı			•••••			
·		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%
Skin: Fibrosarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 3.46%
Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	na, or Fibrous 0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%
Skin: Fibrous Histiocytoma		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:								
Hemangioma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Animal Groups

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Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: 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%
#Skin: Liposarcoma		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: Myxosarcoma		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		0/50 (00/)	0/50 (00)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or S		malignant or NOS) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Neurofibrosarcoma, Neu malignant or NOS)	urofibroma, or	Schwannoma (benign,			•••••			
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%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male				Female	
#Skin: Osteosarcoma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sarcoma								- / / / / / / / / / /
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Skin: Schwannoma Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Skin: Squamous Cell Carcinon	na					•••••		
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%
Skin: Squamous Cell Carcinon Basosquamous Tumor (r			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: Squamous Cell Papillom	a	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			U/:)U (U%)	U/:)U (U%)		U/:)U (U%)		U/:)U (U%)

<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 Management System

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 126

			Male				Female	
Skin: Squamous Cell Papillo	ma or Papillom		0/50 (00()	0/50 (09/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papillo Carcinoma or Keratoac		Squamous Cell						
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%
						· · · · · · · · · · · · · · · · · · ·		
Skin: Squamous Cell Papillo	ma, Papilloma,	or Keratoacanthoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	` ,	` '	` ,	Total	0/150 (0%)	Mean 0%	SD 0%
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
	Total	0/150 (0%)	Mean 0%	SD 0% ′	Total			
Skin: Trichoepithelioma	Total Total	` ,	` '	` ,	Total Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
verall Incidence	Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Trichoepithelioma verall Incidence Skin: Sebaceous Gland: Adenoma	Total	0/150 (0%) 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Skin: Trichoepithelioma verall Incidence Skin: Sebaceous Gland: Adenoma	Total	0/150 (0%)  0/50 (0%)  0/150 (0%)  0/50 (0%)	Mean 0%  0/50 (0%)  Mean 0%  0/50 (0%)	SD 0%  0/50 (0%) SD 0%  0/50 (0%)	Total	0/50 (0%) 0/150 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)
Skin: Trichoepithelioma verall Incidence Skin: Sebaceous Gland:	Total	0/150 (0%)  0/50 (0%)  0/150 (0%)  0/50 (0%)	Mean 0%  0/50 (0%)  Mean 0%  0/50 (0%)	SD 0%  0/50 (0%) SD 0%  0/50 (0%)	Total	0/50 (0%) 0/150 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)

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

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

131011.11072000

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: 127

			Male		Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	2/52 (22)	(004)	0/50 (00)	)(F2 (20))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SI	(0%) 0 0% Total	0/50 (0%) 0/50 (0%) 0 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%) 0/50		0/50 (0%) 0/50 (0%) 0	)/50 (0%)
Overall Incidence	Total	0/150 (0%)	` ,	0 0% Total	0/150 (0%) Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma		0/50 (00()	0/50 /09/\	(00/)	0/50 (09/) 0/50 (09/)	N/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SI	(0%) 0 0% Total	0/50 (0%) 0/50 (0%) 0 0/149 (0%) Mean 0%	0/49 (0%) SD 0%
Spleen: Hemangioma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 1/50 (2%) 0	)/49 (0%)
verall Incidence	Total	0/30 (0%)	` ,	0 % Total	1/149 (0.67%) Mean 0.67%	SD 1.15%
Spleen: Hemangiosarcoma						
verall Incidence	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) 1/50 Mean 2.67% SE	(2%) D 1.15% Total	1/50 (2%) 0/50 (0%) 4 5/149 (3.36%) Mean 3.39%	1/49 (8%) SD 4.25%
Stomach, Forestomach:  Mast Cell Tumor Malignant						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SI	(0%) 0 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	)/50 (0%) SD 0%

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 128

Report Date:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#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	0/150 (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%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
#Stomach, Glandular: Adenoma		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%	0/50 (0%) SD 0%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		(004)						(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<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: 129
Report Date:11/19/2008

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

			Male				Female	
*Testes: Adenoma		0(50 (00/)	0/50 (00/)	0(50 (00))				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Testes: Hemangiosarcoma		0/50 (00/)	0/50 (0%)	0/50 /00/				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Thymus: Thymoma Benign		2/ /22/	047 (00)	(00)				2/17 (20)
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) Mean 0%	0/43 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
*Thymus: Thymoma Malignant		0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	nant, NOS							
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) Mean 0%	0/43 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
*Thyroid Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (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: 130 Report Date:11/19/2008

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

			Male	Female	
*Thyroid Gland: C-Cell: Carcinoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/49 (0%) 0/48 Total 0/146 (0%) Mean 0% Si	B (0%) D 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/48	3 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	( )	D 0%
*Thyroid Gland: Follicular Cell: Adenoma	•••••				(201)
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) 2/50 (4%) Mean 2% SD 2%	2/49 (4%) 0/49 (0%) 1/48 Total 3/146 (2.05%) Mean 2.05% Si	3 (2%) D 2.04%
*Thyroid Gland: Follicular Cell: Carcinoma	•••••				
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/49 (0%) 0/49 (0%) 0/48 Total 0/146 (0%) Mean 0% SI	B (0%) D 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma					
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) 2/50 (4%) Mean 2.67% SD 1.15%	2/49 (4%) 0/49 (0%) 1/48 Total 3/146 (2.05%) Mean 2.05% Si	3 (2%) D 2.04%
#Tissue NOS: Carcinoma		0/50 (00/)	0/50 (00)		(004)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 Total 0/150 (0%) Mean 0% Si	0 (0%) D 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: 131 Report Date:11/19/2008

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

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Tissue NOS: 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%
FTissue NOS: 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%
Tongue: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Tongue: Squamous Cell Carcinoma	or Papillon							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Tongue: Squamous Cell Papilloma								
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%
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%

<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:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Urinary Bladder: Hemangioma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (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%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Adenoma						0/50 (0%)	0/50 /00/	0/50 (00/)
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Carcinoma	•••••••				•••••			
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangioma						0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence					Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%

<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:11/19/2008

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
#Uterus: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Uterus:				
Sarcoma Stromal Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 134 Report Date:11/19/2008

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

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Uterus: Schwannoma Malignant						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Vagina: Squamous Cell Papilloma	•••••							
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
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								
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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:11/19/2008

#### **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	
				Ma	ale			
Battelle Northwest	052001106	07/21/03	729	50 (5)	37(689)	53.4	1-Bromopropane	
Battelle Northwest	059601106	06/11/01	729	50 (5)	38(709)	53.9	Cumene	
Battelle Northwest	059901706	08/18/03	729	50 (5)	31(686)	53.8	Diethylamine	
Battelle Northwest	058800406	09/27/99	729	50 (5)	41(702)	52.2	Divinylbenzene	
Battelle Northwest	059700602	06/05/00	729	50 (5)	40(709)	53.2	Methyl isobutyl ketone	
Battelle Northwest	058800604	07/30/01	729	50 (5)	35(698)	54.9	alpha-Methylstyrene	
Battelle Northwest	059700806	09/17/01	729	50 (5)	37(694)	53.5	Propargyl alcohol	
Battelle Northwest	059302506	06/23/03	729	50 (5)	36(695)	52.9	Tetralin	
				Fen	nale			
Battelle Northwest	052001106	07/21/03	731	50 (5)	36(698)	61.2	1-Bromopropane	
Battelle Northwest	059601106	06/11/01	731	50 (5)	37(685)	60.7	Cumene	
Battelle Northwest	059901706	08/18/03	731	50 (5)	32(684)	60.7	Diethylamine	
Battelle Northwest	058800406	09/27/99	731	50 (5)	33(681)	63.0	Divinylbenzene	
Battelle Northwest	059700602	06/05/00	731	50 (5)	35(695)	60.3	Methyl isobutyl ketone	
Battelle Northwest	058800604	07/30/01	731	50 (5)	39(701)	58.6	alpha-Methylstyrene	
Battelle Northwest	059700806	09/17/01	731	50 (5)	39(699)	58.3	Propargyl alcohol	
Battelle Northwest	059302506	06/23/03	731	50 (5)	31(663)	62.1	Tetralin	

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
		36/50 (72%) 35/50 (70%) 28/50 (56%)	43/50 (86%) 27/50 (54%) 42/50 (84%)	33/50 (66%) 35/50 (70%)		22/50 (44%) 28/50 (56%) 26/50 (52%)	34/50 (68%) 29/50 (58%) 24/50 (48%)	25/50 (50%) 26/50 (52%)
Overall Incidence	Total	279/400 (69.75%)	Mean 69.75%	SD 11.49%	Total	214/400 (53.5%)	Mean 53.5%	SD 7.31%
#All Organs: Malignant Tumors	•••••				•••••			
·		30/50 (60%) 26/50 (52%) 22/50 (44%)	27/50 (54%) 29/50 (58%) 26/50 (52%)	36/50 (72%) 19/50 (38%)		33/50 (66%) 22/50 (44%) 23/50 (46%)	26/50 (52%) 30/50 (60%) 27/50 (54%)	23/50 (46%) 29/50 (58%)
Overall Incidence	Total	215/400 (53.75%)	Mean 53.75%	SD 10.28%	Total	213/400 (53.25%)	Mean 53.25%	SD 7.78%
#All Organs: Malignant and Benign T					• • • • • • • • • • • • • • • • • • • •			
		47/50 (94%) 43/50 (86%) 38/50 (76%)	48/50 (96%) 45/50 (90%) 47/50 (94%)	48/50 (96%) 43/50 (86%)		42/50 (84%) 40/50 (80%) 37/50 (74%)	42/50 (84%) 42/50 (84%) 40/50 (80%)	41/50 (82%) 40/50 (80%)
Overall Incidence	Total	359/400 (89.75%)	Mean 89.75%	SD 6.88%	Total	324/400 (81%)	Mean 81%	SD 3.38%
All Organs: Hemangioma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 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%) 1/50 (2%)
Overall Incidence	Total	3/400 (0.75%)	Mean 0.75%	SD 1.04%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%

<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:11/19/2008

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

Route: INHALATION Vehicle: AIR

			Male				Female	
All Organs: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%)	7/50 (14%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		6/50 (12%)	3/50 (6%)	4/50 (8%)		1/50 (2%)	3/50 (6%)	4/50 (8%)
		2/50 (4%)	4/50 (8%)			2/50 (4%)	2/50 (4%)	
rerall Incidence	Total	28/400 (7%)	Mean 7%	SD 4.54%	Total	22/400 (5.5%)	Mean 5.5%	SD 2.98%
II Organs:				•••••				
Hemangiosarcoma or H	emangioma							
		2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		6/50 (12%)	4/50 (8%)	4/50 (8%)		2/50 (4%)	3/50 (6%)	5/50 (10%)
		2/50 (4%)	5/50 (10%)			2/50 (4%)	2/50 (4%)	
erall Incidence	Total	31/400 (7.75%)	Mean 7.75%	SD 4.2%	Total	24/400 (6%)	Mean 6%	SD 3.02%
All Organs: Histiocytic Sarcoma								
•		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)			1/50 (2%)	2/50 (4%)	
verall Incidence	Total	4/400 (1%)	Mean 1%	SD 1.07%	Total	10/400 (2.5%)	Mean 2.5%	SD 1.77%
All Organs:	•••••							
Malignant Lymphoma: I or Undifferentiated Cell		nphocytic, Mixed, NOS	,					
		2/50 (4%)	2/50 (4%)	2/50 (4%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		11/50 (22%)	13/50 (26%)	15/50 (30%)
		1/50 (2%)	2/50 (4%)	, ,		13/50 (26%)	12/50 (24%)	,
verall Incidence	Total	11/400 (2.75%)	Mean 2.75%	SD 1.49%	Total	96/400 (24%)	Mean 24%	SD 6.68%

<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:11/19/2008

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

			Male	Female
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS			
		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%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25% SD 0.71%	Total 0/400 (0%) Mean 0% SD 0%
#All Organs: Mesothelioma: Malignant	•••••			
Ü		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%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25% SD 0.71%	Total 0/400 (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%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0% SD 0%	Total 0/400 (0%) Mean 0% SD 0%
#All Organs: Osteosarcoma	•••••			
		1/50 (2%) 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%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5% SD 0.93%	Total 0/400 (0%) Mean 0% SD 0%

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Osteosarcoma or Osteoma								
		1/50 (2%) 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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	0/400 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma								
		4/49 (8%) 3/49 (6%) 1/49 (2%)	1/50 (2%) 2/50 (4%) 2/49 (4%)	6/50 (12%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)
Overall Incidence	Total	19/396 (4.8%)	Mean 4.8%	SD 3.86%	Total	2/399 (0.5%)	Mean 0.5%	SD 0.93%
Adrenal Cortex: Sarcoma								
		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (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	0/396 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Benign								
		1/50 (2%) 2/49 (4%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 1/47 (2%)	0/50 (0%) 0/50 (0%)		3/50 (6%) 0/49 (0%) 1/48 (2%)	0/50 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	4/393 (1.02%)	Mean 1.03%	SD 1.55%	Total	8/397 (2.02%)	Mean 2.01%	SD 2.39%

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
Adrenal Medulla: Pheochromocytoma Com	plex							
		0/50 (0%) 0/49 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/393 (0%)	Mean 0%	SD 0%	Total	0/397 (0%)	Mean 0%	SD 0%
drenal Medulla:								
Pheochromocytoma Malig	gnant	0/50 (0%) 0/49 (0%) 0/47 (0%)	0/50 (0%) 1/50 (2%) 0/47 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/49 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/393 (0.25%)	Mean 0.25%	SD 0.71%	Total	1/397 (0.25%)	Mean 0.25%	SD 0.71%
drenal Medulla:								
Pheochromocytoma: Ben	ign, Complex	x, Malignant, NOS 1/50 (2%) 2/49 (4%) 0/47 (0%)	0/50 (0%) 1/50 (2%) 1/47 (2%)	0/50 (0%) 0/50 (0%)		4/50 (8%) 0/49 (0%) 1/48 (2%)	0/50 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)
verall Incidence	Total	5/393 (1.27%)	Mean 1.28%	SD 1.52%	Total	9/397 (2.27%)	Mean 2.26%	SD 2.91%
one Marrow: Hemangiosarcoma							•••••	
Tiemangiosalcoma		0/48 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 2/50 (4%)	0/49 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)
overall Incidence	Total	4/398 (1.01%)	Mean 1%	SD 1.85%	Total	4/398 (1.01%)	Mean 1%	SD 1.51%

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

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

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Bone Marrow: Mast Cell Tumor Malignant								
_		0/48 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/398 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/398 (0%)	Mean 0%	SD 0%
Bone:	•••••		•••••					
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%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma								
		1/50 (2%) 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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	0/400 (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	
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	0/400 (0%)	Mean 0%	SD 0%
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
Ɓrain: Meningioma Benign	•••••				•••••			
		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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain:								
Meningioma: Benign, Malig	nant, NOS		- 4					
		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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
rain: 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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/50 (0%)			0/42 (0%)	0/46 (0%)	
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/356 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/50 (0%)	2.22 (070)		0/42 (0%)	0/46 (0%)	5. 15 (070)
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/356 (0%)	Mean 0%	SD 0%
overall incluence	Total	0/398 (078)	Mean 076	30 0%	Total	0/330 (0 /8)	Weatt 076	30 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: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/50 (0%)	<b>OD</b>		0/42 (0%)	0/46 (0%)	05.00/
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/356 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangioma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/50 (0%)			0/42 (0%)	0/46 (0%)	
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/356 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
_		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	0/43 (0%)
		0/50 (0%)	0/50 (0%)			0/42 (0%)	0/46 (0%)	
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/356 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/45 (0%)	1/43 (2%)
		0/50 (0%)	0/50 (0%)	, ,		0/42 (0%)	0/46 (0%)	, ,
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	1/356 (0.28%)	Mean 0.29%	SD 0.82%

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

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male						Female	
Epididymis: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 1/399 (0.25%)	0/50 (0%) Mean 0.25%	SD 0.71%				
overali incluence	I Ulai	1/399 (0.25%)	Wear 0.25%	30 0.71%				
#Esophagus: Squamous Cell Carcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>.</b>	0/50 (0%)	0/50 (0%)	00.0740/
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Eye: 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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Gallbladder: Adenoma				•••••				
		0/40 (0%)	0/43 (0%)	0/36 (0%)		0/43 (0%)	0/38 (0%)	0/38 (0%)
		1/42 (2%)	0/43 (0%)	0/42 (0%)		0/45 (0%)	0/42 (0%)	0/47 (0%)
		0/40 (0%)	0/43 (0%)			0/41 (0%)	0/42 (0%)	
Overall Incidence	Total	1/329 (0.3%)	Mean 0.3%	SD 0.84%	Total	0/336 (0%)	Mean 0%	SD 0%

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

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Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Harderian Gland: Adenoma								
		7/50 (14%) 5/50 (10%) 3/50 (6%)	8/50 (16%) 5/50 (10%) 2/50 (4%)	4/50 (8%) 10/50 (20%)		3/50 (6%) 4/50 (8%) 4/50 (8%)	8/50 (16%) 6/50 (12%) 1/50 (2%)	3/50 (6%) 3/50 (6%)
verall Incidence	Total	44/400 (11%)	Mean 11%	SD 5.35%	Total	32/400 (8%)	Mean 8%	SD 4.28%
Harderian Gland: Carcinoma								
		3/50 (6%) 1/50 (2%) 3/50 (6%)	4/50 (8%) 2/50 (4%) 3/50 (6%)	4/50 (8%) 1/50 (2%)		2/50 (4%) 2/50 (4%) 0/50 (0%)	5/50 (10%) 1/50 (2%) 1/50 (2%)	2/50 (4%) 1/50 (2%)
Overall Incidence	Total	21/400 (5.25%)	Mean 5.25%	SD 2.38%	Total	14/400 (3.5%)	Mean 3.5%	SD 2.98%
Harderian Gland: Carcinoma or Adenoma								
		10/50 (20%) 6/50 (12%) 6/50 (12%)	11/50 (22%) 7/50 (14%) 5/50 (10%)	8/50 (16%) 11/50 (22%)		5/50 (10%) 6/50 (12%) 4/50 (8%)	12/50 (24%) 7/50 (14%) 2/50 (4%)	5/50 (10%) 4/50 (8%)
Overall Incidence	Total	64/400 (16%)	Mean 16%	SD 4.78%	Total	45/400 (11.25%)	Mean 11.25%	SD 5.95%
Harderian 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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	
Heart: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma	•••••							
•		0/50 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)		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	4/400 (1%)	Mean 1%	SD 1.51%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
Heart: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Intestine 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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyoma					•••••			
•		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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Intestine Large: Cecum: Polyp Adenomatous								
		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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectum	n:				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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	0/50 (0%) 0/400 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/400 (0.25%)	1/50 (2%) Mean 0.25%	SD 0.71%
Overali incidence	rotai	0/400 (0%)	Mean 0%	SD 0%	rotai	1/400 (0.25%)	Mean 0.25%	SD 0.71%

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Length of Study: CHRONIC

Vehicle: AIR

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			Male				Female	
#Intestine Small: Duodenum: 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%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
	ı olai	1/400 (0.23%)	ivicaii 0.25/6	30 0.71%	ı Olai	1/400 (0.25%)	iviean 0.25%	0.71%
#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%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/50 (0%)	1/50 (2%)	00 0740/
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
#Intestine Small: Duodenum: Polyp Adenomatous								
. ,,		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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			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%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.007	<b>.</b>	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
fintestine Small: lleum: 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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	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	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
fIntestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

SIOII. 140V2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
fIntestine Small: Jejunum: Carcinoma								
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Institutes	T-4-1	1/50 (2%)	0/50 (0%)	CD 0.040/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
verall Incidence	Total	11/400 (2.75%)	Mean 2.75%	SD 3.01%	Total	0/400 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: 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%)
and the statement	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
wanali laakkanaa	T-4-1	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous								
<i>,</i> .		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Intestine Small: Site Unsp Adenoma	ecified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
N	T-1-1	0/50 (0%)	0/50 (0%)	OD 0.740/	T-1-1	0/50 (0%)	0/50 (0%)	00 0740/
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Intestine Small: Site Unsp Carcinoma	ecified:							
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	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%)	
verall Incidence	Total	11/400 (2.75%)	Mean 2.75%	SD 3.01%	Total	0/400 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:							
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	12/400 (3%)	Mean 3%	SD 2.83%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
gg		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

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Report Date:11/19/2008

Species: MICE Strain: B6C3F1

Vehicle: AIR

			Male				Female	
fIntestine Small: Site Unspe Leiomyosarcoma	ecified:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 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%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Intestine Small: Site Unspo Polyp Adenomatous								
		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%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
slets, Pancreatic: Adenoma					•••••			
		0/48 (0%) 1/49 (2%) 1/49 (2%)	0/50 (0%) 1/49 (2%) 2/49 (4%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 0/48 (0%) 0/50 (0%)	1/49 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	7/394 (1.78%)	Mean 1.78%	SD 1.69%	Total	1/396 (0.25%)	Mean 0.26%	SD 0.72%
slets, Pancreatic: Carcinoma					•••••			
		0/48 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 1/48 (2%) 1/50 (2%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/394 (0.25%)	Mean 0.25%	SD 0.71%	Total	2/396 (0.51%)	Mean 0.51%	SD 0.95%

<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				0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) tal 0/398 (0%) Mean 0% SD 0%  0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) tal 0/398 (0%) Mean 0% SD 0%		Female				
Islets, Pancreatic: Carcinoma or Adenoma												
		0/48 (0%)	0/50 (0%)	2/50 (4%)								
		1/49 (2%)	1/49 (2%)	1/50 (2%)				0/49 (0%)				
		1/49 (2%)	2/49 (4%)			` ,	` '					
Overall Incidence	Total	8/394 (2.03%)	Mean 2.03%	SD 1.53%	Total	3/396 (0.76%)	Mean 0.77%	SD 1.06%				
Kidney: Renal Tubule: Adenoma						•••••	•••••					
		0/49 (0%)	0/50 (0%)	0/50 (0%)			()					
		0/50 (0%)	0/50 (0%)	0/50 (0%)				0/50 (0%)				
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/397 (0%)	Mean 0%	SD 0%	Total							
Kidney: Renal Tubule: Carcinoma												
		0/49 (0%)	0/50 (0%)	0/50 (0%)								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		` ,		0/50 (0%)				
		0/49 (0%)	0/49 (0%)			` ,	` '					
Overall Incidence	Total	1/397 (0.25%)	Mean 0.25%	SD 0.71%	Total	` ,						
Kidney: Renal Tubule: Carcinoma or Adenoma												
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)				
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)					

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Hemangiosarcoma								
		0/49 (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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/49 (0%)	0/49 (0%)	00.00/	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/397 (0%)	Mean 0%	SD 0%	Total	0/398 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Liver: 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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
<b>5</b>		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%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	

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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 11/19/2008

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male Female \*Liver: Hemangiosarcoma 1/50 (2%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)(6%)(0%)(2%) 3/50 2/50 (4%)(8%)0/49 1/50 1/50 (2%)(2%)1/49 1/49 (2%)0/50 (0%)2/50 (4%)SD 2.56% Overall Incidence Total 14/398 (3.52%)Mean 3.51% Total 5/399 (1.25%) Mean 1.25% SD 1.49% \*Liver: Hepatoblastoma 1/50 (2%)(2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (0%) (0%)(0%)(0%)0/49 (0%)1/50 (2%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 0/49 **Overall Incidence** Total 3/398 (0.75%) Mean 0.75% SD 1.04% Total 1/399 (0.25%) Mean 0.25% SD 0.71% \*Liver: Hepatocellular Adenoma 30/50 (60%)34/50 (68%)28/50 (56%)19/50 (38%)18/50 (36%)14/50 (28%)22/50 (44%) 17/50 (34%)24/50 (48%)17/49 (35%) 13/50 (26%)10/50 (20%)21/49 (43%)(67%)15/50 (30%)(28%)33/49 14/50 **Overall Incidence** Total 209/398 (52.51%) Mean 52.53% SD 12.29% Total 120/399 (30.08%)Mean 30.09% SD 5.93% \*Liver: **Hepatocellular Carcinoma** 15/50 (30%)13/50 (26%)20/50 (40%)5/50 (10%)10/50 (20%)4/50 (8%)13/50 (26%)12/50 (24%)10/50 (20%)5/49 (10%)6/50 (12%)3/50 (6%)10/49 (20%)11/49 (22%)4/50 (8%)7/50 (14%)**Overall Incidence** 104/398 (26.13%) Mean 26.11% SD 6.5% Total 44/399 (11.03%) Mean 11.03% SD 4.4% Total 

<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:11/19/2008

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

			Male				Female	
*Liver:								
Hepatocellular Carcino	oma or Hepatob		4.4/50 (200/)	20/50 (400/)		E/EO (100/)	10/50 (200/)	4/50 (80/)
		16/50 (32%) 13/50 (26%)	14/50 (28%) 12/50 (24%)	20/50 (40%) 10/50 (20%)		5/50 (10%) 5/49 (10%)	10/50 (20%) 6/50 (12%)	4/50 (8%) 3/50 (6%)
		10/49 (20%)	11/49 (22%)	10/30 (20%)		4/50 (8%)	7/50 (12%)	3/30 (6%)
Overall Incidence	Total	106/398 (26.63%)	Mean 26.61%	SD 6.73%	Total	44/399 (11.03%)	Mean 11.03%	SD 4.4%
overall illicidence	ı Olai	100/398 (20.0378)	IVICATI 20.0176	30 0.73%	TOLAI	44/399 (11.0376)	Wealt 11.03%	30 4.470
Liver:								
Hepatocellular Carcino	oma or Hepatoce							
		38/50 (76%)	40/50 (80%)	40/50 (80%)		24/50 (48%)	25/50 (50%)	16/50 (32%)
		30/50 (60%)	27/50 (54%)	28/50 (56%)		19/49 (39%)	17/50 (34%)	13/50 (26%)
		26/49 (53%)	37/49 (76%)			17/50 (34%)	20/50 (40%)	
Overall Incidence	Total	266/398 (66.83%)	Mean 66.82%	SD 12.1%	Total	151/399 (37.84%)	Mean 37.85%	SD 8.11%
Liver: Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	38/50 (76%)	41/50 (82%)	40/50 (80%)		24/50 (48%)	25/50 (50%)	16/50 (32%)
		30/50 (60%)	27/50 (54%)	28/50 (56%)		19/49 (39%)	17/50 (34%)	13/50 (26%)
		26/49 (53%)	37/49 (76%)	25 (2.42)		17/50 (34%)	20/50 (40%)	00.0444
Overall Incidence	Total	267/398 (67.09%)	Mean 67.07%	SD 12.43%	Total	151/399 (37.84%)	Mean 37.85%	SD 8.11%
Liver:								
Hepatocholangiocarci	noma	1/50 (20/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		1/50 (2%) 1/50 (2%)	0/50 (0%) 5/50 (10%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/30 (0%)		0/50 (0%)	0/50 (2%)	0/30 (0%)
Overall Incidence	Total	7/398 (1.76%)	Mean 1.75%	SD 3.45%	Total	2/399 (0.5%)	Mean 0.51%	SD 0.94%
Jveran incluence	TOIAI	1/390 (1.10%)	Weatt 1.75%	3D 3.45%	i Ulai	2/388 (0.3%)	Weatt 0.51%	SD 0.94%

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

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

Strain: B6C3F1

I. NUV2006

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver: Ito Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Liver:								
Ito Cell Tumor Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/49 (0%)	0/49 (0%)	1/30 (2/0)		0/49 (0%)	0/50 (0%)	0/30 (0/0)
overall Incidence	Total	1/398 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/399 (0%)	Mean 0%	SD 0%
Liver: 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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Lung: 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%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/399 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (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: 159 Report Date:11/19/2008

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

			Male				Female	
Lung:								
Alveolar/Bronchiolar A	denoma	0/50 (400/)	40/50 (000/)	4/50 (00/)		4/50 (00/)	4/50 (00/)	0/50 (40/)
		6/50 (12%) 12/49 (24%)	13/50 (26%) 9/50 (18%)	4/50 (8%) 8/50 (16%)		1/50 (2%) 4/50 (8%)	1/50 (2%) 4/50 (8%)	2/50 (4%) 1/50 (2%)
		10/50 (20%)	10/50 (20%)	8/50 (16%)		3/50 (6%)	6/50 (12%)	1/50 (2%)
verall Incidence	Total	72/399 (18.05%)	Mean 18.06%	SD 6.02%	Total	22/400 (5.5%)	Mean 5.5%	SD 3.66%
verall incluence		,				` ,	iviean 5.5%	3D 3.00%
.ung:								
Alveolar/Bronchiolar C	arcinoma							
		8/50 (16%)	9/50 (18%)	12/50 (24%)		0/50 (0%)	3/50 (6%)	3/50 (6%)
		5/49 (10%)	5/50 (10%)	5/50 (10%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
		7/50 (14%)	11/50 (22%)			2/50 (4%)	0/50 (0%)	
verall Incidence	Total	62/399 (15.54%)	Mean 15.53%	SD 5.5%	Total	11/400 (2.75%)	Mean 2.75%	SD 2.6%
Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar						
	arcinoma or Alv		19/50 (38%)	15/50 (30%)		1/50 (2%)	4/50 (8%)	5/50 (10%)
Alveolar/Bronchiolar C	arcinoma or Alv	13/50 (26%)	19/50 (38%) 14/50 (28%)	15/50 (30%) 13/50 (26%)		1/50 (2%) 6/50 (12%)	4/50 (8%) 4/50 (8%)	5/50 (10%) 2/50 (4%)
Alveolar/Bronchiolar C	arcinoma or Alv	13/50 (26%)	19/50 (38%) 14/50 (28%) 20/50 (40%)				` ,	
Alveolar/Bronchiolar C Adenoma	arcinoma or Alv	13/50 (26%) 16/49 (33%)	14/50 (28%)		Total	6/50 (12%)	4/50 (8%)	
Adenoma  Overall Incidence	Total	13/50 (26%) 16/49 (33%) 17/50 (34%) 127/399 (31.83%)	14/50 (28%) 20/50 (40%) Mean 31.83%	13/50 (26%) SD 5.29%		6/50 (12%) 5/50 (10%) 33/400 (8.25%)	4/50 (8%) 6/50 (12%) Mean 8.25%	2/50 (4%) SD 3.62%
Alveolar/Bronchiolar C Adenoma Overall Incidence Lung:	Total	13/50 (26%) 16/49 (33%) 17/50 (34%) 127/399 (31.83%)	14/50 (28%) 20/50 (40%) Mean 31.83%	13/50 (26%) SD 5.29%		6/50 (12%) 5/50 (10%) 33/400 (8.25%)	4/50 (8%) 6/50 (12%) Mean 8.25%	2/50 (4%) SD 3.62%
Alveolar/Bronchiolar C Adenoma Overall Incidence	Total	13/50 (26%) 16/49 (33%) 17/50 (34%) 127/399 (31.83%)	14/50 (28%) 20/50 (40%) Mean 31.83%	13/50 (26%) SD 5.29%		6/50 (12%) 5/50 (10%) 33/400 (8.25%)	4/50 (8%) 6/50 (12%) Mean 8.25%	2/50 (4%) SD 3.62%
Alveolar/Bronchiolar C Adenoma Dverall Incidence Lung:	Total	13/50 (26%) 16/49 (33%) 17/50 (34%) 127/399 (31.83%)	14/50 (28%) 20/50 (40%) Mean 31.83% 0/50 (0%)	13/50 (26%) SD 5.29% 0/50 (0%)		6/50 (12%) 5/50 (10%) 33/400 (8.25%)	4/50 (8%) 6/50 (12%) Mean 8.25%	2/50 (4%) SD 3.62%
Alveolar/Bronchiolar C Adenoma Overall Incidence Lung:	Total	13/50 (26%) 16/49 (33%) 17/50 (34%) 127/399 (31.83%)	14/50 (28%) 20/50 (40%) Mean 31.83%	13/50 (26%) SD 5.29%		6/50 (12%) 5/50 (10%) 33/400 (8.25%)	4/50 (8%) 6/50 (12%) Mean 8.25%	2/50 (4%) SD 3.62%

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

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

131011. 11072000

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	
Lung: Fibrous Histiocytoma								
·		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/399 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma					•••••			
·		0/50 (0%) 0/49 (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%) 1/50 (2%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/399 (0.25%)	Mean 0.25%	SD 0.71%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
Lung: Sarcoma								
		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/399 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Lymph Node: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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:11/19/2008

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: INHALATION Vehicle: AIR

			Male				Female	
#Lymph Node: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Lymph Node: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma								
. <b>.</b>		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Lymph Node, Mandibular: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: 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%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
· ·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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:11/19/2008

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

			Male		Female	
#Lymph Node, Mesenteric: Hemangioma						
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0° 0/50 (0%) 0/50 (0° 0/50 (0%)			(0%) (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0% SD 0%	Total 0/400 (0%)	Mean 0% SD 09	%
#Lymph Node, Mesenteric: Hemangiosarcoma						
Č		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0° 0/50 (0%) 0/50 (0° 0/50 (0%)			(2%) (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25% SD 0.71	,	Mean 0.25% SD 0.	
#Mammary Gland: Adenoacanthoma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0° 0/50 (0%) 0/50 (0° 0/50 (0%)			(0%) (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0% SD 0%	Total 0/400 (0%)	Mean 0% SD 09	
#Mammary Gland: 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%) (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0% SD 0%	Total 0/400 (0%)	Mean 0% SD 09	%

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

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

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	4/50 (8%)
		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%)	1/50 (2%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	10/400 (2.5%)	Mean 2.5%	SD 2.56%
Mammary Gland: Carcinoma or Adenoma				•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	4/50 (8%)
		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%)	1/50 (2%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	10/400 (2.5%)	Mean 2.5%	SD 2.56%
Mammary Gland: Fibroadenoma				•••••				
		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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
#Mammary Gland: Fibroma, Fibroadenoma or	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%)
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/50 (0%)	, ,

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

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

#Mammary Gland:     Fibroma, Fibroadenoma, Carcinom  Overall Incidence Tota  #Mesentery:     Fibrosarcoma  Overall Incidence Tota	0/50 (0%) 0/50 (0%) 0/50 (0%)  I 0/400 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)	Total	2/50 (4%) 0/50 (0%) 0/50 (0%) 11/400 (2.75%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 1/50 (2%) Mean 2.75%	5/50 (10%) 1/50 (2%) SD 3.2%
Overall Incidence Tota  #Mesentery: Fibrosarcoma  Overall Incidence Tota	0/50 (0%) 0/50 (0%) 0/50 (0%)  I 0/400 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/50 (0%) 0/50 (0%) 11/400 (2.75%) 0/50 (0%)	1/50 (2%) 1/50 (2%) Mean 2.75%	1/50 (2%) SD 3.2% 0/50 (0%)
#Mesentery: Fibrosarcoma  Overall Incidence  Tota	0/50 (0%) 0/50 (0%) I 0/400 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/50 (0%) 0/50 (0%) 11/400 (2.75%) 0/50 (0%)	1/50 (2%) 1/50 (2%) Mean 2.75%	1/50 (2%) SD 3.2% 0/50 (0%)
#Mesentery: Fibrosarcoma  Overall Incidence  Tota	0/50 (0%) 0/400 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)		0/50 (0%) 11/400 (2.75%) 	1/50 (2%) Mean 2.75%	SD 3.2% 0/50 (0%)
Mesentery: Fibrosarcoma  verall Incidence  Tota	0/400 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		11/400 (2.75%) 0/50 (0%)	Mean 2.75%	0/50 (0%)
Mesentery: Fibrosarcoma  verall Incidence  Tota	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Mesentery: Fibrosarcoma  verall Incidence  Tota	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	0/50 (0%) 0/50 (0%)	0/50 (0%)					
	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (00/.)
	` ,	0/50 (0%)				3/30 (0/0)	0/30 (0/8)
	0/400 (00/)	-, ( - , - ,			0/50 (0%)	0/50 (0%)	
	I 0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
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%)
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence Tota	I 0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma				•••••			
<del> </del>	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
	0/50 (0%)	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 Tota	` ,	Mean 0.25%	SD 0.71%	Total	4/400 (1%)	Mean 1%	SD 1.51%

<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	
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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Nose: Hemangioma								
·		0/50 (0%) 0/50 (0%) 0/49 (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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	1/399 (0.25%)	Mean 0.25%	SD 0.71%
Nose: Mast Cell Tumor Maligi								
		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary	nx, 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%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%

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

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Vehicle: AIR

Report Date:11/19/2008

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

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcing		nx, Tooth, Gingiva):						
·		0/50 (0%) 1/50 (2%) 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%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	0/400 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	, Tongue, Phary	nx, Tooth, Gingiva):						
·		0/50 (0%) 1/50 (2%) 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%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
#Oral Mucosa: Squamous Cell Carcino	oma							
		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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma					•••••			
						0/50 (0%) 0/48 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)
Overall Incidence					Total	0/391 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Vehicle: AIR

5

Report Date:11/19/2008

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Male				Fem	ale		
*Ovary:							
Cystadenoma							
		3/50	(6%)	5/48	(10%)	3/49	(6%)
		3/48	(6%)	0/49	(0%)	2/48	(4%)
		6/49	(12%)	2/50	(4%)		
Overall Incidence	Total	24/391	(6.14%)	Mea	n 6.15%	SD	3.81%
*Ovary:							
Fibrous Histiocytoma							
•		0/50	(0%)	0/48	(0%)	0/49	(0%)
		0/48	(0%)	0/49	(0%)	0/48	(0%)
		0/49	(0%)	0/50	(0%)		
Overall Incidence	Total	0/391	(0%)	Mea	n 0%	SD	0%
*Ovary: Granulosa Cell Tumor Benign							
Grandiosa Cen Fundi Berngh		0/50	(0%)	0/48	(0%)	0/49	(0%)
		0/48	(0%)	0/49	(0%)	0/48	(0%)
		0/49	(0%)	0/50	(0%)	0/ 10	(070)
Overall Incidence	Total	0/391	,		n 0%	SD	0%
			,				
**	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •
*Ovary:							
Granulosa Cell Tumor Malignant		0/50	(00()	0/40	(00()	0/40	(00/)
		0/50	(0%)	0/48	(0%)	0/49	(0%)
		0/48	(0%)	0/49	(0%)	0/48	(0%)
Occupation of the second	<b>+</b>	0/49	(0%)	0/50	(0%)	05	00/
Overall Incidence	Total	0/391	(0%)	Mea	n 0%	SD	υ%

<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	
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)	0/48 (0%)
overall Incidence	Total	0/391 (0%)	Mean 0%	SD 0%
		` ,		
Ovary: Hemangioma				
		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/391 (0%)	0/50 (0%) Mean 0%	SD 0%
		` ,	Weatt 076	3D 0/6
Ovary: Hemangiosarcoma				
·		0/50 (0%)	0/48 (0%)	1/49 (2%)
		0/48 (0%)	0/49 (0%)	0/48 (0%)
Normal Hand Steeres	Total	0/49 (0%)	0/50 (0%)	OD 0.700/
verall Incidence	Total	1/391 (0.26%)	Mean 0.26%	SD 0.72%
	• • • • • • • • • • • • • • • • • • • •			
Ovary: Leiomyosarcoma		2/22 (221)	(201)	2442 (224)
		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%) 1/49 (2%)	0/49 (0%) 0/50 (0%)	0/48 (0%)
		1, 10 (2,70)	0,00 (0,70)	

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: INHALATION
Vehicle: AIR

Length of Study: CHRONIC

Page: 170

	Male			Female	
*Ovary:					
Luteoma			4/50 (00/)	0/40 (00/)	0/40 (00/)
			1/50 (2%) 1/48 (2%)	0/48 (0%) 0/49 (0%)	0/49 (0%) 0/48 (0%)
			0/49 (0%)	1/50 (2%)	0/40 (076)
Overall Incidence		Total	3/391 (0.77%)	Mean 0.76%	SD 1.05%
			` ,		
				• • • • • • • • • • • • • • • • • • • •	
*Ovary: Teratoma Benign					
reratorna berngir			0/50 (0%)	1/48 (2%)	0/49 (0%)
			0/48 (0%)	0/49 (0%)	0/48 (0%)
			0/49 (0%)	1/50 (2%)	()
Overall Incidence		Total	2/391 (0.51%)	Mean 0.51%	SD 0.95%
*Ovary:					
Teratoma Malignant					
•			0/50 (0%)	0/48 (0%)	0/49 (0%)
			0/48 (0%)	0/49 (0%)	0/48 (0%)
			0/49 (0%)	1/50 (2%)	
Overall Incidence		Total	1/391 (0.26%)	Mean 0.25%	SD 0.71%
*Ovary:					
Tubulostromal Adenoma			0.000	2/12 (22/)	2/12 (22/)
			0/50 (0%)	0/48 (0%)	0/49 (0%)
			0/48 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)	0/48 (0%)
Overall Incidence		Total	()	` ,	SD 00/
Overall incidence		Total	0/391 (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: 171

			Male				Female	
Pancreas: Adenoma								
		0/48 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/48 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/394 (0%)	Mean 0%	SD 0%	Total	0/396 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma	•••••							
		1/48 (2%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/48 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/394 (0.25%)	Mean 0.26%	SD 0.74%	Total	0/396 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma					•••••			
		1/48 (2%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/48 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/394 (0.25%)	Mean 0.26%	SD 0.74%	Total	0/396 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		1/46 (2%) 0/48 (0%) 0/47 (0%)	1/48 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)		5/46 (11%) 8/47 (17%) 4/50 (8%)	8/50 (16%) 7/50 (14%) 6/49 (12%)	10/50 (20%) 4/50 (8%)
Overall Incidence	Total	2/387 (0.52%)	Mean 0.53%	SD 0.99%	Total	52/392 (13.27%)	Mean 13.27%	SD 4.3%

<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	
Pituitary Gland: Pars Dist Carcinoma	alis or Unspecif	ied Site:						
		0/46 (0%) 0/48 (0%) 0/47 (0%)	0/48 (0%) 0/5 0/50 (0%) 0/4 0/50 (0%)	` '		1/46 (2%) 0/47 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/387 (0%)	` '	SD 0%	Total	2/392 (0.51%)	Mean 0.52%	SD 0.97%
Pituitary Gland: Pars Dist Carcinoma or Adenom	alis or Unspecif	ied Site:			•••••			
		1/46 (2%) 0/48 (0%) 0/47 (0%)	1/48 (2%) 0/5 0/50 (0%) 0/4 0/50 (0%)			6/46 (13%) 8/47 (17%) 5/50 (10%)	8/50 (16%) 7/50 (14%) 6/49 (12%)	10/50 (20%) 4/50 (8%)
Overall Incidence	Total	2/387 (0.52%)	Mean 0.53%	SD 0.99%	Total	54/392 (13.78%)	Mean 13.79%	SD 3.87%
Pituitary Gland: Pars Inte Adenoma	rmedia:							
		0/46 (0%) 0/48 (0%) 0/47 (0%)	0/48 (0%) 0/5 0/50 (0%) 1/4 0/50 (0%)	` '		0/46 (0%) 1/47 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total	1/387 (0.26%)	` ,	SD 0.74%	Total	6/392 (1.53%)	Mean 1.52%	SD 1.78%
Pituitary Gland: Pars Inte Carcinoma or Adenom								
		0/46 (0%) 0/48 (0%) 0/47 (0%)	0/48 (0%) 0/5 0/50 (0%) 1/4 0/50 (0%)			0/46 (0%) 1/47 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total	1/387 (0.26%)	` '	SD 0.74%	Total	6/392 (1.53%)	Mean 1.52%	SD 1.78%

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

Strain: B6C3F1

1. 14072000

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female
Prostate: Adenoma					
		0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	
Prostate: Carcinoma or Adenoma					
		0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	
Prostate: Hemangioma					
_		0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	
Salivary Glands: Carcinoma					
		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total 1/399 (0.25%) Mean 0.25% SD 0.71%

<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	
*Salivary Glands: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	1/399 (0.25%)	Mean 0.25%	SD 0.71%
Salivary Glands: Mast Cell Tumor Malignant					•••••			
-		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/398 (0%)	Mean 0%	SD 0%	Total	0/399 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma					•••••			
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%				
#Skeletal Muscle: Fibrosarcoma					••••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 175

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Skeletal Muscle: Myxosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma							•••••	
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
≴Skeletal Muscle: Rhabdomyosarcoma or Rl	habdomvom	а	•••••				•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/50 (0%)	, ,

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

31011: 11012000

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: 176

			Male				Female	
#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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Adenoma or	Basosquamous	s 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba Trichoepithelioma	asosquamous 7							
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		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				Total			
	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence #Skin: Basal Cell Carcinoma	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Inci

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 177

			Male				Female	
Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	us Tumor (malignant or						
NOO,		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma, I Tumor (benign, maligna								
ramer (semgii, maigii	ant of 1100), of	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin: Basal or Sq. Cell Carcir or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma,	Papilloma, Sq						
,	, , , , , , , , , , , , ,	0/50 (0%) 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%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
Skin: Basosquamous Tumor	Benign							
	· ·· <b>·9</b> ··	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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:11/19/2008

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

			Male				Female	
Skin: Fibroma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin:				•••••				
Fibroma, Fibrosarcom Fibrous Histiocytoma	a, Sarcoma, My	koma, Myxosarcoma, o	r					
1 ibi oud i notico y toma		0/50 (0%)	2/50 (4%)	1/50 (2%)		8/50 (16%)	0/50 (0%)	4/50 (8%)
		3/50 (6%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	6/50 (12%)
	T-1-1	0/50 (0%)	2/50 (4%)	00.0000	T-1-1	2/50 (4%)	1/50 (2%)	OD 5 500/
verall Incidence	Total	9/400 (2.25%)	Mean 2.25%	SD 2.25%	Total	26/400 (6.5%)	Mean 6.5%	SD 5.53%
Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin:	a Muyacaraam	o or Eibroug						
Fibrosarcoma, Sarcom Histiocytoma	ia, wiyxosarcom	a, or Fibrous						
<b>,</b>		0/50 (0%)	2/50 (4%)	1/50 (2%)		8/50 (16%)	0/50 (0%)	4/50 (8%)
		3/50 (6%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	6/50 (12%)
		0/50 (0%)	2/50 (4%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	9/400 (2.25%)	Mean 2.25%	SD 2.25%	Total	26/400 (6.5%)	Mean 6.5%	SD 5.53%

<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: 179

			Male				Female	
#Skin: Fibrous Histiocytoma								
		0/50 (0%) 2/50 (4%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/400 (1.25%)	Mean 1.25%	SD 1.49%	Total	3/400 (0.75%)	Mean 0.75%	SD 1.49%
#Skin: Hemangioma								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		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	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 2/50 (4%)	1/50 (2%) 1/50 (2%)		1/50 (2%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	4/400 (1%)	Mean 1%	SD 1.51%	Total	4/400 (1%)	Mean 1%	SD 1.07%
#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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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

Route: INHALATION Vehicle: AIR

			Male				Female	
≮Skin: Myxosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
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%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Skin:			•••••					•••••
Neurofibrosarcoma or S	Schwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma, Ne malignant or NOS)								
9		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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				
#Skin: 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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%	
#Skin: Sarcoma	•••••				•••••				
		0/50 (0%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)		7/50 (14%) 1/50 (2%) 2/50 (4%)	0/50 (0%) 2/50 (4%) 1/50 (2%)	4/50 (8%) 6/50 (12%)	
Overall Incidence	Total	4/400 (1%)	Mean 1%	SD 1.07%	Total	23/400 (5.75%)	Mean 5.75%	SD 5.06%	
∜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%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Carcinoma	•••••				•••••				
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female			
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma  0/50 (0%)										
Overall Incidence	Total	0/50 (0%) 0/400 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/400 (0.25%)	0/50 (0%)	0.71%		
#Skin: Squamous Cell Papillon										
Squamous Cen Fapinoi	illa	0/50 (0%) 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 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)		
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25% SD	0.71%		
Skin: Squamous Cell Papillor	ma 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%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)		
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	` '	0.71%		
#Skin: Squamous Cell Papillo Carcinoma or Keratoac		Squamous Cell								
		0/50 (0%) 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%)	1/50 (2%) 0/50 0/50 (0%) 0/50 0/50 (0%)	(0%) (0%)		
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	2/400 (0.5%)	Mean 0.5% SD	0.93%		

<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	
Skin:								
Squamous Cell Papillom	a, Papilloma,		0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	05 0 - 404
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Skin: Trichoepithelioma			•••••	•••••		•••••	•••••	•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: 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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(/		0/50 (0%)	0/50 (0%)	(/
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
	10101	5, 100 (0,0)	1110411 070	62 676	10101	5, 100 (070)	1110411 070	02 070

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

08 Toxicology Da

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/400 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/400 (0.25%)	1/50 (2%) Mean 0.25%	SD 0.71%
Spinal Cord:								
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%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma								
,		0/48 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/395 (0%)	Mean 0%	SD 0%	Total	0/398 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/48 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/395 (0%)	Mean 0%	SD 0%	Total	0/398 (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			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%  SD 0%  0/50 (0%)		
Spleen: Hemangiosarcoma								
_		2/48 (4%)	0/50 (0%)	3/50 (6%)				
		1/49 (2%)	1/50 (2%)	1/50 (2%)				0/50 (0%)
		1/49 (2%)	1/49 (2%)			` ,	` '	
Overall Incidence	Total	10/395 (2.53%)	Mean 2.54%	SD 1.79%	Total	6/398 (1.51%)	Mean 1.5%	SD 1.41%
Stomach, Forestomach: 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%)			` ,	` '	
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	` ,		SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
•		0/50 (0%)	0/50 (0%)	2/50 (4%)		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%)	
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 1.41%	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
Stomach, Forestomach: Squamous Cell Carcinoma	or Panillom	na Squamous		•••••			•••••	
oquamous sen surementa v	or rapilion	0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	()		1/50 (2%)	1/50 (2%)	(=/-/

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

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 1/50 (2%) 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%)	0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%	Total	4/400 (1%)	Mean 1%	SD 1.07%
#Stomach, Glandular: 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%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		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	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%

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

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Total 0/49 (0%) 0/49 (0%) 0/47 (0%) 0/49 (0%) 0/48 (0%) 0/49 (0%) 0/48 (0%) Total 0/390 (0%) Mean 0% SD 0%  0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%)			
*Testes: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%				
*Testes: Hemangiosarcoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign						•••••		
		0/38 (0%)	0/45 (0%)	0/38 (0%)				
		0/44 (0%)	0/42 (0%)	0/41 (0%)		` ,	` ,	0/50 (0%)
		0/47 (0%)	0/47 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/342 (0%)	Mean 0%	SD 0%		` '		
*Thymus: Thymoma Malignant						•••••		
		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)		0/47 (0%)
		0/44 (0%)	1/42 (2%)	0/41 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/47 (0%)	0/47 (0%)			0/49 (0%)	0/48 (0%)	

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

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

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma: Benign, Maligr	nant, NOS							
	·	0/38 (0%) 0/44 (0%) 0/47 (0%)	0/45 (0%) 1/42 (2%) 0/47 (0%)	0/38 (0%) 0/41 (0%)		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%) 0/48 (0%)	0/47 (0%) 0/50 (0%)
Overall Incidence	Total	1/342 (0.29%)	Mean 0.3%	SD 0.84%	Total	0/390 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma								
		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (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%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	Total	0/398 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma					•••••			
		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	Total	1/398 (0.25%)	Mean 0.25%	SD 0.71%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma					•••••			
		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	Total	1/398 (0.25%)	Mean 0.25%	SD 0.71%

<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				0/49 (0%) 1/50 (2%) 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) tal 3/398 (0.75%) Mean 0.75% SD 1.04%   0/49 (0%) 2/50 (4%) 0/50 (0%) 0/49 (0%) 1/50 (2%) 3/50 (6%) 2/50 (4%) 1/50 (2%) tal 9/398 (2.26%) Mean 2.25% SD 2.25%		
Thyroid Gland: Follicular Cell: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	3/50 (6%)		0/49 (0%)	0/50 (0%)	3/50 (6%)
		0/49 (0%)	0/49 (0%)			2/50 (4%)	0/50 (0%)	
verall Incidence	Total	3/396 (0.76%)	Mean 0.75%	SD 2.12%	Total	6/398 (1.51%)	Mean 1.5%	SD 2.33%
Гhyroid Gland: Follicular Cell: Carcinoma	•••••				•••••			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)				0/50 (0%)
		0/49 (0%)	0/49 (0%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/396 (0%)	Mean 0%	SD 0%	Total	,		
Гhyroid Gland: Follicular Cell: Сагсіпота ог Adenoma					•••••			
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	3/50 (6%)		0/49 (0%)	1/50 (2%)	3/50 (6%)
		0/49 (0%)	0/49 (0%)			2/50 (4%)	1/50 (2%)	
verall Incidence	Total	3/396 (0.76%)	Mean 0.75%	SD 2.12%	Total	9/398 (2.26%)	Mean 2.25%	SD 2.25%
Tissue NOS: 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%)
		0/50 (0%)	0/50 (0%)	,		1/50 (2%)	0/50 (0%)	` '

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 190 Report Date:11/19/2008

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

Length of Study: CHRONIC

			Male				Female	
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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Tissue NOS: 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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
Fongue: Squamous Cell Carcinom			•••••					•••••
•		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%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%	Total	0/400 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinom								•••••
•	•	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%)
		; ; ;	0/50 (00/)	` '		1/50 (2%)	0/50 (0%)	, ,
		0/50 (0%)	0/50 (0%)			1/30 (2/0)	0/30 (0 /8)	

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

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

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#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%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	1/400 (0.25%)	Mean 0.25%	SD 0.71%
fTooth: Odontoma					•••••			
		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%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/400 (0.75%)	Mean 0.75%	SD 1.49%	Total	0/400 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma					• • • • • • • • • • • • • • • • • • • •			
		0/47 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/393 (0%)	Mean 0%	SD 0%	Total	0/395 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma					•••••			
-		0/47 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/393 (0%)	Mean 0%	SD 0%	Total	1/395 (0.25%)	Mean 0.25%	SD 0.71%

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Report Date:11/19/2008

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		Male					Female	
*Urinary Bladder: Sarcoma								
		0/47 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/393 (0%)	Mean 0%	SD 0%	Total	0/395 (0%)	Mean 0%	SD 0%
#Uterus:								•••••
Adenoma						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)
Overall Incidence					Total	2/400 (0.5%)	Mean 0.5%	SD 0.93%
#Uterus:								
Carcinoma						0/50 (0%) 0/50 (0%) 0/50 (0%)	3/50 (6%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	5/400 (1.25%)	Mean 1.25%	SD 2.12%
#Uterus: Hemangioma								
						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/400 (0%)	Mean 0%	SD 0%

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Report Date:11/19/2008

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

Vehicle: AIR

Length of Study: CHRONIC

	Male				Female	
Uterus:						
Hemangiosarcoma			0/=0 /0		0/=0 (00/)	0.400 (00.4)
					0/50 (0%)	0/50 (0%)
					1/50 (2%) 1/50 (2%)	1/50 (2%)
verall Incidence		Total	3/400 (0.75	,	Mean 0.75%	SD 1.04%
rerail incidence		l'Ulai	3/400 (0.75	070)	Wear 0.75%	3D 1.04%
	•••••	• • • • • • • • • • • • • • • • • • • •			•••••	• • • • • • • • • • • • • • • • • • • •
Jterus:						
Leiomyoma			0/50 /0		0/50 (00/)	0/50 (00/)
					0/50 (0%)	0/50 (0%)
					0/50 (0%) 0/50 (0%)	1/50 (2%)
verall Incidence		Total	1/400 (0.25	,	Mean 0.25%	SD 0.71%
			,	,		
Manua		• • • • • • • • • • • • • • • • • • • •			•••••	• • • • • • • • • • • • • • • • • • • •
Uterus: Leiomyosarcoma						
Leidinyosaicoma			0/50 (0	1%)	0/50 (0%)	0/50 (0%)
					0/50 (0%)	0/50 (0%)
					1/50 (2%)	(0,0)
verall Incidence		Total	2/400 (0.5%	6) <sup>´</sup>	Mean 0.5%	SD 0.93%
			`	<i>.</i>		
Jterus:						
Polyp Stromal						
. oryp or or or			0/50 (0	1%)	3/50 (6%)	1/50 (2%)
					3/50 (6%)	3/50 (6%)
						` ,
			2/50 (4	·%)	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** 

Vehicle: AIR

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male		Female
#Uterus: Sarcoma Stromal			
			/50 (0%) 0/50 (0%) /50 (2%) 0/50 (0%)
			/50 (2%) 0/50 (0%) /50 (0%)
Overall Incidence	Tota	1/400 (0.25%)	Mean 0.25% SD 0.71%
#Uterus:			
Sarcoma Stromal or Polyp Stromal		0/50 (0%) 3,	/50 (6%) 1/50 (2%)
		` ,	/50 (8%) 1/50 (2%) /50 (8%) 3/50 (6%)
			/50 (2%)
Overall Incidence	Tota	,	Mean 3.75% SD 2.71%
#Uterus:			
Schwannoma Malignant		0/50 (0%) 0/	/50 (0%) 0/50 (0%)
			/50 (0%) 0/50 (0%) /50 (0%) 0/50 (0%)
			/50 (0%)
Overall Incidence	Tota	l 0/400 (0%)	Mean 0% SD 0%
#Vagina: Squamous Cell Carcinoma			
oquamous con sursmana		0/50 (0%) 0.	/50 (0%) 0/50 (0%)
			/50 (0%) 0/50 (0%)
Overall Incidence	Total	` '	/50 (0%)
Overall incidence	Tota	l 0/400 (0%)	Mean 0% SD 0%

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

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

ai Groups

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Report Date:11/19/2008

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

			Male				Female	
#Vagina: 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%)
Overall Incidence					Total	0/400 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (0%)	Mean 0%	SD 0%
tZymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/400 (0%)	Mean 0%	SD 0%	Total	0/400 (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:11/19/2008

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

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
				M	ale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813804 059902704 050517406 059900706 059201306 052000804	09/14/99 07/29/02 N/A 05/12/03 02/03/00 03/25/03	730 729 N/A 729 729 729	50 (1) 50 (1) 0 (0) 50 (1) 50 (1) 50 (1)	44(717) 46(715) 0(0) 43(715) 45(717) 45(712)	46.0 50.0 N/A 48.3 46.1 49.8	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fer	nale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	058813804 059902704 050517406 059900706 059201306 052000804	09/13/99 07/29/02 08/20/02 05/12/03 02/03/00 03/25/03	729 732 728 732 734 732	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	40(706) 45(698) 41(696) 44(718) 42(706) 40(714)	46.2 50.3 51.8 51.9 45.6 51.0	Benzophenone Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

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: FEED Page: 197

			Male				Female	
All Organs: Benign Tumors								
<b>g</b>		27/50 (54%)	28/50 (56%)			15/50 (30%)	16/50 (32%)	16/50 (32%)
		28/50 (56%)	26/50 (52%)	21/50 (42%)		17/50 (34%)	18/50 (36%)	18/50 (36%)
verall Incidence	Total	130/250 (52%)	Mean 52%	SD 5.83%	Total	100/300 (33.33%)	Mean 33.33%	SD 2.42%
All Organs: Malignant Tumors						•••••		
		17/50 (34%)	24/50 (48%)			16/50 (32%)	22/50 (44%)	20/50 (40%)
		20/50 (40%)	15/50 (30%)	29/50 (58%)		13/50 (26%)	20/50 (40%)	19/50 (38%)
verall Incidence	Total	105/250 (42%)	Mean 42%	SD 11.22%	Total	110/300 (36.67%)	Mean 36.67%	SD 6.53%
All Organs: Malignant and Benign T	umors							
		38/50 (76%)	40/50 (80%)			25/50 (50%)	31/50 (62%)	29/50 (58%)
		38/50 (76%)	34/50 (68%)	39/50 (78%)		26/50 (52%)	29/50 (58%)	32/50 (64%)
verall Incidence	Total	189/250 (75.6%)	Mean 75.6%	SD 4.56%	Total	172/300 (57.33%)	Mean 57.33%	SD 5.47%
All Organs: Hemangioma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
All Organs: Hemangiosarcoma								
		3/50 (6%)	2/50 (4%)	0/50 (00/)		1/50 (2%)	3/50 (6%)	1/50 (2%)
S	T-1-1	2/50 (4%)	1/50 (2%)	3/50 (6%)	T-1-1	1/50 (2%)	3/50 (6%)	2/50 (4%)
Overall Incidence	Total	11/250 (4.4%)	Mean 4.4%	SD 1.67%	Total	11/300 (3.67%)	Mean 3.67%	SD 1.97%

<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:11/19/2008

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#All Organs: Hemangiosarcoma or He	mangioma							
riemangiosarcoma or rie	mangioma	3/50 (6%)	2/50 (4%)			1/50 (2%)	3/50 (6%)	1/50 (2%)
Overall Incidence	Total	2/50 (4%) 12/250 (4.8%)	1/50 (2%) Mean 4.8%	4/50 (8%) SD 2.28%	Total	1/50 (2%) 12/300 (4%)	3/50 (6%) Mean 4%	3/50 (6%) SD 2.19%
verali iliciuelice	ı olai	12/230 (4.876)	ivieaii 4.0%	3D 2.20%	TOLAI	12/300 (476)	ivicali 470	3D 2.1976
All Organs:								
Histiocytic Sarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%
Malignant Lymphoma: Hi or Undifferentiated Cell T overall Incidence		2/50 (4%) 1/50 (2%) 14/250 (5.6%)	, 2/50 (4%) 3/50 (6%) Mean 5.6%	6/50 (12%) SD 3.85%	Total	8/50 (16%) 6/50 (12%) 44/300 (14.67%)	5/50 (10%) 7/50 (14%) Mean 14.67%	7/50 (14%) 11/50 (22%) SD 4.13%
All Organs: Mesothelioma: Benign, N	falignant, NO	0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
All Organs: Mesothelioma: Malignant	t	0/50 (09/)	0/50 (09/)			0/50 (09/)	0/50 (09/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Overall incluence	i Ulai	0/230 (0/0)	IVICALI U/0	3D 070	i Ulai	0/300 (0/0)	IVICALI U/0	30 0/0

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 199

			Male				Female	
tAll 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%)
verall Incidence	Total	0/250 (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%)
Normall In all Innas	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Osteosarcoma or Osteoma		0/50 (00/)	0/50 (00/)			4/50 (00/)	0/50 /00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Adrenal Cortex: Adenoma					•••••			
		0/50 (0%)	0/50 (0%)	4/50 (20/)		1/50 (2%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	2/50 (4%) 7/250 (2.8%)	4/50 (8%) Mean 2.8%	1/50 (2%) SD 3.35%	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		, ,						
Adrenal Cortex: Sarcoma		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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

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

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

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: FEED Page: 200

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	nign							
•	· ·	0/50 (0%)	0/49 (0%)			1/50 (2%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%
Adrenal Medulla: Pheochromocytoma Co								
	•	0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Ma	lignant					•••••		
·	_	0/50 (0%)	0/49 (0%)			0/50 (0%)	1/49 (2%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.11%
Adrenal Medulla:		. Mallana and NOO						
Pheochromocytoma: Be	enign, Complex	0/50 (0%)	0/49 (0%)			1/50 (2%)	1/49 (2%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	4/297 (1.35%)	Mean 1.35%	SD 1.04%
Bone Marrow: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)	4/40 (00/)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	<b>+</b>	0/50 (0%)	1/50 (2%)	1/49 (2%)	<b>-</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 201

			Male				Female	
Bone Marrow: Mast Cell Tumor Malignant		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Bone: Hemangiosarcoma	• • • • • • • • • • • • • • • • • • • •	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Bone: Osteosarcoma								
overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%
Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%	1/50 (2%) 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: ORAL Vehicle: FEED Page: 202

			Male				Female	
Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	SD 0%
Brain:						•••••		
Meningioma Benign		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
3		0/50 (0%)	0/50 (0%)			0/50 (0%)	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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain:						•••••		
Meningioma: Benign, Ma	lignant, 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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (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

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 203

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	4/50 (00/)		0/50 (0%)	0/44 (0%)	0/49 (0%)
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/290 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/44 (0%)	1/49 (2%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/290 (0.34%)	Mean 0.34%	SD 0.83%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/290 (0.34%)	Mean 0.34%	SD 0.83%
Clitoral/Preputial Gland: Hemangioma								
<b>U</b>		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/290 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/44 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/47 (0%)
overan incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/290 (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: FEED Page: 204

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/44 (0%) 0/50 (0%)	0/49 (0%) 0/47 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/290 (0%)	Mean 0%	SD 0%
Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)					
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Esophagus: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/50 (0%) 0/250 (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%
Eye: Sarcoma	•••••							
verall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Gallbladder: Adenoma		0/45 (0%)	0/46 (0%)		•••••	0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/47 (0%) 0/227 (0%)	0/44 (0%) Mean 0%	0/45 (0%) SD 0%	Total	0/48 (0%) 0/286 (0%)	0/47 (0%) Mean 0%	0/44 (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: FEED Page: 205

			Male				Female	
Harderian Gland: Adenoma								
		6/50 (12%)	5/50 (10%)			1/50 (2%)	7/50 (14%)	6/50 (12%)
		7/50 (14%)	4/50 (8%)	5/50 (10%)		5/50 (10%)	6/50 (12%)	6/50 (12%)
verall Incidence	Total	27/250 (10.8%)	Mean 10.8%	SD 2.28%	Total	31/300 (10.33%)	Mean 10.33%	SD 4.27%
larderian Gland: Carcinoma								
		1/50 (2%)	1/50 (2%)	0/50 (00/)		0/50 (0%)	2/50 (4%)	1/50 (2%)
	<b>-</b>	2/50 (4%)	1/50 (2%)	0/50 (0%)	<b>.</b>	2/50 (4%)	1/50 (2%)	2/50 (4%)
verall Incidence	Total	5/250 (2%)	Mean 2%	SD 1.41%	Total	8/300 (2.67%)	Mean 2.67%	SD 1.63%
Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%)	5/50 (10%)			1/50 (2%)	9/50 (18%)	7/50 (14%)
		9/50 (18%)	5/50 (10%)	5/50 (10%)		7/50 (14%)	7/50 (14%)	8/50 (16%)
verall Incidence	Total	31/250 (12.4%)	Mean 12.4%	SD 3.58%	Total	39/300 (13%)	Mean 13%	SD 5.62%
Harderian 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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Heart: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 206

			Male				Female	
Heart: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
leart: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyoma					••••			
		0/50 (0%)	0/50 (0%)	2/22 (22/)		0/50 (0%)	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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

Page: 207

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

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Report Date:11/19/2008

Page: 208

			Male				Female	
Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	2/22 (221)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Second Head days	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	1/50 (2%)	2/22 (221)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: 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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female	
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: 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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Jejunum: Polyp Adenomatous			•••••		•••••		•••••	
r oryp Adenomatods		0/50 (0%)	0/50 (0%)			0/50 (0%)	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Hntestine Small: Site Unspeci Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	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

Page: 210 Report Date:11/19/2008

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

Length of Study: CHRONIC

			Male				Female	
Intestine Small: Site Uns	pecified:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Site Uns Carcinoma or Adenom							•••••	•••••
		0/50 (0%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.83%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Site Uns 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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns	pecified:							•••••
		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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Site Uns Polyp Adenomatous								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (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

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: FEED Page: 211

			Male				Female	
slets, Pancreatic:								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)	0/49 (0%)		1/48 (2%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/296 (0.68%)	Mean 0.68%	SD 1.05%
slets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/40 (00/)		0/50 (0%)	2/50 (4%)	0/50 (0%)
N	T-1-1	0/49 (0%)	0/49 (0%)	0/49 (0%)	T-1-1	0/48 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	2/296 (0.68%)	Mean 0.67%	SD 1.63%
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	2/50 (4%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)	0/49 (0%)		1/48 (2%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	4/296 (1.35%)	Mean 1.35%	SD 1.64%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	2/50 (4%)			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	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/299 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	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

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: FEED Page: 212

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 /00/	2/50 (60/)			0/50 (00/)	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%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%	Total	0/299 (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%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Liver:			•••••					
Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	2/22 (224)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
*Liver: Hemangioma								
······································		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Overali incidence	lotal	0/250 (0%)	wean 0%	SD 0%	rotai	0/300 (0%)	wean 0%	2D 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: FEED Page: 213

			Male				Female	
Liver: Hemangiosarcoma		0/50 (0%)	2/50 (4%)			0/50 (0%)	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	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatoblastoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		11/50 (22%)	21/50 (42%)			5/50 (10%)	1/50 (2%)	4/50 (8%)
		22/50 (44%)	17/50 (34%)	12/50 (24%)		3/50 (6%)	4/50 (8%)	3/50 (6%)
Overall Incidence	Total	83/250 (33.2%)	Mean 33.2%	SD 10.06%	Total	20/300 (6.67%)	Mean 6.67%	SD 2.73%
Liver: Hepatocellular Carcinoma								
riopatoconalai caromonia		8/50 (16%)	15/50 (30%)			0/50 (0%)	3/50 (6%)	1/50 (2%)
		8/50 (16%)	10/50 (20%)	17/50 (34%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	58/250 (23.2%)	Mean 23.2%	SD 8.32%	Total	8/300 (2.67%)	Mean 2.67%	SD 2.73%
Liver: Hepatocellular Carcinoma		lastoma	15/50 (30%)			0/50 (0%)		1/50 (2%)
		8/50 (16%) 9/50 (18%)	10/50 (30%)	17/50 (34%)		3/50 (6%)	3/50 (6%) 1/50 (2%)	0/50 (2%)
Overall Incidence	Total	59/250 (23.6%)	Mean 23.6%	SD 7.92%	Total	8/300 (2.67%)	Mean 2.67%	SD 2.73%

<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: FEED Page: 214

			Male				Female	
*Liver: Hepatocellular Carcinoma	or Henator	allular Adenoma						
•	·	18/50 (36%) 26/50 (52%)	32/50 (64%) 23/50 (46%)	26/50 (52%)	Tatal	5/50 (10%) 6/50 (12%)	4/50 (8%) 5/50 (10%)	4/50 (8%) 3/50 (6%)
Overall Incidence	Total	125/250 (50%)	Mean 50%	SD 10.2%	Total	27/300 (9%)	Mean 9%	SD 2.1%
Liver: Hepatocellular Carcinoma	a, Hepatocell	ular Adenoma, or						
Hepatoblastoma		18/50 (36%) 26/50 (52%)	32/50 (64%) 23/50 (46%)	26/50 (52%)		5/50 (10%) 6/50 (12%)	4/50 (8%) 5/50 (10%)	4/50 (8%) 3/50 (6%)
Overall Incidence	Total	125/250 (50%)	Mean 50%	SD 10.2%	Total	27/300 (9%)	Mean 9%	SD 2.1%
Liver: Hepatocholangiocarcinor	na	0/50 (00()	0/50 /00/			0/50 (0%)	0/50 (0%)	0/50 (00/)
		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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (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%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Liver: Ito 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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 215

			Male				Female	
Liver: 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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Lung: Alveolar/Bronchiolar Ad	lenoma		•••••					
Overall Incidence	Total	14/50 (28%) 4/50 (8%) 40/250 (16%)	13/50 (26%) 8/50 (16%) Mean 16%	1/50 (2%) SD 11.22%	Total	0/50 (0%) 4/50 (8%) 11/300 (3.67%)	1/50 (2%) 0/50 (0%) Mean 3.67%	5/50 (10%) 1/50 (2%) SD 4.27%
Lung: Alveolar/Bronchiolar Ca	rcinoma							
Overall Incidence	Total	2/50 (4%) 6/50 (12%) 23/250 (9.2%)	3/50 (6%) 2/50 (4%) Mean 9.2%	10/50 (20%) SD 6.87%	Total	1/50 (2%) 1/50 (2%) 9/300 (3%)	1/50 (2%) 3/50 (6%) Mean 3%	2/50 (4%) 1/50 (2%) SD 1.67%
Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Alv	veolar/Bronchiolar						
		16/50 (32%) 10/50 (20%)	16/50 (32%) 9/50 (18%)	11/50 (22%)		1/50 (2%) 5/50 (10%)	2/50 (4%) 3/50 (6%)	5/50 (10%) 2/50 (4%)

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 216

			Male		Female
*Lung: Fibrosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Lung: Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 0/300 (0%)	Mean 0% SD 0%
*Lung: Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 0/300 (0%)	Mean 0% SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/300 (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: ORAL Vehicle: FEED Page: 217

			Male				Female	
Lymph Node: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
verali ilicidence		` ,				, ,		
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (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%	1/50 (2%) SD 0.82%
werall incidence	Total	0/250 (0%)	Mean 0%	3D 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node, Bronchial: Hemangiosarcoma				•••••		•••••		
<b>3</b>		0/50 (0%)	0/50 (0%)			0/50 (0%)	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Implidance	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 218

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node, Mandibular: Mast Cell Tumor Malignant	••••••							
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
verali incluence	Total	0/250 (0%)	iviean 0%	3D 0%	ı Olal	0/300 (0%)	iviean 0%	3D 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma	••••••							
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 219

			Male				Female	
Mammary Gland: Adenoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
veran incidence	Total	0/250 (0%)	Mean 0%		Total	0/300 (0%)	Mean 0%	
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In address a	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma				•••••		•••••		
		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%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Mammary Gland: Carcinoma or Adenoma				•••••		•••••		
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Mammary Gland: Fibroadenoma					••••			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 220

			Male				Female	
Mammary Gland: Fibroma, Fibroadenom	na 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%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland:								
Fibroma, Fibroadenom	na, Carcinoma, c		0/50 (00/)			4/50 (004)	(22)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	3/300 (1%)	1/50 (2%) Mean 1%	0/50 (0%) SD 1.1%
veran incluence	ı Uldi	0/200 (0%)	iviean 0%	3D 0%	ıvıal	3/300 (170)	Weatt 170	3D 1.170
Mesentery: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery:								
Hemangioma								- / / / / / / / / / /
		0/50 (0%)	0/50 (0%)	4/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	0/50 (0%)	0/50 (0%)	1/50 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Toxicology Data I

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: FEED Page: 221

			Male				Female	
#Mesentery: Sarcoma								
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%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Nose:								
Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Oursell Institutes	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malignan								
gg.	•	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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, To		nx, Tooth, Gingiva):						
Papilloma Squamous or Pa	apilloma	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Second the statement	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ngue, Phary							
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (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: 222

Report Date: 11/19/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Mean 0% SD 0% Total 0/250 (0%)Mean 0% Total 0/300 (0%) ..... **#Oral Mucosa:** Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%) (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/250 (0%) SD 0% SD 0% **Overall Incidence** Total Mean 0% Total 0/300 (0%) Mean 0% Choriocarcinoma 0/49 (0%)0/48 (0%)0/50 (0%)(0%) 0/49 0/48 (0%)0/46 (0%)**Overall Incidence** Total 0/290 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 1/49 0/48 (0%)1/50 (2%)3/49 (6%)2/48 (4%)(2%)1/46 SD 2.11% **Overall Incidence** Total 8/290 (2.76%) Mean 2.75% \*Ovary: **Fibrous Histiocytoma** 0/49(0%)0/48 0/50 (0%)(0%)0/49 (0%)0/48 0/46 (0%)**Overall Incidence** Total 0/290 (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: 223

Report Date:11/19/2008

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

Route: ORAL Vehicle: FEED

	Male	Female	
*Ovary: Granulosa Cell Tumor Benign		0/49 (0%) 2/48 (4%) 0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 2/48 (4%) 0/46 (0%) 4/290 (1.38%) Mean 1.39% SD 2.15%	
*Ovary: Granulosa Cell Tumor Malignant		0/49 (0%) 1/48 (2%) 0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 0/48 (0%) 0/46 (0%) 1/290 (0.34%) Mean 0.35% SD 0.85%	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			
Overall Incidence	Total	0/49 (0%) 3/48 (6%) 0/50 (0%) 0/49 (0%) 2/48 (4%) 0/46 (0%) 5/290 (1.72%) Mean 1.74% SD 2.77%	
*Ovary: Hemangioma			
Overall Incidence	Total	0/49 (0%) 0/48 (0%) 0/50 (0%) 0/49 (0%) 0/48 (0%) 0/46 (0%) 0/290 (0%) Mean 0% SD 0%	
		, ,	
*Ovary: Hemangiosarcoma		0/49 (0%) 0/48 (0%) 0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 0/48 (0%) 0/46 (0%) 0/290 (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: 224

Report Date:11/19/2008

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
*Ovary: Leiomyosarcoma					
•			0/49 (0%) 0/49 (0%)	0/48 (0%) 0/48 (0%)	0/50 (0%) 0/46 (0%)
Overall Incidence		Γotal 0/2	90 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Luteoma			0/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	т		0/49 (0%) 190 (0%)	0/48 (0%) Mean 0%	0/46 (0%) SD 0%
*Ovary: Teratoma Benign					
			0/49 (0%) 0/49 (0%)	0/48 (0%) 0/48 (0%)	0/50 (0%) 0/46 (0%)
Overall Incidence	т		90 (0%)	Mean 0%	SD 0%
*Ovary:					
Teratoma Malignant		0	)/49 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	т		0/49 (0%) 290 (0%)	0/48 (0%) Mean 0%	0/46 (0%) SD 0%
			,		
*Ovary: Tubulostromal Adenoma					
Tubulostionial Adenoma			/49 (2%)	0/48 (0%)	0/50 (0%)
Overall Incidence	т		0/49 (0%) 290 (0.34%)	0/48 (0%) Mean 0.34%	0/46 (0%) SD 0.83%

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

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

Strain: B6C3F1

. NUV2006

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 225

			Male				Female	
Pancreas:								
Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/296 (0%)	Mean 0%	SD 0%
Pancreas:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	0/40 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	0/49 (0%)		0/48 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/296 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma					•••••			
		0/48 (0%)	0/48 (0%)			2/50 (4%)	1/47 (2%)	2/50 (4%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	5/49 (10%)	2/49 (4%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	12/295 (4.07%)	Mean 4.07%	SD 3.41%
Pituitary Gland: Pars Distalis Carcinoma								
		0/48 (0%)	0/48 (0%)			0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	0/295 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Page: 226 Report Date:11/19/2008

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

Vehicle: FEED

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma or Adenom		ied Site:						
		0/48 (0%)	0/48 (0%)			2/50 (4%)	1/47 (2%)	2/50 (4%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	5/49 (10%)	2/49 (4%)
verall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	12/295 (4.07%)	Mean 4.07%	SD 3.41%
Pituitary Gland: Pars Inte Adenoma	rmedia:							
		0/48 (0%)	0/48 (0%)	2/12 (22/)		0/50 (0%)	1/47 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/295 (0.34%)	Mean 0.35%	SD 0.87%
Pituitary Gland: Pars Inte Carcinoma or Adenom	rmedia:					•••••		
		0/48 (0%)	0/48 (0%)			0/50 (0%)	1/47 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/295 (0.34%)	Mean 0.35%	SD 0.87%
Prostate:	•••••		•••••					•••••
Adenoma		0/50 (0%)	1/50 (2%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%				
Prostate: Carcinoma or Adenom	 na							
		0/50 (0%)	1/50 (2%)	0/50 (00/)				
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%				

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

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

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 227

			Male				Female	
Prostate: Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Salivary Glands: Carcinoma or Adenoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)		••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)		•••••			
Overall Incidence	Total	0/50 (0%) 0/250 (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

1.14072000

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: FEED Page: 228

			Male				Female	
Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0.750 (00.4)		0/50 (0%)	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	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	4/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N	T-1-1	0/50 (0%)	1/50 (2%)	1/50 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Myxosarcoma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skeletal Muscle: Rhabdomyosarcoma or l								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 229
Report Date:11/19/2008

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

			Male				Female	
Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	<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	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin:	_							
Basal Cell Adenoma or	: Basosquamou	•	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous∃	Tumor Benign, or	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin: Basal Cell Carcinoma								
Dasai Celi Calcillollia		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0/0)						, ,
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
:Skin:		0/250 (0%)	Mean 0%	` '	Total			
#Skin: Basal Cell Carcinoma		0/250 (0%)	Mean 0%	` '	Total	0/300 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%  0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%) 0/50 (0%)

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 230 Report Date:11/19/2008

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

			Male				Female					
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma  0/50 (0%)												
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacantl	ma, Adenoma,	Papilloma, Sq pithelioma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%				
#Skin: Basosquamous 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%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%				
#Skin: Fibroma		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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%				
#Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	, Sarcoma, My											
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 4/250 (1.6%)	1/50 (2%) 0/50 (0%) Mean 1.6%	3/50 (6%) SD 2.61%	Total	1/50 (2%) 3/50 (6%) 16/300 (5.33%)	2/50 (4%) 2/50 (4%) Mean 5.33%	5/50 (10%) 3/50 (6%) SD 2.73%				

<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: FEED Page: 231

			Male				Female	
#Skin: Fibrosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	4/50 (8%) 3/50 (6%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	11/300 (3.67%)	Mean 3.67%	SD 2.66%
#Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	,	4/50 (00)			4/50 (00/)	0/50 (404)	5/50 (400)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 3/250 (1.2%)	1/50 (2%) 0/50 (0%) Mean 1.2%	2/50 (4%) SD 1.79%	Total	1/50 (2%) 3/50 (6%) 16/300 (5.33%)	2/50 (4%) 2/50 (4%) Mean 5.33%	5/50 (10%) 3/50 (6%) SD 2.73%
#Skin: Fibrous Histiocytoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	2/50 (4%) SD 1.79%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%	1/50 (2%) SD 0.82%
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	2/50 (4%) SD 1.79%	Total	0/50 (0%) 2/300 (0.67%)	2/50 (4%) Mean 0.67%	0/50 (0%) SD 1.63%

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

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

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 232 Report Date:11/19/2008

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

			Male				Female	
#Skin: Liposarcoma								
zipoda doma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:								
Myxosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor			•••••		•••••			
Neural Crest Tullion		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma or	Schwannoma (ı	malignant or NOS) 1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (2%)	0/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Skin: Neurofibrosarcoma, Ne malignant or NOS)	eurofibroma, or	Schwannoma (benign,						
manynam or NOS)		1/50 (2%)	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%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/19/2008

Page: 233

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

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female		
#Skin: Osteosarcoma		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	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 4/300 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.63%	
#Skin: Schwannoma Malignant	······	1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	
#Skin: Squamous Cell Carcino	ma	0/50 (00()	0/50 (0%)			0/50 (0%)	0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	
#Skin: Squamous Cell Carcino Basosquamous Tumor (	ma, Basal Cell	Carcinoma,							
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	

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

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

**Toxicology Data Management System** 

Vehicle: FEED

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

trol Animal Groups

Page: 234

Report Date:11/19/2008

Species: MICE Strain: B6C3F1

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Squamous Cell Papilloma	1	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (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%)
Overall Incidence	Total	0/50 (0%) 0/250 (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%
#Skin: Squamous Cell Papilloma Carcinoma or Keratoacar Overall Incidence		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
#Skin: Squamous Cell Papilloma	a, 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%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 235 Report Date:11/19/2008

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

			Male	Female
#Skin: Sebaceous Gland: Adenoma				
		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%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 1/300 (0.33%) Mean 0.33% SD 0.82%
#Skin: Sebaceous 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%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/300 (0%) Mean 0% SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 1/300 (0.33%) Mean 0.33% SD 0.82%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/300 (0%) Mean 0% SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/30 (0%) 0/30 (0%) 0/48 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/295 (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: ORAL Vehicle: FEED Page: 236

			Male				Female	
Spleen: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/48 (0%)
N	T-1-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/48 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/295 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)	0.770 (404)		0/50 (0%)	2/50 (4%)	1/48 (2%)
		1/50 (2%)	0/49 (0%)	2/50 (4%)		1/48 (2%)	2/49 (4%)	0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6%	SD 1.67%	Total	6/295 (2.03%)	Mean 2.04%	SD 1.81%
Stomach, Forestomach: Mast Cell Tumor Malignant						•••••		
		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	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
·		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Stomach, Forestomach: Squamous Cell Carcinoma o								
		1/50 (2%)	2/50 (4%)	0.750 (00.4)		2/50 (4%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 237

			Male				Female	
Stomach, Forestomach: Squamous Cell Papilloma								
		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%
Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)	2/52 (22/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma			•••••					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma			•••••					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Testes: Adenoma					•••••			
		0/50 (0%)	0/50 (0%)	1/50 (20/)				
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%				

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

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

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 238

						Female	
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Total	0/250 (0%)	Mean 0%	SD 0%				
							0/50 (0%)
	0/40 (0%)	0/41 (0%)	0/45 (0%)		0/40 (0%)	0/49 (0%)	0/49 (0%)
Total	0/224 (0%)	Mean 0%	SD 0%	Total	0/292 (0%)	Mean 0%	SD 0%
				•••••			
	()	()	0/45 (00/)		()	( /	0/50 (0%)
Total	0/44 (0%)	0/48 (0%) Mean 0%	0/45 (0%) SD 0%	Total	0/49 (0%) 0/292 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%
 int, NOS				•••••			
	0/46 (0%)	0/41 (0%)			0/46 (0%)	0/49 (0%)	0/50 (0%)
	()	` '	` '		(/	` ,	0/49 (0%)
	0/224 (0%)			Total	` ,		SD 0%
			•••••	•••••			
			0/40 (00/)				0/48 (0%)
Total	` ,	` ,	` ,	Total	` ,	` ,	0/50 (0%) SD 0.82%
	Total  Total  Int, NOS	0/50 (0%) Total 0/250 (0%)  0/46 (0%) 0/44 (0%) Total 0/224 (0%)  0/46 (0%) 0/44 (0%) Total 0/224 (0%)  Int, NOS  0/46 (0%) 0/44 (0%) Total 0/224 (0%)  0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0%  0/46 (0%) 0/41 (0%) 0/44 (0%) 0/48 (0%) Total 0/224 (0%) Mean 0%  0/46 (0%) 0/41 (0%) 0/44 (0%) 0/48 (0%) Total 0/224 (0%) Mean 0%  Int, NOS  0/46 (0%) 0/41 (0%) 0/48 (0%) 0/44 (0%) 0/48 (0%) Total 0/224 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/50 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%)  Total O/250 (0%) Mean 0% SD 0%  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0%  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0%  Int, NOS  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0%  O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/48 (0%)	O/50 (0%) O/50 (0%) O/50 (0%)  Total O/250 (0%) Mean 0% SD 0%  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0% Total  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0% Total  oint, NOS  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0% Total  oint, NOS  O/46 (0%) O/41 (0%) O/44 (0%) O/48 (0%) O/45 (0%)  Total O/224 (0%) Mean 0% SD 0% Total	Total 0/250 (0%) 0/50 (0%) Nean 0% SD 0%    O/46 (0%) 0/41 (0%) 0/45 (0%) 0/49 (0%)     Total 0/224 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0%    O/46 (0%) 0/41 (0%) 0/48 (0%) 0/45 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)   Total 0/224 (0%) Mean 0% SD 0% Total 0/292 (0%) Mean 0%    O/46 (0%) 0/48 (0%) 0/48 (0%) 0/45 (0%) 0/49 (0%) 0/49 (0%)   Total 0/224 (0%) Mean 0% SD 0% Total 0/292 (0%) Mean 0%    O/46 (0%) 0/48 (0%) 0/48 (0%) 0/45 (0%) 0/49 (0%) 0/49 (0%)   Total 0/224 (0%) Mean 0% SD 0% Total 0/292 (0%) Mean 0%    O/46 (0%) 0/49 (0%) 0/49 (0%)   O/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%) 0/50 (0%) 0/50 (0%)   O/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (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: FEED Page: 239

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)	2/12 (22/)		0/50 (0%)	0/50 (0%)	0/48 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/48 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/40 (00/)		0/50 (0%)	0/50 (0%)	0/48 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/48 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Adenoma							•••••	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/48 (0%)
		1/50 (2%)	1/50 (2%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2%	SD 1.1%	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%
Thyroid Gland: Follicular Cell: Carcinoma							•••••	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%)	0/50 (0%)	0/49 (00/)		0/50 (0%)	1/50 (2%)	0/48 (0%)
Querall Incidence	Total	1/50 (2%)	1/50 (2%)	0/48 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2%	SD 1.1%	Total	1/298 (0.34%)	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

**31011.** 11012000

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: FEED Page: 240

			Male				Female	
Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Implication	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	1/50 (2%)	0/50 (0%)
	<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	0/250 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Tissue NOS: Schwannoma Malignant	••••••							•••••
		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%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma								
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma o			0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 241

			Male				Female	
Tongue: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
verali incidence	Total	0/250 (0%)	Mean 0%		Total	0/300 (0%)	Mean 0%	
Tooth: Odontoma								
		1/50 (2%)	0/50 (0%)	2/52 (22/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Hemangiosarcoma						•••••		
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Urinary Bladder: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Normall Implications	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/298 (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: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%) (0%) 0/50 0/50 0/50 **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/300 (0%) Mean 0% **#Uterus:** Hemangiosarcoma (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/300 (0%) Mean 0% SD 0% Total #Uterus: Leiomyoma 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%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:11/19/2008

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male	Female						
#Uterus:								
Leiomyosarcoma		0/50 (0%)	2/50 (4%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%				
#Uterus: Polyp Stromal								
		4/50 (8%) 2/50 (4%)	2/50 (4%) 0/50 (0%)	0/50 (0%) 4/50 (8%)				
Overall Incidence	Total	12/300 (4%)	Mean 4%	SD 3.58%				
Overall molacines	rotar	12/000 (470)	Wican 470	OD 0.0070				
#Ilkania.								
#Uterus: Sarcoma Stromal								
Sar Sorina Sar Saria		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Uterus:								
Sarcoma Stromal or Polyp Stromal		5/50 (10%)	2/50 (4%)	0/50 (0%)				
		2/50 (4%)	0/50 (0%)	4/50 (8%)				
Overall Incidence	Total	13/300 (4.33%)	Mean 4.33%	SD 4.08%				
#Uterus:								
Schwannoma Malignant		2/52 (22/)	. (== (==()	2/22 (22/)				
		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%				
	Total	2,000 (0.01 70)	1110411 0.07 70	22 1.0070				

<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:11/19/2008

Contract/Lab: All Laboratories

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

Vehicle: FEED

			Male		Female			
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
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%
#Vagina: Squamous Cell Papilloma						0/50 (00/)	0/50 (00/)	0/50 (00/)
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%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Zymbal's Gland: Carcinoma or Adenoma								0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%

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

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 245

Report Date:11/19/2008

### **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
				М	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	729 729 729 729	50 (1) 50 (1) 49 (1) 50 (1)	33(700) 38(696) 31(685) 40(697)	55.6 54.1 52.5 54.0	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fer	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	735 734 734 731	50 (5) 50 (5) 50 (5) 50 (5)	35(701) 36(693) 38(708) 35(705)	64.3 63.0 64.3 60.9	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

			Male				Female	
#All Organs: Benign Tumors								
Ū		42/50 (84%) 32/50 (64%)	41/50 (82%)	25/49 (51%)		27/50 (54%) 29/50 (58%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	140/199 (70.35%)	Mean 70.26%	SD 15.66%	Total	117/200 (58.5%)	Mean 58.5%	SD 4.12%
All Organs: Malignant Tumors								
		31/50 (62%) 29/50 (58%)	36/50 (72%)	23/49 (47%)		22/50 (44%) 31/50 (62%)	38/50 (76%)	36/50 (72%)
Overall Incidence	Total	119/199 (59.8%)	Mean 59.73%	SD 10.37%	Total	127/200 (63.5%)	Mean 63.5%	SD 14.27%
All Organs: Malignant and Benign T								
		49/50 (98%) 41/50 (82%)	47/50 (94%)	37/49 (76%)		36/50 (72%) 44/50 (88%)	43/50 (86%)	42/50 (84%)
Overall Incidence	Total	174/199 (87.44%)	Mean 87.38%	SD 10.43%	Total	165/200 (82.5%)	Mean 82.5%	SD 7.19%
All Organs: Hemangioma						•••••	•••••	
-		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	6/200 (3%)	Mean 3%	SD 2.58%
All Organs: Hemangiosarcoma								
		4/50 (8%) 1/50 (2%)	3/50 (6%)	4/49 (8%)		2/50 (4%) 3/50 (6%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 2.87%	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%

<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

pups Report Date:11/19/2008

Page: 247

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC Route: ORAL Vehicle: WATER

			Male				Female	
#All Organs: Hemangiosarcoma or Hei	mangioma							
-	-	4/50 (8%) 2/50 (4%)	4/50 (8%)	4/49 (8%)		3/50 (6%) 3/50 (6%)	3/50 (6%)	4/50 (8%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04%	SD 2.03%	Total	13/200 (6.5%)	Mean 6.5%	SD 1%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%) 4/50 (8%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	7/200 (3.5%)	Mean 3.5%	SD 3.42%
Overall Incidence	Total	2/50 (4%) 0/50 (0%) 4/199 (2.01%)	2/50 (4%) Mean 2%	0/49 (0%) SD 2.31%	Total	7/50 (14%) 9/50 (18%) 61/200 (30.5%)	18/50 (36%) Mean 30.5%	27/50 (54%) SD 18.36%
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 2.31%	Total	61/200 (30.5%)	Mean 30.5%	SD 18.36%
#All Organs: Mesothelioma: Benign, M	alignant, NO							
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant					•••••			
_		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Report Date:11/19/2008 Vehicle: WATER

Page: 248

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Osteosarcoma	•••••							
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma			•••••			•••••		
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Cortex: Adenoma								
		7/49 (14%) 6/50 (12%)	9/50 (18%)	3/49 (6%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	25/198 (12.63%)	Mean 12.6%	SD 4.98%	Total	0/199 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 249

			Male				Female	
Adrenal Medulla: Pheochromocytoma B	enian							
	Jg.:	0/49 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma C								
•	·	0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma M	alignant							
·	·	0/49 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma: E								
•	<b>3</b> / 1	0/49 (0%) 1/49 (2%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	2/197 (1.02%)	Mean 1.02%	SD 1.18%	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%
Bone Marrow: Hemangiosarcoma								
		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/196 (1.02%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 250

			Male				Female	
Bone Marrow: Mast Cell Tumor Malignant								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Hemangiosarcoma					•••••			•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma								•••••
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

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

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: 251

			Male				Female	
Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant	••••••							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, M								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 252

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 1/49 (2%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
verall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/190 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma				•••••				
		0/50 (0%) 1/49 (2%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
overall Incidence	Total	1/196 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/190 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangioma								
•		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
verall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (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: 253

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
verall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
Epididymis: Sarcoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Esophagus: Squamous Cell Carcinoma							•••••	
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Sarcoma								
Curonia		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Gallbladder: Adenoma								
		0/47 (0%) 0/47 (0%)	0/45 (0%)	0/39 (0%)		0/44 (0%) 0/46 (0%)	0/42 (0%)	0/47 (0%)
Overall Incidence	Total	0/178 (0%)	Mean 0%	SD 0%	Total	0/179 (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: 254

			Male				Female	
#Harderian Gland: Adenoma								
		6/50 (12%) 5/50 (10%)	5/50 (10%)	3/49 (6%)		4/50 (8%) 6/50 (12%)	1/50 (2%)	9/50 (18%)
Overall Incidence	Total	19/199 (9.55%)	Mean 9.53%	SD 2.46%	Total	20/200 (10%)	Mean 10%	SD 6.73%
#Harderian Gland: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 2/50 (4%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	6/200 (3%)	Mean 3%	SD 1.15%
Harderian Gland: Carcinoma or Adenoma				•••••			••••••	
		6/50 (12%) 5/50 (10%)	5/50 (10%)	3/49 (6%)		5/50 (10%) 8/50 (16%)	3/50 (6%)	10/50 (20%)
Overall Incidence	Total	19/199 (9.55%)	Mean 9.53%	SD 2.46%	Total	26/200 (13%)	Mean 13%	SD 6.22%
Harderian Gland: Sarcoma	••••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Hemangioma								
ŭ		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 255

			Male				Female	
Heart: Hemangiosarcoma								
ŭ		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Sarcoma					•••••	•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma					•••••			
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

			Male				Female	
fintestine Large: Cecum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectun Leiomyosarcoma	า:							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Adenoma								•••••
		1/50 (2%) 1/50 (2%)	3/50 (6%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Small: Duodenum: Carcinoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 257

			Male				Female	
Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0 /0)	0/49 (070)		0/50 (0%)	0/30 (0/8)	0/30 (0/8)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Polyp Adenomatous								
, ,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 258

			Male				Female	
fIntestine Small: Jejunum: Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma	•••••							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous			•••••				•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspeci Adenoma			•••••			•••••		
		1/50 (2%) 1/50 (2%)	3/50 (6%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 2.52%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 259

			Male				Female	
#Intestine Small: Site Uns Carcinoma	pecified:							
		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Intestine Small: Site Uns Carcinoma or Adenom			•••••				•••••	
		1/50 (2%) 1/50 (2%)	5/50 (10%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.5%	SD 4.43%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Intestine Small: Site Uns Hemangiosarcoma								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Uns Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 260

			Male				Female	
Islets, Pancreatic:								
		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/46 (0%)		1/49 (2%) 1/49 (2%)	1/49 (2%)	1/49 (2%)
verall Incidence	Total	5/195 (2.56%)	Mean 2.53%	SD 2.57%	Total	4/196 (2.04%)	Mean 2.04%	SD 0%
slets, Pancreatic: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/46 (0%)		1/49 (2%) 1/49 (2%)	1/49 (2%)	1/49 (2%)
Overall Incidence	Total	5/195 (2.56%)	Mean 2.53%	SD 2.57%	Total	4/196 (2.04%)	Mean 2.04%	SD 0%
Kidney: Renal Tubule: Adenoma							•••••	
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 261

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma								
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Liver: Fibrous Histiocytoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%

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

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

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 262

			Male				Female	
Liver: Hemangiosarcoma								
-		1/50 (2%) 0/50 (0%)	2/50 (4%)	1/49 (2%)		1/49 (2%) 2/50 (4%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	4/198 (2.02%)	Mean 2.02%	SD 1.63%
Liver: Hepatoblastoma	•••••				•••••			
		17/50 (34%) 1/50 (2%)	4/50 (8%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	22/199 (11.06%)	Mean 11%	SD 15.71%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Liver: Hepatocellular Adenoma	•••••				•••••			
•		36/50 (72%) 29/50 (58%)	27/50 (54%)	18/49 (37%)		14/49 (29%) 19/50 (38%)	27/50 (54%)	19/49 (39%)
Overall Incidence	Total	110/199 (55.28%)	Mean 55.18%	SD 14.52%	Total	79/198 (39.9%)	Mean 39.84%	SD 10.52%
Liver: Hepatocellular Carcinoma								
		14/50 (28%) 24/50 (48%)	19/50 (38%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	3/49 (6%)
Overall Incidence	Total	71/199 (35.68%)	Mean 35.64%	SD 9.43%	Total	35/198 (17.68%)	Mean 17.61%	SD 9.08%
Liver: Hepatocellular Carcinoma o					•••••			
		25/50 (50%) 24/50 (48%)	21/50 (42%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	4/49 (8%)
Overall Incidence	Total	84/199 (42.21%)	Mean 42.14%	SD 9.67%	Total	36/198 (18.18%)	Mean 18.12%	SD 8.24%

<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: ORAL Vehicle: WATER Page: 263

			Male				Female	
Liver:	or Honotoo	Mular Adanama						
Hepatocellular Carcinoma	ог ператос	42/50 (84%) 37/50 (74%)	34/50 (68%)	28/49 (57%)		17/49 (35%) 27/50 (54%)	31/50 (62%)	22/49 (45%)
verall Incidence	Total	141/199 (70.85%)	Mean 70.79%	SD 11.24%	Total	97/198 (48.99%)	Mean 48.9%	SD 11.77%
iver: Hepatocellular Carcinoma								
Hepatoblastoma		46/50 (92%) 37/50 (74%)	35/50 (70%)	28/49 (57%)		17/49 (35%) 27/50 (54%)	31/50 (62%)	22/49 (45%)
verall Incidence	Total	146/199 (73.37%)	Mean 73.29%	SD 14.4%	Total	97/198 (48.99%)	Mean 48.9%	SD 11.77%
_iver: Hepatocholangiocarcinom	a	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%
iver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%
iver: Ito Cell Tumor Malignant	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		2/50 (4%)	,	,		0/50 (0%)	,	,
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/198 (0%)	Mean 0%	SD 0%

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

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

49 1 49 1

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: 264

			Male				Female	
Liver:								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A		15/50 (30%)	4/50 (8%)	7/49 (14%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	6/50 (12%) 32/199 (16.08%)	Mean 16.07%	SD 9.64%	Total	3/50 (6%) 7/200 (3.5%)	Mean 3.5%	SD 1.91%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		3/50 (6%) 4/50 (8%)	12/50 (24%)	5/49 (10%)		2/50 (4%) 6/50 (12%)	6/50 (12%)	1/50 (2%)
Overall Incidence	Total	24/199 (12.06%)	Mean 12.05%	SD 8.15%	Total	15/200 (7.5%)	Mean 7.5%	SD 5.26%
Lung: Alveolar/Bronchiolar C Adenoma	Carcinoma or Alv	/eolar/Bronchiolar						
		16/50 (32%) 10/50 (20%)	15/50 (30%)	12/49 (24%)		2/50 (4%) 9/50 (18%)	8/50 (16%)	2/50 (4%)
Overall Incidence	Total	53/199 (26.63%)	Mean 26.62%	SD 5.44%	Total	21/200 (10.5%)	Mean 10.5%	SD 7.55%

<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: 265

			Male				Female	
Lung: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma				•••••				
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Sarcoma				•••••		•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node: Fibrous Histiocytoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 266

			Male				Female	
Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma	•••••					•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 267

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma								
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

2131011: 110V2000

Toxicology Data Management System

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Mammary Gland: Adenoacanthoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 Mean 0% **Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% #Mammary Gland: Adenoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 0% SD 1.91% Total 0/199 (0%) Mean 0% Total 3/200 (1.5%) Mean 1.5% #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 0/199 (0%) SD 0% 3/200 (1.5%) SD 1.91% Total Mean 0% Total Mean 1.5% #Mammary Gland: Fibroadenoma (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 

Page: 268

<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: 269

			Male				Female	
Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland:								
Fibroma, Fibroadenoma	a, Carcinoma, o		0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (40/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%
Mesentery:								•••••
Hemangioma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%)	Maan 00/	SD 0%	Total	0/50 (0%)	Maan 0 50/	SD 1%
	Total	0/199 (0%)	Mean 0%		Total	1/200 (0.5%)	Mean 0.5%	
Mesentery: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 270

			Male				Female	
#Mesentery: Sarcoma								
Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Nose: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Maligna	ınt							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, T Papilloma Squamous or	Tongue, Phary	nx, Tooth, Gingiva):						
	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Oral Cavity (Oral Mucosa, T Squamous Cell Carcinon	ongue, Phary							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Page: 271

Report Date: 11/19/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/199 (0%) SD 0% SD 2% Total Mean 0% Total 2/200 (1%) Mean 1% **#Oral Mucosa:** Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 **Overall Incidence** 0/199 (0%) SD 0% 0/200 (0%) SD 0% Total Mean 0% Total Mean 0% Choriocarcinoma 0/50 (0%)0/47 (0%)(0%)(2%) 1/50 **Overall Incidence** Total 1/196 (0.51%) Mean 0.5% SD 1% \*Ovary: Cystadenoma 1/50 (2%)(4%)(0%)1/50 (2%)**Overall Incidence** 4/196 (2.04%) Total Mean 2.06% SD 1.74% \*Ovary: **Fibrous Histiocytoma** 0/50 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Report Date:11/19/2008

Page: 272

	Male			Female	
Ovary: Granulosa Cell Tumor Benign			0/50 (0%) 1/50 (2%)	0/47 (0%)	0/49 (0%)
verall Incidence		Total	1/196 (0.51%)	Mean 0.5%	SD 1%
Ovary: Granulosa Cell Tumor Malignant			0/50 (0%)	0/47 (0%)	0/49 (0%)
overall Incidence		Total	0/50 (0%) 0/196 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			0/50 (0%)	0/47 (0%)	0/49 (0%)
verall Incidence		Total	1/50 (2%) 1/196 (0.51%)	Mean 0.5%	SD 1%
vary: Hemangioma		•••••			•••••
Hemangioma			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary: Hemangiosarcoma					
			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence		Total	0/196 (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: 273
Report Date:11/19/2008

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

	Male			Female	
Ovary:					
Leiomyosarcoma			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
verall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary:					
Luteoma			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign					
reratorna Berngh			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
verall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary:					
Teratoma Malignant			0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
verall Incidence		Total	0/196 (0%)	Mean 0%	SD 0%
Ovary:					
Tubulostromal Adenoma			0/50 (0%) 1/50 (2%)	0/47 (0%)	0/49 (0%)
Overall Incidence		Total	1/196 (0.51%)	Mean 0.5%	SD 1%

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

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

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 274

			Male				Female	
Pancreas: Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
Pancreas: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
Pituitary Gland: Pars Distalis Adenoma					• • • • • • • • • • • • • • • • • • • •			
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)
overall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%
Pituitary Gland: Pars Distalis Carcinoma		ied Site:			• • • • • • • • • • • • • • • • • • • •			
2 2		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/193 (0%)	Mean 0%	SD 0%	Total	0/191 (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:11/19/2008

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

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma or Adenom		ied Site:						
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%
Pituitary Gland: Pars Inte Adenoma			•••••					•••••
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%
Pituitary Gland: Pars Inte Carcinoma or Adenom	rmedia:				•••••			
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%
Prostate: Adenoma			•••••					•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)				
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenom					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)				
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: WATER

Route: ORAL

Length of Study: CHRONIC

Male Female \*Prostate: Hemangioma 0/50 (0%)0/50 (0%)0/48 (0%)(0%)0/50 0/198 (0%) **Overall Incidence** Total Mean 0% SD 0% \*Salivary Glands: Carcinoma 0/49 (0%)0/50 (0%)(0%)(0%)1/50 (2%)0/50 (0%) **Overall Incidence** Total Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% 1/198 (0.51%) \*Salivary Glands: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** Mean 0.5% SD 1% SD 0% Total 1/198 (0.51%) Total 0/200 (0%) Mean 0% \*Salivary Glands: **Mast Cell Tumor Malignant** (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/198 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% **#Seminal Vesicle:** Adenoma (0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0%

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

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

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: ORAL Vehicle: WATER

			Male				Female	
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or l	Rhabdomyom	a			•••••			
- -	-	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 278
Report Date:11/19/2008

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

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin:								
Basal Cell Adenoma or E	Basosquamou	_						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous <sup>·</sup>	7 Tumor Benign, or 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
Buour con curomoma		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or NOS)	Basosquamo	us Tumor (malignant or						
-,		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

oratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER

Page: 279

Report Date:11/19/2008

			Male				Female	
Skin: Basal Cell Carcinoma, E Tumor (benign, maligna		Trichoepithelioma 1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adenoi Papilloma, Keratoacantl	ma, Adenoma,	Papilloma, Sq	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
≴Skin: Basosquamous Tumor l Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Fibroma		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	, Sarcoma, Myx	koma, Myxosarcoma, or						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	12/200 (6%)	Mean 6%	SD 2.31%

<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

DRAL WATER Page: 280

			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 4/50 (8%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	6/200 (3%)	Mean 3%	SD 3.46%
#Skin: Fibrosarcoma, Sarcoma, Histiocytoma								
nistiocytoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	12/200 (6%)	Mean 6%	SD 2.31%
#Skin: Fibrous Histiocytoma			•••••	•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.83%
#Skin: Hemangioma			•••••	•••••	••••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Hemangiosarcoma	•••••				•••••			
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

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

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

II. NOV2008

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: 281

			Male				Female	
#Skin: Liposarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:			•••••				•••••	
Neurofibrosarcoma or \$	Schwannoma (	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Ne malignant or NOS)	urofibroma, or	Schwannoma (benign,						
angilani oi 1100)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

711: 140V2000

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: 282

			Male				Female	
#Skin: Osteosarcoma			0.50					(201)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
≮Skin: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	(474)	(575)		0/50 (0%)	(0,0)	(5,5)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinoma						•••••	•••••	
- 1		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, Basosquamous Tumor (mal								
(IIIII	.gu 31 1	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 283

			Male				Female	
Skin: Squamous Cell Papillon	ma							
oquamous och i apinon	na	0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillon	ma or Papilloma	a						
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Papillon Carcinoma or Keratoaca			1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Papillon Carcinoma or Keratoaca	anthoma	0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Papillon Carcinoma or Keratoaca Overall Incidence	anthoma Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Papillon Carcinoma or Keratoaca Overall Incidence	anthoma Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%) or Keratoacanthoma	Mean 0.5%	SD 1%		0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Papillon Carcinoma or Keratoaca Overall Incidence Skin:	anthoma Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%)	Mean 0.5%	SD 1%		0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Papillon Carcinoma or Keratoaca Overall Incidence Skin: Squamous Cell Papillon	anthoma Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%) or Keratoacanthoma 0/50 (0%)	Mean 0.5%	SD 1%		0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
Carcinoma or Keratoaca  Overall Incidence  #Skin:	Totalna, Papilloma,	0/50 (0%) 0/50 (0%) 1/199 (0.5%) or Keratoacanthoma 0/50 (0%) 0/50 (0%)	Mean 0.5%	SD 1%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0% 0/50 (0%)
Squamous Cell Papillon Carcinoma or Keratoaca  Overall Incidence  #Skin: Squamous Cell Papillon  Overall Incidence	Totalna, Papilloma,	0/50 (0%) 0/50 (0%) 1/199 (0.5%) or Keratoacanthoma 0/50 (0%) 0/50 (0%)	Mean 0.5%	SD 1%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0% 0/50 (0%)

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

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

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: 284

			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sebaceous Gland: Carcinoma	•••••			•••••	•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Spinal Cord: Meningioma Malignant	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma				•••••				
•		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/48 (0%) 0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/195 (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: 285

			Male				Female	
Spleen: Hemangioma								
		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/47 (0%)		0/48 (0%) 0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.5%	SD 1%	Total	0/195 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma						•••••		
		2/49 (4%) 1/50 (2%)	1/50 (2%)	2/47 (4%)		1/48 (2%) 0/48 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	6/196 (3.06%)	Mean 3.08%	SD 1.25%	Total	2/195 (1.03%)	Mean 1.03%	SD 1.19%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
v		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c								
- 4		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/49 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.92%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

<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: 286 Report Date:11/19/2008

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

Route: ORAL Vehicle: WATER

			Male				Female	
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/49 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
Stomach, Glandular: Adenoma	•••••					•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Carcinoma or Adenoma		•••••	•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Гestes: Adenoma	•••••							
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%				

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 287

			Male				Female	
Testes: Hemangiosarcoma								
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)				
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%				
Thymus: Thymoma Benign			•••••					
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
Overall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant								
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
Overall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Thymus: Thymoma: Benign, Malig			•••••					
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
Overall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

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

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

version. Nov2000

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: 288

			Male				Female	
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Thyroid Gland: Follicular Cell: Adenoma								
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%

<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: 289

			Male				Female	
Tissue NOS: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma	a							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
FTongue: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	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: ORAL Vehicle: WATER Page: 290

			Male				Female	
#Tongue: Squamous Cell Papillom	a	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	,	(0.10)		0/50 (0%)	(4,4)	,
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tooth: Odontoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
<b>3</b>		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
232 23		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:11/19/2008

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

	Male				Female	
#Uterus: Adenoma						
Adenoma			0/50	(0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	-	Total (	0/50 0/200 (	(0%) (0%)	Mean 0%	SD 0%
				•••••		
#Uterus:						
Carcinoma			0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	-	Total (	0/30	` '	Mean 0%	SD 0%
#Uterus: Hemangioma						
-			0/50 0/50	(0%) (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	-	Total	1/200		Mean 0.5%	SD 1%
#Uterus:			•••••			•••••
Hemangiosarcoma			0/=0	(227)	0/50 (00)	. (
			0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	-	Total (	0/200	(0%)	Mean 0%	SD 0%
			• • • • • • • • • • • • • • • • • • • •			
#Uterus: Leiomyoma						
			0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	-	Total (		(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: 292

Report Date:11/19/2008

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

	Male		Female						
#Uterus:									
Leiomyosarcoma			0/50	(0%)	0/50 (0%)	0/50 (0%)			
Our reliable to the second		T-1-1	0/50	(0%)	Maria 00/	00.00/			
Overall Incidence		Total	0/200	(0%)	Mean 0%	SD 0%			
#Uterus:									
Polyp Stromal									
			1/50 1/50	(2%) (2%)	2/50 (4%)	1/50 (2%)			
Overall Incidence		Total	5/200	` '	Mean 2.5%	SD 1%			
#Uterus: Sarcoma Stromal									
Jaicoma Stromai			0/50	(0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence		Total	0/50 0/200	(0%)	Mean 0%	SD 0%			
				` ,					
#Uterus:									
Sarcoma Stromal or Polyp Stromal			1/50	(2%)	2/50 (4%)	1/50 (2%)			
			1/50	(2%)	2/30 (4/8)	1/30 (2/6)			
Overall Incidence		Total	5/200	(2.5%)	Mean 2.5%	SD 1%			
			•••••						
#Uterus: Schwannoma Malignant									
-			0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence		Total	0/50 0/200	` ,	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: 293

			Male			Female			
#Vagina: Squamous Cell Carcinoma						2/52 (221)			
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%	
#Vagina: Squamous Cell Papilloma									
						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma				•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 294

Report Date:11/19/2008

#### **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
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/03/02 06/25/02 05/08/00	728 730 729	50 (1) 50 (1) 50 (1)	37(682) 34(702) 39(710)	53.5 54.2 52.6	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/02/02 06/24/02 05/08/00	727 729 732	50 (1) 50 (1) 50 (1)	31(692) 33(693) 33(674)	60.8 60.9 65.7	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

# **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: 295

			Male				Female	
All Organs:								
Benign Tumors		44/50 (000/)	40/50 (000/)	00/50 (500/)		07/50 (540()	00/50 (700/)	05/50 /700/)
		41/50 (82%)	40/50 (80%)	29/50 (58%)		27/50 (54%)	39/50 (78%)	35/50 (70%)
verall Incidence	Total	110/150 (73.33%)	Mean 73.33%	SD 13.32%	Total	101/150 (67.33%)	Mean 67.33%	SD 12.22%
All Organs:								
Malignant Tumors		00/50 /500/)	07/50 (540/)	07/50 (540()		04/50 (000()	04/50 (000/)	00/50 /500/)
		26/50 (52%)	27/50 (54%)	27/50 (54%)		31/50 (62%)	31/50 (62%)	26/50 (52%)
verall Incidence	Total	80/150 (53.33%)	Mean 53.33%	SD 1.15%	Total	88/150 (58.67%)	Mean 58.67%	SD 5.77%
All Organs:								
Malignant and Benign Tur	mors							
		48/50 (96%)	45/50 (90%)	42/50 (84%)		44/50 (88%)	46/50 (92%)	47/50 (94%)
verall Incidence	Total	135/150 (90%)	Mean 90%	SD 6%	Total	137/150 (91.33%)	Mean 91.33%	SD 3.06%
All Organs:					• • • • • • • • • • • • • • • • • • • •			
Hemangioma								
_		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
All Organs:				•••••		•••••		
Hemangiosarcoma								
		5/50 (10%)	6/50 (12%)	0/50 (0%)		7/50 (14%)	1/50 (2%)	4/50 (8%)
verall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 6.43%	Total	12/150 (8%)	Mean 8%	SD 6%
		,				,		
All Organs:	_							
Hemangiosarcoma or Her	nangioma		0/=0 (4.004)	. (== (==()		2/22 (4.224)	. (=0 (00)	0/=0 (4004)
		7/50 (14%)	6/50 (12%)	1/50 (2%)		8/50 (16%)	1/50 (2%)	6/50 (12%)
verall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 6.43%	Total	15/150 (10%)	Mean 10%	SD 7.21%

<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 Report Date:11/19/2008

Page: 296

			Male				Female	
All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	1/50 (2%)	3/50 (6%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%
All Organs: Malignant Lymphoma: or Undifferentiated Cel		nphocytic, Mixed, NOS,	,					
		0/50 (0%)	1/50 (2%)	2/50 (4%)		9/50 (18%)	14/50 (28%)	10/50 (20%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	33/150 (22%)	Mean 22%	SD 5.29%
All Organs: Mesothelioma: Benign	, Malignant, NO	<b>S</b> 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%
All Organs: Mesothelioma: Maligna	ant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
All Organs:								
Osteoma								
- Colovina		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%
All Organs: Osteosarcoma		0/50 (00/)	0/50 (001)	0/50 (00/)		0/50 (40/)	4/50 (001)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 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**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 297

			Male	Female
#All Organs: Osteosarcoma or Osteoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	2/50 (4%) 1/50 (2%) 0/50 (0%)  Total 3/150 (2%) Mean 2% SD 2%
*Adrenal Cortex: Adenoma		6/49 (12%)	6/50 (12%) 5/50 (10%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	17/149 (11.41%)	6/50 (12%) 5/50 (10%) Mean 11.41% SD 1.23%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Adrenal Cortex: Sarcoma		(201)		
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 2/50 (4%) 0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0% SD 0%	Total 2/149 (1.34%) Mean 1.33% SD 2.31%
*Adrenal Medulla: Pheochromocytoma Comple		0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0% SD 0%	Total 0/149 (0%) Mean 0% SD 0%
*Adrenal Medulla: Pheochromocytoma Maligna	nnt	0/40 (004)	4/50 (00)	
Overall Incidence	Total	0/49 (0%) 1/148 (0.68%)	1/50 (2%) 0/49 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/49 (0%)  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

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:11/19/2008

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				Ma	ale						Fema	ale		
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  0/49 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%) 2/50 (4%) 0/49 (0%)														
verall Incidence	Total	0/49 1/148 (	(0%) (0.68%)		(2%) 0.67%	0/49 SD 1	` ,	Total	0/50 2/149 (*	` ,	2/50 Mear	(4%) າ 1.33%	0/49 SD	(0%) 2.31%
			` ,						`	,				
one Marrow: Hemangiosarcoma		4/50	(00/)	4/50	(00()	0/40	(00()		4/50	(00()	0/50	(00()	4/40	(00()
verall Incidence	Total	1/50 2/149 (	(2%)		(2%) 1.33%	0/49 SD 1	(0%)	Total	1/50 2/149 ( <i>°</i>	(2%)	0/50	(0%) າ 1.35%	1/49	(2%) 1.17%
	Total		,					Total	,	,			_	
Bone Marrow: Mast Cell Tumor Malignant														
	<b>.</b>	0/50	(0%)		(0%)		(0%)	<b>.</b>	0/50	(0%)	0/50	(0%)	0/49	(0%)
verall Incidence	Total	0/149 (	` ,	Mean		SD 0		Total	0/149 (0	,	Mear		SD	
Bone: Hemangiosarcoma		0/50	(0%)		(0%)		(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	0/50	` '	0/30 Mean	` '	0/30 SD 0	` '	Total	0/50	` ,	0/50 Mear	` '	0/30 SD	` ,
	Total	0/100 (		wican			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		0/100 (		IVICAI			
Bone: Osteoma														
		0/50	(0%)		(0%)		(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
verall Incidence	Total	0/150 (	(0%)	Mean	0%	SD 0	%	Total	0/150 (0	)%)	Mear	າ 0%	SD	0%
Bone: Osteosarcoma														
	<b>.</b>	0/50	(0%)		(0%)		(0%)	<b>.</b>	2/50	(4%)	1/50	(2%)	0/50	(0%)
verall Incidence	Total	0/150 (	(0%)	Mean	υ%	SD 0	%	Total	3/150 (2	2%)	Mear	า 2%	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: SKIN Vehicle: ETHANOL Report Date:11/19/2008

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			Male				Female	
#Bone: Osteosarcoma or Osteoma	1	0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%
Bone: Sarcoma	•••••							0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Benign		0/50 (00()	0/50 (00/)	0/40 /00/)		0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma Malignant	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Maliç	gnant, NOS							
overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Schwannoma Malignant		0/50 (0%)		0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	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

# **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: 300

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
Clitoral/Preputial Gland: Carcinoma		0/70 (004)	0/50 (004)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/40 /00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma					•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
litoral/Preputial Gland: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)		
verall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	0/50 (0%) Mean 0.67%	0/46 (0%) SD 1.15%
litoral/Preputial Gland: Hemangiosarcoma		0.50				-()		
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
litoral/Preputial Gland: Squamous Cell Carcinoma					•••••			
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (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

SKIN

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			Male			Female			
*Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%					
#Esophagus: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Eye: Sarcoma		1/50 (2%)	0/50 (0%)	1/50 (29/)		0/50 (0%)	0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Gallbladder: Adenoma		0/50 (0%)	0/49 (0%)	0/45 (0%)		0/50 (0%)	0/50 (0%)	0/42 (0%)	
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%	Total	0/142 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Adenoma					•••••				
Overall Incidence	Total	10/50 (20%) 26/150 (17.33%)	7/50 (14%) Mean 17.33%	9/50 (18%) SD 3.06%	Total	3/50 (6%) 18/150 (12%)	6/50 (12%) Mean 12%	9/50 (18%) SD 6%	
#Harderian Gland: Carcinoma			(004)		•••••		0/20 (10)	(20)	
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 (2%) SD 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**

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#Harderian Gland: Carcinoma or Adenoma		12/50 (24%)	7/50 (14%) 10/50 (20%)	3/50 (6%) 8/50 (16%) 10/50 (20%)
Overall Incidence	Total	29/150 (19.33%)	Mean 19.33% SD 5.03%	Total 21/150 (14%) Mean 14% SD 7.21%
#Harderian Gland: Sarcoma	•••••			0/50 (00/) 0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Heart: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Heart: Hemangiosarcoma	•••••	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%
*Heart: Sarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Cecum: Carcinoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Leiomyoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)SD 0% **Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Intestine Large: Cecum: Polyp Adenomatous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Leiomyosarcoma 0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/150 (0%) Mean 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) SD 0% #Intestine Small: Duodenum: Adenoma (0%) 0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Intestine Small: Duodenum: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total 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

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Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Duodenum: 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: Polyp Adenomatous		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	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								(20)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: 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%
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: 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%

<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: 305

			Male				Female	
Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Hemangiosarcoma	•••••	0(50 (00))	0/50 (00/)	0/50 (00/)	••••	0/50 (00/)	0/50 (00/)	0/50 (00/)
	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%
Intestine Small: Jejunum: Leiomyosarcoma								
		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%
Intestine Small: Jejunum: Polyp Adenomatous		0/50 (0%)	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	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%
veran incluence		,	Mean 076	30 0%	ı Olai	0/130 (0/8)	Weall 076	3D 0%
Intestine Small: Site Unspecifie Adenoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Intestine Small: Site Unspecifie Carcinoma	d:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/19/2008

SD 0%

Mean 0%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female #Intestine Small: Site Unspecified: Carcinoma or Adenoma (0%)(0%)(2%)(0%)0/50 (0%)(2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Intestine Small: Site Unspecified: Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #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 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Polyp Adenomatous 0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Islets, Pancreatic: Adenoma (0%)0/50 (0%)1/49 (2%)0/50 (0%)(2%)0/50 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 1/150 (0.67%) Mean 0.67% SD 1.15% \*Islets, Pancreatic: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Mean 0%

0/150 (0%)

Total

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

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

: SKIN

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			Male			Female			
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	4/40 (00/)		0/50 (00/)	4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
*Kidney: Renal Tubule: Adenoma	•••••	0/50 (00)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
*Kidney: Renal Tubule: Carcinoma	•••••	0/50 (00)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
Kidney: Renal Tubule: Hemangiosarcoma		(00)	(00)		•••••		(004)	(00)	
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
*Liver: Cholangiocarcinoma	•••••	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%	

<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: 308

			Male		Female	
Liver: Fibrous Histiocytoma		0/50 (00()	0/50 (0%) 0/50	(00/)	0/50 (00/) 4/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 1/50 (2%) 1/150 (0.67%) Mean 0.67%	0/50 (0%) SD 1.15%
Liver: Hemangioma	•••••	0/50 (00())	0/50 /00/) 0/50	(00()	0/50 (00/) 0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
.iver: Hemangiosarcoma		4/50 (00/)	4/50 (00)	(001)	0/50 (44) 4/50 (53)	
verall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) 0/50 Mean 1.33% SD	(0%) 1.15% Total	2/50 (4%) 1/50 (2%) 4/150 (2.67%) Mean 2.67%	1/50 (2%) SD 1.15%
.iver: Hepatoblastoma					0/50 (00/) 4/50 (00/)	
verall Incidence	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) 0/50 Mean 2.67% SD	(0%) 2.31% Total	0/50 (0%) 1/50 (2%) 1/150 (0.67%) Mean 0.67%	0/50 (0%) SD 1.15%
iver: Hepatocellular Adenoma						
verall Incidence	Total	33/50 (66%) 86/150 (57.33%)	35/50 (70%) 18/50 Mean 57.33% SD	(36%) 18.58% Total	22/50 (44%) 31/50 (62%) 74/150 (49.33%) Mean 49.33%	21/50 (42%) SD 11.02%
Liver: Hepatocellular Carcinoma					0/50 (00) 0/50 (400)	
Overall Incidence	Total	14/50 (28%) 51/150 (34%)	17/50 (34%) 20/50 Mean 34% SD	(40%) 6% Total	3/50 (6%) 8/50 (16%) 21/150 (14%) Mean 14%	10/50 (20%) SD 7.21%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: ETHANOL

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:11/19/2008

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Carcinoma	or Hepatobl	astoma 15/50 (30%)	19/50 (38%)	20/50 (40%)		3/50 (6%)	9/50 (18%)	10/50 (20%)
Overall Incidence	Total	54/150 (36%)	Mean 36%	SD 5.29%	Total	22/150 (14.67%)	Mean 14.67%	SD 7.57%
*Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma 40/50 (80%)	41/50 (82%)	35/50 (70%)		22/50 (44%)	32/50 (64%)	29/50 (58%)
Overall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 6.43%	Total	83/150 (55.33%)	Mean 55.33%	SD 10.26%
*Liver: Hepatocellular Carcinoma Hepatoblastoma	, Hepatocelli	·	(0.00)					
Overall Incidence	Total	40/50 (80%) 116/150 (77.33%)	41/50 (82%) Mean 77.33%	35/50 (70%) SD 6.43%	Total	22/50 (44%) 83/150 (55.33%)	32/50 (64%) Mean 55.33%	29/50 (58%) SD 10.26%
*Liver: Hepatocholangiocarcinom	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 310

			Male			Female			
*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: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 /00/	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Lung: Alveolar/Bronchiolar Ac	lenoma	G/EQ /429/\	10/50 (20%)	6/F0 (139/)	•••••	4/50 (29/)	2/50 //2/\	A/EO (99/\	
Overall Incidence	Total	6/50 (12%) 22/150 (14.67%)	10/50 (20%) Mean 14.67%	6/50 (12%) SD 4.62%	Total	1/50 (2%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	4/50 (8%) SD 3.06%	
Lung: Alveolar/Bronchiolar Ca	ırcinoma	F/F0 (400/)	0/50 (400/)	0/50 (494)	•••••	4/50 (00()	2/50 /(20/)	0/50 /00/	
Overall Incidence	Total	5/50 (10%) 13/150 (8.67%)	6/50 (12%) Mean 8.67%	2/50 (4%) SD 4.16%	Total	4/50 (8%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	0/50 (0%) SD 4.16%	
Lung: Alveolar/Bronchiolar Ca Adenoma		veolar/Bronchiolar			•••••				
Overall Incidence	Total	11/50 (22%) 34/150 (22.67%)	15/50 (30%) Mean 22.67%	8/50 (16%) SD 7.02%	Total	5/50 (10%) 14/150 (9.33%)	5/50 (10%) Mean 9.33%	4/50 (8%) SD 1.15%	
Lung: Fibrosarcoma	•••••	0/50 (0%)	0/50 (09/)	0/50 (09()	•••••	0/50 (00()	0/50 /09/	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

<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: 311

			Male				Female	
*Lung: Fibrous Histiocytoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	4/50 (00/)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma		0/50 (0%)	0/50 (09/)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (09/)
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%
#Lymph Node: Fibrous Histiocytoma		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%
#Lymph Node: Hemangioma		0/50 (00/)	0/50 /00//	0/50 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (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

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			Male				Female	
#Lymph Node: 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%
#Lymph Node, Bronchial: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Lymph Node, Mandibular: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant	•••••							
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%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
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%)	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

# **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: 313

			Male				Female	
Lymph Node, Mesenteric: Hemangioma								
		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%
_ymph Node, Mesenteric: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma			- 1 1					
		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%
lammary Gland: 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%
lammary Gland: Carcinoma					•••••			
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%
Mammary Gland: Carcinoma or Adenoma		4/50 (00/)	0/50 (00)	4/50 (00)		0/50 /40/	0/50 (00)	4/50 (00)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	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: SKIN Vehicle: ETHANOL Report Date:11/19/2008

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			Male				Female	
Mammary Gland: Fibroadenoma								
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%
 Mammary Gland: Fibroma, Fibroadenoma	ı or Adenoma					•••••		
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%
Mammary Gland: Fibroma, Fibroadenoma verall Incidence	n, Carcinoma, c	or Adenoma 1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
Mesentery: Fibrosarcoma	•••••		0/50 (00/)				0/50 (0%)	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%
lesentery: Hemangioma	••••							
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Hemangiosarcoma		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%)	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%

<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: 315

			Male				Female	
#Mesentery: Sarcoma		0/50 (00/)	0/50 (0%)	0/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
overall illiciaence	I Olai	0/130 (0/6)	IVICALI U/0	30 0%	I Olai	1/130 (0.07/8)	Weatt 0.07 /6	30 1.13%
Nose: Hemangioma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Verali ilicidelice	I Olai	0/149 (076)	Mean 076	30 0%	I Olai	0/130 (0%)	Weatt 076	3D 0%
Nose: Mast Cell Tumor Maligna	ınt	0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total	,		3D 0%	Total	0/130 (0%)	Medii 0%	SD 0%
Oral Cavity (Oral Mucosa, T Papilloma Squamous or	ongue, Phary	, , ,		0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,	Weatt 0%	3D 0%
Oral Cavity (Oral Mucosa, T Squamous Cell Carcinon	ongue, Phary					•••••	•••••	
•		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 Mucosa, T Squamous Cell Carcinon Papilloma	ongue, Phary	Squamous, or						
	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%
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

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Oral Mucosa: Squamous Cell Carcinoma	a	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%
*Ovary: Choriocarcinoma								0/40 /00/
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	2/50 (4%) 6/149 (4.03%)	3/50 (6%) Mean 4.01%	1/49 (2%) SD 1.98%
*Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%
*Ovary: Granulosa Cell Tumor Ber	nign							
Overall Incidence					Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%
*Ovary: Granulosa Cell Tumor Mal								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (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: 317

Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%
*Ovary: Hemangioma				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Hemangiosarcoma				
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%
*Ovary: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Luteoma				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Teratoma Benign				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (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

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			Male				Female	
*Ovary: Teratoma Malignant						0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/149 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma		0/50 (0%)	0/50 (0%)	0/49 (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%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pituitary Gland: Pars Distalis Adenoma	or Unspecif	fied Site:						
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/50 (0%) Mean 0.67%	0/48 (0%) SD 1.15%	Total	4/49 (8%) 13/147 (8.84%)	5/50 (10%) Mean 8.83%	4/48 (8%) SD 1.01%

<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: 319

Report Date:11/19/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Pituitary Gland: Pars Distalis	or Unspecif	ied Site:						
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/49 (0%) 1/147 (0.68%)	0/50 (0%) Mean 0.69%	1/48 (2%) SD 1.2%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma		ied Site:	0/50 (00)	0/40 (00/)		4/40 (00/)	5/50 (400)	5/40 /400()
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/50 (0%) Mean 0.67%	0/48 (0%) SD 1.15%	Total	4/49 (8%) 14/147 (9.52%)	5/50 (10%) Mean 9.53%	5/48 (10%) SD 1.2%
*Pituitary Gland: Pars Interme Adenoma								
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/50 (0%) Mean 0.67%	0/48 (0%) SD 1.15%	Total	0/49 (0%) 1/147 (0.68%)	1/50 (2%) Mean 0.67%	0/48 (0%) SD 1.15%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:	1/50 (2%)	0/50 (0%)	0/48 (0%)	•••••	0/49 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
*Prostate: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Prostate: Carcinoma or Adenoma		0(50 (00))	0/50 (00)	0/50 (00)	•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

<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: 320

			Male				Female	
Prostate: Hemangioma		4/50 (00/)	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%				
Salivary Glands: Carcinoma	• • • • • • • • • • • • • • • • • • • •	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Salivary Glands: Carcinoma or Adenoma								
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%
alivary Glands: 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%
Seminal Vesicle: Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%				
Skeletal Muscle: Fibrosarcoma								0/50 (0%)
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

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: SKIN Strain: B6C3F1 Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 321

			Male				Female	
Skeletal Muscle: 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%
Skeletal Muscle: Myxosarcoma		0.50	(00)				(00)	
		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%
Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (09/)	1/50 (2%)		0/50 (0%)	0/50 (09/)	0/50 (09/)
N	T-1-1	` '	0/50 (0%)		T-1-1	` ,	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	thabdomyom	a						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma		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%
veran incluence	ı Ulai	0/100 (0%)	iviean 070	3D U%	I Ulal	0/100 (0%)	iviean 0%	3D 0%
Skin: Basal Cell Adenoma or B	asosquamou							
	-	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%

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Page: 322

Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female				
#Skin: Basal Cell Adenoma, B Trichoepithelioma	asosquamous <sup>·</sup>	Tumor Benign, or							
Trichoephnehoma		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		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: Basal Cell Carcinoma o NOS)				0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign	Basal Cell Ader	noma, Basosquamous	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence	Basal Cell Ader ant or NOS), or Total	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign Overall Incidence	Basal Cell Ader ant or NOS), or Total noma, Carcinon oma, Adenoma,	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign: Overall Incidence  #Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adence	Basal Cell Ader ant or NOS), or Total noma, Carcinon oma, Adenoma,	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign)  Overall Incidence  #Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adency Papilloma, Keratoacant	Basal Cell Ader ant or NOS), or Total noma, Carcinon ma, Adenoma, thoma, Trichoe	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)	Total	0/50 (0%) 1/150 (0.67%) 0/50 (0%)	1/50 (2%) Mean 0.67% 1/50 (2%)	0/50 (0%) SD 1.15% 0/50 (0%)	
#Skin: Basal Cell Carcinoma, Tumor (benign, malign: Overall Incidence  #Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adence	Basal Cell Ader ant or NOS), or Total noma, Carcinon oma, Adenoma, thoma, Trichoe	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)	Total	0/50 (0%) 1/150 (0.67%) 0/50 (0%)	1/50 (2%) Mean 0.67% 1/50 (2%)	0/50 (0%) SD 1.15% 0/50 (0%)	

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 323

Report Date:11/19/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Fibroma		2/20 (201)	(201)			2(72 (224)	2(72 (224)	2/20 (201)
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: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, Myz	xoma, Myxosarcoma, o	r					
•		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
	Total	` ,			Total	` ,		
Skin: Fibrosarcoma, Sarcoma, I Histiocytoma	Myxosarcom	a, or Fibrous						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin: Fibrous Histiocytoma		0(50 (00/)	0(50 (00))	0/50 (00/)		0(50 (004)	0/50 (00/)	0(50 (00))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,		
∜Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
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%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
Jveran meluence	i otai	0/100 (0/0)	IVICALL 070	OD 0/0	iotai	2/100 (1.00/0)	ivicali 1.55/0	OD 2.3170

<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: 324

Report Date:11/19/2008

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Skin: Liposarcoma		2(72 (224)	- ( ( ( ( ( ( ( ( ( (	0(50)		2(22)	- ( ( ( ( ( ( ( ( ( (	(20)
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: Myxosarcoma		0/50 /00/	0/50 (00()	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or Sc	:hwannoma (	malignant or NOS)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%
#Skin: Neurofibrosarcoma, Neur malignant or NOS)	rofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%

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

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

# Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 325

			Male				Female	
Skin: Osteosarcoma								
		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: Sarcoma		- ()				- 4		
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
verali ilicidence	Total	0/130 (0/8)	ivieaii 070	30 0%	I Olai	1/130 (0.07/8)	Weall 0.07 /6	3D 1.13%
Skin: Schwannoma Malignant	t		(00)	(00)			(00)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
Skin: Squamous Cell Carcino	ma							
		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: Squamous Cell Carcino Basosquamous Tumor (			0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Squamous Cell Papillon	na	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%
, voi aii illoidellee	i Otal	3/130 (0/0)	WCair 070	OD 070	iotai	3/130 (0/0)	MCail 070	OD 070

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Page: 326

Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Squamous Cell Papillo	ma or Papillom	a 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 Papillo Carcinoma or Keratoac		Squamous Cell			•••••			
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: Squamous Cell Papillo	ma, Papilloma,	or Keratoacanthoma 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: Trichoepithelioma		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: Sebaceous Gland: 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%
Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (00%)	0/50 /00/		0/50 (00/)	0/50 /00/	0/50 (00/)
			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

<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

Vehicle: ETHANOL

r Selected Control Animal Groups

Route: SKIN

Page: 327

Report Date:11/19/2008

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

Length of Study: CHRONIC

			Male	Female
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (001)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Spinal Cord: Meningioma Malignant				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%) 0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	Total 1/149 (0.67%) Mean 0.67% SD 1.15%
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	Total 0/149 (0%) Mean 0% SD 0%
*Spleen: Hemangiosarcoma			4/50 (00) 040 (00)	
Overall Incidence	Total	3/50 (6%) 4/149 (2.68%)	1/50 (2%) 0/49 (0%) Mean 2.67% SD 3.06%	5/50 (10%) 0/50 (0%) 1/49 (2%) Total 6/149 (4.03%) Mean 4.01% SD 5.28%
#Stomach, Forestomach: 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%

<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

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			Male				Female				
#Stomach, Forestomach: Squamous Cell Carcinoma											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Overall incluence	I Olai	0/150 (0%)	iviean 0%	30 0%	I Ulai	0/150 (0%)	iviean 0%	30 0%			
#Stomach, Forestomach:	or Donillon	ma Caucamaua									
Squamous Cell Carcinoma	or Papillon	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%			
#Stomach, Forestomach: Squamous Cell Papilloma											
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%			
#Stomach, Glandular: 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%			
#Stomach, Glandular: 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%			
#Stomach, Glandular:					•••••						
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

Route: SKIN Vehicle: ETHANOL Page: 329

	Male					Female			
*Testes:									
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%					
*Testes:									
Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign									
Overall Incidence	Total	0/49 (0%) 0/143 (0%)	0/47 (0%) Mean 0%	0/47 (0%) SD 0%	Total	0/50 (0%) 0/143 (0%)	0/47 (0%) Mean 0%	0/46 (0%) SD 0%	
*Thymus: Thymoma Malignant									
Overall Incidence	Total	0/49 (0%) 1/143 (0.7%)	1/47 (2%) Mean 0.71%	0/47 (0%) SD 1.23%	Total	0/50 (0%) 1/143 (0.7%)	1/47 (2%) Mean 0.71%	0/46 (0%) SD 1.23%	
*Thymus: Thymoma: Benign, Maligi	nant, NOS								
Overall Incidence	Total	0/49 (0%) 1/143 (0.7%)	1/47 (2%) Mean 0.71%	0/47 (0%) SD 1.23%	Total	0/50 (0%) 1/143 (0.7%)	1/47 (2%) Mean 0.71%	0/46 (0%) SD 1.23%	
*Thyroid Gland: Adenoma		0/50 (00()	0/50 (00)			0/50 (00)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (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: SKIN Vehicle: ETHANOL Page: 330

	Male					Female			
Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	0/40 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		` '							
Thyroid Gland: Follicular Cell: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	
overall incluence		` ,		30 0%	IUlai	3/130 (2%)	iviean 270	3D 3.40%	
Thyroid Gland: Follicular Cell: Carcinoma									
huanali lu alidanaa	Tatal	1/50 (2%)	0/50 (0%)	0/49 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Гhyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
verall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 3.46%	
Tissue NOS: Carcinoma		0/50 (00)	0/50 (00)	0(50 (00))	•••••	0/50 (00/)	0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

**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: 331

			Male				Female	
#Tissue NOS: Hemangiosarcoma		0/50 /00/\	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: 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%
#Tongue: Squamous Cell Carcinoma	a	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 Carcinoma	a or Papillon	na Squamous 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%
#Tooth: Odontoma		4/50 (00()	0/50 (0%)	0/50 /00/		0/50 (00/)	0/50 /00/	0/50 /00/)
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%

<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: 332

Report Date:11/19/2008

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female				
*Urinary Bladder: Hemangioma									
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%	
Urinary Bladder: 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%	
Urinary Bladder: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Uterus:		•••••						•••••	
Carcinoma  Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Uterus: Hemangioma						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (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: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 333 Report Date:11/19/2008

	Male			Female	
#Uterus: Hemangiosarcoma					
nemangiosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus:					
Leiomyoma			0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus:					
Leiomyosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
			` ,		
#Uterus:					
Polyp Stromal			(201)	. (=0.1)	
Overall Incidence		Total	0/50 (0%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	4/50 (8%) SD 4.16%
Overall incluence		TOtal	5/150 (5.55%)	Weall 3.33%	3D 4.10%
			•••••		
#Uterus: Sarcoma Stromal					
ourooma ouromar			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus:					
Sarcoma Stromal or Polyp Stromal			0/50 (0%)	1/50 (2%)	4/50 (8%)
Overall Incidence		Total	5/150 (3.33%)	Mean 3.33%	4/30 (6%) SD 4.16%
		- <del></del>			

<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

Poutor SKIN

Page: 334

Report Date:11/19/2008

Strain: B6C3F1 Length of Study: CHRONIC Route: SKIN Vehicle: ETHANOL

		Male					Female			
Uterus: Schwannoma Malignant						0/50 (0%)	0/50 (0%)	0/50 (0%)		
overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		
Vagina: Squamous Cell Carcinoma										
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
/agina: Squamous Cell Papilloma						0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%		
'ymbal's Gland: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	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%		
Zymbal's Gland: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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