

NTP Historical Controls Report

By Route and Vehicle

MICE

March 2010

REPORT DESCRIPTION

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

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

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

Male
M1
M2
М3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

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

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

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

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Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 4

Report Date: 03/22/2010

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/09/02 08/24/04 04/11/02 04/15/03 02/04/03	728 730 728 730 728	50(1) 50(1) 50(1) 50(1) 50(1)	39(688) 34(689) 34(692) 38(691) 35(702)	56.7 56.4 56.2 56.6 52.7	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene
					Female		
Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/08/02 08/23/04 04/10/02 04/14/03 02/03/03	727 729 727 729 731	49(5) 50(5) 50(5) 49(5) 50(5)	34(679) 38(695) 39(705) 35(705) 35(675)	65.0 66.2 64.1 64.9 63.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		33/50 (66%) 30/50 (60%)	34/50 (68%) 30/50 (60%)	33/50 (66%)		20/49 (41%) 27/49 (55%)	26/50 (52%) 24/50 (48%)	21/50 (42%)
Overall Incidence	Total	160/250 (64%)	Mean 64%	SD 3.74%	Total	118/248 (47.58%)	Mean 47.58%	SD 6.19%
#All Organs: Malignant Tumors								
		20/50 (40%) 19/50 (38%)	32/50 (64%) 28/50 (56%)	30/50 (60%)		21/49 (43%) 20/49 (41%)	19/50 (38%) 13/50 (26%)	14/50 (28%)
Overall Incidence	Total	129/250 (51.6%)	Mean 51.6%	SD 11.87%	Total	87/248 (35.08%)	Mean 35.13%	SD 7.66%
#All Organs: Malignant and Benign To								
		43/50 (86%) 38/50 (76%)	47/50 (94%) 41/50 (82%)	43/50 (86%)		34/49 (69%) 40/49 (82%)	39/50 (78%) 29/50 (58%)	30/50 (60%)
Overall Incidence	Total	212/250 (84.8%)	Mean 84.8%	SD 6.57%	Total	172/248 (69.35%)	Mean 69.4%	SD 10.51%
#All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	4/248 (1.61%)	Mean 1.61%	SD 1.68%
#All Organs: Hemangiosarcoma								
		3/50 (6%) 3/50 (6%)	6/50 (12%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 3/49 (6%)	1/50 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	22/250 (8.8%)	Mean 8.8%	SD 3.9%	Total	6/248 (2.42%)	Mean 2.43%	SD 2.24%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Route: GAVAGE

Contract/Lab: All Laboratories

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

Length of Study: CHRONIC

Page: 6

			Male				Female	
#All Organs: Hemangiosarcoma or H	lemangioma							
		3/50 (6%) 3/50 (6%)	8/50 (16%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 4/49 (8%)	1/50 (2%) 1/50 (2%)	3/50 (6%)
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.98%	Total	10/248 (4.03%)	Mean 4.04%	SD 2.88%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 3/49 (6%)	3/50 (6%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	7/248 (2.82%)	Mean 2.82%	SD 3.07%
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 5/250 (2%)	2/50 (4%) 1/50 (2%) Mean 2%	1/50 (2%) SD 1.41%	Total	11/49 (22%) 6/49 (12%) 32/248 (12.9%)	6/50 (12%) 2/50 (4%) Mean 12.94%	7/50 (14%) SD 6.57%
#All Organs:			Wedit 270	05 1.4170		02/240 (12.070)	Wedi 12.0470	GD 6.6770
Mesothelioma: Benign,	Malignant, NOS	S 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%)	
Overall Incidence	Total	` ,	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
	•••••	0/50 (0%)	` ,	SD 0%	Total	()	` ,	SD 0%
Overall Incidence #All Organs: Mesothelioma: Maligna Overall Incidence	•••••	0/50 (0%)	` ,	SD 0% 0/50 (0%) SD 0%	Total	()	` ,	SD 0% 0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

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

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: 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%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#All Organs: Osteosarcoma or Oste								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Adrenal Cortex:				•••••				•••••
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/50 (2%) 9/250 (3.6%)	3/50 (6%) Mean 3.6%	SD 2.61%	Total	1/49 (2%) 2/246 (0.81%)	0/49 (0%) Mean 0.81%	SD 1.11%
Adrenal Cortex: Plasma Cell Tumor Mal	lignant							
	J	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/246 (0%)	0/49 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enign							
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma	alignant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%
Adrenal Medulla: Pheochromocytoma: B	enign, Complex	, Malignant, NOS						
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/246 (0.81%)	Mean 0.82%	SD 1.12%
*Bone Marrow: Hemangioma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 9

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** *Bone Marrow: Hemangiosarcoma 0/50 (0%)2/50 (4%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)1/247 (0.4%) Overall Incidence Total 2/250 (0.8%) Mean 0.8% SD 1.79% Total Mean 0.41% SD 0.91% *Bone Marrow: **Plasma Cell Tumor Malignant** (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/48 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (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%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% #Bone: Osteoma 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%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% #Bone: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/49 0/50 (0%)0/50 (0%)

SD 0%

0/49

1/248 (0.4%)

Total

(0%)

0/50

(0%)

SD 0.91%

Mean 0.41%

Total

0/50

0/250 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
#Bone: Osteosarcoma or Osteoma	ı							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maliç	ınant, NOS							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/247 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/241 (0.41%)	Mean 0.41%	SD 0.91%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/241 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/241 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 12

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
#Esophagus: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		8/50 (16%) 6/50 (12%)	5/50 (10%) 6/50 (12%)	9/50 (18%)		3/49 (6%) 7/49 (14%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
Overall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	33/248 (13.31%)	Mean 13.28%	SD 8.77%
#Harderian Gland: Carcinoma								
		4/50 (8%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		1/49 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%	Total	2/248 (0.81%)	Mean 0.82%	SD 1.12%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 13

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%) 7/50 (14%)	5/50 (10%) 6/50 (12%)	9/50 (18%)		4/49 (8%) 8/49 (16%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
Overall Incidence	Total	39/250 (15.6%)	Mean 15.6%	SD 5.55%	Total	35/248 (14.11%)	Mean 14.1%	SD 8.48%
#Harderian Gland: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Heart: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
'Heart: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
fIntestine Small: Duodenum: Carcinoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female	
#Intestine Small: Duodenum: Leiomyosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (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%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female	
#Intestine Small: Jejunum: Adenoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89	9% Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Jejunum: Carcinoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 2/50 (4%)	(0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2% SD 1.79	9% Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Jejunum: Hemangiosarcoma							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89	9% Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 09	% Total	0/248 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma							
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79	9% Total	l 2/248 (0.81%)	Mean 0.8%	SD 1.79%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
#Intestine Small: Site Uns Carcinoma	specified:							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Uns Carcinoma or Adenoma	•							
		0/50 (0%) 0/50 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.83%	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%
Intestine Small: Site Uns Hemangiosarcoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Leiomyosarcoma	specified:							
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
fintestine Small: Site Uns Polyp Adenomatous	specified:							
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18 Report Date: 03/22/2010

Mean 0.41%

Mean 0%

(0%)

(0%)

0/50

0/49

SD 0.91%

SD 0%

(0%)

0/50

			Male				Female	
*Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	3/245 (1.22%)	Mean 1.22%	SD 1.82%
*Kidney: Renal Tubule: Adenoma		•••••						
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)

SD 1.1%

0/50

SD 0%

(0%)

Total

Total

1/245 (0.41%)

(0%)

(0%)

0/47

0/49

0/245 (0%)

Total

Total

3/250 (1.2%)

0/50

0/50

0/250 (0%)

(0%)

(0%)

Mean 1.2%

(0%)

(0%)

0/50

0/50

Mean 0%

Overall Incidence

Overall Incidence

*Kidney: Renal Tubule: Carcinoma

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Kidney: Renal Tubule: Hemangioma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: GAVAGE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Vehicle: CORN OIL

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			Male				Female	
Liver: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
_iver: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
		0/230 (0/0)				0/247 (0 /0)		
Liver: Hemangiosarcoma								
		1/50 (2%)	5/50 (10%)	5/50 (10%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 12/250 (4.8%)	1/50 (2%) Mean 4.8%	SD 4.82%	Total	0/49 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0.4%	SD 0.89%
	10tai	12/230 (4.676)	4.0 /6			1/247 (0.476)		
Liver: Hepatoblastoma								
		3/50 (6%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	4/50 (8%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	10/250 (4%)	Mean 4%	SD 3.16%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
•		24/50 (48%) 22/50 (44%)	27/50 (54%) 22/50 (44%)	26/50 (52%)		11/49 (22%) 13/49 (27%)	8/50 (16%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	121/250 (48.4%)	Mean 48.4%	SD 4.56%	Total	41/247 (16.6%)	Mean 16.62%	SD 8.13%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male				Female	
Liver: Hepatocellular Carcino	ma							
		8/50 (16%) 13/50 (26%)	20/50 (40%) 17/50 (34%)	14/50 (28%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	72/250 (28.8%)	Mean 28.8%	SD 9.01%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%
*Liver: Hepatocellular Carcino	ma or Hepatobl	lastoma						
•		11/50 (22%) 13/50 (26%)	20/50 (40%) 19/50 (38%)	16/50 (32%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	79/250 (31.6%)	Mean 31.6%	SD 7.67%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%
*Liver: Hepatocellular Carcinol Overall Incidence	ma or Hepatoce	ellular Adenoma 28/50 (56%) 29/50 (58%) 162/250 (64.8%)	38/50 (76%) 34/50 (68%) Mean 64.8%	33/50 (66%) SD 8.07%	Total	13/49 (27%) 17/49 (35%) 51/247 (20.65%)	10/50 (20%) 4/49 (8%) Mean 20.68%	7/50 (14%) SD 10.4%
Liver: Henatocellular Carcino	ma Henatocelli	ular Adenoma, or Hepatok	olastoma					
riopatoconaia: caronio	ma, riopatocom	30/50 (60%) 29/50 (58%)	38/50 (76%) 34/50 (68%)	34/50 (68%)		13/49 (27%) 17/49 (35%)	10/50 (20%) 4/49 (8%)	7/50 (14%)
		20/00 (00/0)	, ,					
Overall Incidence	Total	165/250 (66%)	Mean 66%	SD 7.21%	Total	51/247 (20.65%)	Mean 20.68%	SD 10.4%
		165/250 (66%)			Total			
Overall Incidence *Liver: Hepatocholangiocarcin		` ,	Mean 66% 4/50 (8%) 1/50 (2%)	SD 7.21% 	Total	51/247 (20.65%) 0/49 (0%) 0/49 (0%)	Mean 20.68% 0/50 (0%) 0/49 (0%)	SD 10.4% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22

			Male				Female	
Liver: Hepatocholangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignan								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Plasma Cell Tumor Mali	gnant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 23 Report Date: 03/22/2010

			Male				Female	
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A	denoma							
		6/50 (12%) 6/50 (12%)	9/50 (18%) 5/50 (10%)	8/50 (16%)		4/48 (8%) 1/49 (2%)	2/50 (4%) 3/49 (6%)	4/50 (8%)
Overall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	14/246 (5.69%)	Mean 5.7%	SD 2.68%
Lung: Alveolar/Bronchiolar C								
		2/50 (4%) 3/50 (6%)	2/50 (4%) 3/50 (6%)	5/50 (10%)		0/48 (0%) 2/49 (4%)	2/50 (4%) 0/49 (0%)	2/50 (4%)
Overall Incidence	Total	15/250 (6%)	Mean 6%	SD 2.45%	Total	6/246 (2.44%)	Mean 2.42%	SD 2.21%
Lung: Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar Adeno	ma					
		7/50 (14%) 9/50 (18%)	11/50 (22%) 7/50 (14%)	13/50 (26%)		4/48 (8%) 3/49 (6%)	4/50 (8%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	47/250 (18.8%)	Mean 18.8%	SD 5.22%	Total	20/246 (8.13%)	Mean 8.12%	SD 2.4%
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24

			Male				Female	
Lung: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig								
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data M

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%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Malig								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
#Lymph Node, Mandibular: Fibrous Histiocytoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Malignar	nt							
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (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%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
#Lymph Node, Mesenteric: Hemangioma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Adenoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/248 (0.4%)	0/50 (0%) Mean 0.41%	SD 0.91%
#Mammary Gland: Carcinoma or Adenoma	a							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Fibroadenoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma						
·	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29 Report Date: 03/22/2010

			Male				Female	
#Mesentery: Fibrosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mesentery: Hemangioma								
		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%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
fMesentery: Hemangiosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Papilloma Squamous or Papilloma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%			
Oral Cavity (Oral Mucos Squamous Cell Carcing	sa, Tongue, Phar	ynx, Tooth, Gingiva):									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%			
Squamous Cell Carcino	oma, Papilloma S	Squamous, or Papilloma 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/50 (0%)			
Squamous Cell Carcino	oma, Papilloma 🤄	-									
	oma, Papilloma S	-	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Overall Incidence 		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total	0/49 (0%)	0/50 (0%)	,			
Squamous Cell Carcing Overall Incidence *Ovary: Choriocarcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total	0/49 (0%)	0/50 (0%)	,			
Overall Incidence *Ovary: Choriocarcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	,	Total Total	0/49 (0%) 0/248 (0%) 0/48 (0%)	0/50 (0%) Mean 0% 0/49 (0%)	SD 0%			
Overall Incidence *Ovary: Choriocarcinoma Overall Incidence		0/50 (0%) 0/50 (0%)	0/50 (0%)	,		0/49 (0%) 0/248 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/49 (0%) 0/49 (0%)	SD 0% 0/50 (0%)			
Overall Incidence *Ovary: Choriocarcinoma Overall Incidence *Ovary:		0/50 (0%) 0/50 (0%)	0/50 (0%)	,		0/49 (0%) 0/248 (0%) 0/48 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/49 (0%) 0/49 (0%)	SD 0% 0/50 (0%)			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
*Ovary: Fibrous Histiocytoma				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
	I Olal	` '		
*Ovary: Granulosa Cell Tumor Benign				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Insidence	Total	1/49 (2%)	0/49 (0%)	CD 0.040/
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Ovary: Granulosa Cell Tumor Malignant				
-		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
*Ovary: Hemangioma				
		0/48 (0%) 1/49 (2%)	0/49 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.82%	SD 1.12%
		• •		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32

Male			Female	
Ovary:				
Hemangiosarcoma				
		0/48 (0%)	0/49 (0%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	00.000
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%
Ovary: Leiomyosarcoma				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	. ,
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
			•••••	
Ovary: Luteoma				
		0/48 (0%)	1/49 (2%)	1/50 (2%)
		0/49 (0%)	0/49 (0%)	
overall Incidence	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%
Ovary: Plasma Cell Tumor Malignant				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	,
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign				
•		0/48 (0%)	0/49 (0%)	0/50 (0%)
		0/49 (0%)	1/49 (2%)	. ,
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 33

			Male				Female	
*Ovary: Teratoma Malignant								
						0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence					Total	0/245 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
						0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence					Total	0/245 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Species: MICE
Strain: B6C3F1

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

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma											
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		4/47 (9%) 2/49 (4%)	2/50 (4%) 1/49 (2%)	1/50 (2%)			
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%			
*Pituitary Gland: Pars Dis Carcinoma											
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Dis Carcinoma or Adenom	•		0/49 (0%)	0/49 (0%)		4/47 (Q9/L)	2/50 (4%)	1/50 (2%)			
*Pituitary Gland: Pars Dis	•	0/50 (0%)	0/49 (0%)	0/49 (0%)		4/47 (9%)	2/50 (4%)	1/50 (2%)			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence	a Total		0/49 (0%) 0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	4/47 (9%) 2/49 (4%) 10/245 (4.08%)	2/50 (4%) 1/49 (2%) Mean 4.13%	1/50 (2%) SD 2.65%			
*Pituitary Gland: Pars Dis	a Total	0/50 (0%) 0/50 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	2/49 (4%) 10/245 (4.08%)	1/49 (2%) Mean 4.13%	SD 2.65%			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int	a Total	0/50 (0%) 0/50 (0%)	0/49 (0%)	(,	Total	2/49 (4%)	1/49 (2%)	,			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence 	Total eermedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0% 1/49 (2%)	SD 0%	Total Total	2/49 (4%) 10/245 (4.08%) 0/47 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%)	SD 2.65%			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int Adenoma	Total termedia: Total termedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) Mean 0% 1/49 (2%) 0/49 (0%)	SD 0% 0/49 (0%)		2/49 (4%) 10/245 (4.08%) 0/47 (0%) 0/49 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%) 0/49 (0%)	SD 2.65% 0/50 (0%)			
*Pituitary Gland: Pars Dis Carcinoma or Adenoma Overall Incidence *Pituitary Gland: Pars Int Adenoma Overall Incidence *Pituitary Gland: Pars Int	Total termedia: Total termedia:	0/50 (0%) 0/50 (0%) 0/247 (0%) 0/50 (0%) 0/50 (0%) 1/247 (0.4%)	0/49 (0%) Mean 0% 1/49 (2%) 0/49 (0%)	SD 0% 0/49 (0%)		2/49 (4%) 10/245 (4.08%) 0/47 (0%) 0/49 (0%)	1/49 (2%) Mean 4.13% 1/50 (2%) 0/49 (0%)	SD 2.65% 0/50 (0%)			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Prostate: Adenoma								
		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%				
*Prostate: Carcinoma or Adenoma								
		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%				
*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%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male				Female	
Salivary Glands: Mast Cell Tumor Malignan	t							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		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%				
#Skeletal Muscle: Fibrosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
≇Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

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

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/49 (0%) 5/248 (2.02%)	2/50 (4%) Mean 2%	SD 2.83%
#Skeletal Muscle: Rhabdomyosarcoma o	or Rhabdomyoma	······						
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%
#Skeletal Muscle: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
tSkin: Basal Cell Adenoma οι	r Basosquamous	Tumor Benign						
	•	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%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal Cell Adenoma. B	Basosquamous T	umor Benign, or Trichoe	pithelioma					
		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%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
∜Skin: Basal Cell Carcinoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma	or Basosquamou	o/50 (0%) 0/50 (0%) 0/50 (0%)	NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
		oma, Basosquamous Tu 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
Basal Cell Carcinoma, NOS), or Trichoepitheli		•			Total	0/49 (0%) 0/49 (0%) 1/248 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin:	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%)	0/50 (0%)	,
NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%)	0/50 (0%)	,
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%)	0/50 (0%) SD 0% a,	Total	0/49 (0%) 1/248 (0.4%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89%
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total Total noma, Carcinom Sq Papilloma, Ke Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% a, 0/50 (0%)	Total	0/49 (0%) 1/248 (0.4%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89% 1/50 (2%)
Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence #Skin: Basal or Sq. Cell Carcinoma, Squadenoma, Papilloma, Squadenoma, Papilloma, Squadenoma, Sq	Total Total noma, Carcinom Sq Papilloma, Ke Total	0/50 (0%) 0/50 (0%) 0/250 (0%) a, Basosq. Tumor (M or ratoacanthoma, Trichoe 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenom pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% a, 0/50 (0%)	Total Total	0/49 (0%) 1/248 (0.4%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0.4% 	SD 0.89% 1/50 (2%)

^{*:} 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: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

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			Male				Female	
#Skin: Fibroma								
		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%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Fibroma, Fibrosarcoma, S								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24%	SD 2.33%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/248 (1.21%)	Mean 1.21%	SD 1.1%
#Skin: Fibrosarcoma, Sarcoma,								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24%	SD 2.33%
#Skin: Fibrous Histiocytoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

^{*:} 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 Species: MICE Route: GAVAGE Strain: B6C3F1

Length of Study: CHRONIC

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Report Date: 03/22/2010

Vehicle: CORN OIL

			Male				Female	
#Skin: Granular Cell Tumor Ben	nign							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
∕Skin: Hemangioma								
		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%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
∜Skin: Hemangiosarcoma								
_		1/50 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 4/250 (1.6%)	1/50 (2%) Mean 1.6%	SD 0.89%	Total	0/49 (0%) 2/248 (0.81%)	0/50 (0%) Mean 0.81%	SD 1.11%
#Skin: Liposarcoma								
·		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skin: Mast Cell Tumor Benign								
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
¢Skin: Myxosarcoma								
		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%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma or	· Schwannoma (n	nalignant or NOS)						
	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%
#Skin: Neurofibrosarcoma, N Overall Incidence	leurofibroma, or \$ Total	Schwannoma (benign, ma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 2/49 (4%) 3/248 (1.21%)	0/50 (0%) 1/50 (2%) Mean 1.22%	0/50 (0%) SD 1.82%
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Skin: Osteosarcoma	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Osteosarcoma Overall Incidence	Total	0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	(3.2.2)
#Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%)	0/50 (0%)	, ,	Total	0/49 (0%)	0/50 (0%)	(3.2.2)

^{*:} 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: GAVAGE Vehicle: CORN OIL Page: 42

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%
#Skin: Squamous Cell Carcinoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	•	` •	,		0/49 (0%)	0/50 (0%)	0/50 (0%)
	, Basal Cell C Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	or NOS), 0/50 (0%) SD 0%	Total	0/49 (0%) 0/49 (0%) 0/248 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or 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%		0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/49 (0%) 0/248 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	SD 0%
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/49 (0%) 0/248 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 1/50 (2%)	SD 0% 0/50 (0%)
or Carcinoma Overall Incidence #Skin: Squamous Cell Papilloma Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)		0/49 (0%) 0/248 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 1/50 (2%)	SD 0% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 43

			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0)%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papilloma			0/50 (0%) 0/50 0/50 (0%)) (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD ()%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Trichoepithelioma				•••••				
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0)%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD (Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD ()%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 44

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
'Spleen: Hemangiosarcoma								
-		0/50 (0%) 2/50 (4%)	2/50 (4%) 2/50 (4%)	1/49 (2%)		1/48 (2%) 1/49 (2%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	7/249 (2.81%)	Mean 2.81%	SD 1.78%	Total	2/244 (0.82%)	Mean 0.82%	SD 1.13%

^{*:} 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: GAVAGE Vehicle: CORN OIL mal Groups Report Date: 03/22/2010

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			Male				Female	
Spleen: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/244 (0.41%)	Mean 0.41%	SD 0.91%
*Spleen: Plasma Cell Tumor Malignaı								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Mast Cell Tumor Malignant								
		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	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
-	-	0/50 (0%) 1/50 (2%)	9/50 (18%) 1/50 (2%)	0/50 (0%)		1/49 (2%) 2/49 (4%)	3/50 (6%) 2/50 (4%)	1/50 (2%)
Overall Incidence	Total	11/250 (4.4%)	Mean 4.4%	SD 7.67%	Total	9/248 (3.63%)	Mean 3.62%	SD 1.67%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 46

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	8/50 (16%) 1/50 (2%)	0/50 (0%)		1/49 (2%) 2/49 (4%)	3/50 (6%) 2/50 (4%)	1/50 (2%)
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 6.99%	Total	9/248 (3.63%)	Mean 3.62%	SD 1.67%
#Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
Testes: Adenoma								
		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%				
*Thymus: Thymoma Benign								
-		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%

^{*:} 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: GAVAGE Vehicle: CORN OIL Page: 47

			Male				Female	
Thymus: Thymoma Malignant								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
*Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Ce Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/246 (0.81%)	Mean 0.81%	SD 1.11%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 48 Report Date: 03/22/2010

			Male				Female	
Thyroid Gland: Follicular Carcinoma	Cell:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
*Thyroid Gland: Follicular Carcinoma or Adenoma	Cell:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 2/49 (4%)	0/50 (0%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	5/246 (2.03%)	Mean 2.03%	SD 2.04%
#Tissue NOS: Carcinoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maliç	gnant							
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 49

			Male				Female	
#Tissue NOS: Sarcoma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma								
		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	na or Papillom	a Squamous						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma	a							
•		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%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 03/22/2010

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

Length of Study: CHRONIC

			Male				Female	
#Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Mali	ignant							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 03/22/2010

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% **#Uterus:** Carcinoma (0%) 0/49(0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Hemangioma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Hemangiosarcoma 0/49 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Uterus: Leiomyoma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)

Total

0/248 (0%)

.....

Overall Incidence

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

^{#:} 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:** 52

	Male		Female	
#Uterus: Leiomyosarcoma				
		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				
		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%
#Uterus: Sarcoma Stromal				
		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Uterus: Sarcoma Stromal or Polyp Stromal				
		1/49 (2%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.21%	SD 1.79%
#Uterus: Schwannoma Malignant				
		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 53

Male			Female	
#Vagina: Liposarcoma		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute Southern Research Institute	059902408 059903706	12/16/02 06/30/03	729 729	50(1) 50(1)	36(687) 40(701)	53.8 53.9	Androstenedione alpha/beta Thujone mixture
					Female		
Southern Research Institute Southern Research Institute	059902408 059903706	12/16/02 06/30/03	733 731	50(5) 50(5)	35(690) 37(668)	65.3 64.7	Androstenedione alpha/beta Thujone mixture

Strain: B6C3F1

Toxicology Data Management System

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Mean 3%

SD 1.41%

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
#All Organs: Benign Tumors		38/50 (76%)	32/50 (64%)			27/50 (54%)	22/50 (44%)	
Overall Incidence	Total	70/100 (70%)	Mean 70%	SD 8.49%	Total	49/100 (49%)	Mean 49%	SD 7.07%
#All Organs: Malignant Tumors		37/50 (74%)	30/50 (60%)			27/50 (54%)	19/50 (38%)	
Overall Incidence	Total	67/100 (67%)	Mean 67%	SD 9.9%	Total	46/100 (46%)	Mean 46%	SD 11.31%
#All Organs: Malignant and Benign Tumo Overall Incidence	rs Total	47/50 (94%) 92/100 (92%)	45/50 (90%) Mean 92%	SD 2.83%	Total	40/50 (80%) 75/100 (75%)	35/50 (70%) Mean 75%	SD 7.07%
All Organs: Hemangioma	•••••	1/50 (2%)	0/50 (0%)			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%
#All Organs: Hemangiosarcoma	Total	5/50 (10%)	4/50 (8%)	SD 1.41%	Total	1/50 (2%)	1/50 (2%)	SD 09/
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
#All Organs: Hemangiosarcoma or Hema	ngioma	5/50 (10%)	4/50 (8%)			2/50 (4%)	1/50 (2%)	
		3,33 (1070)	1/00 (070)			2,00 (470)	1700 (270)	

SD 1.41%

3/100 (3%)

Total

Total

9/100 (9%)

Mean 9%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	1/50 (2%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 0%
All Organs: Malignant Lymphoma: Hist	iocytic, Lym _l	phocytic, Mixed, NOS, or	Undifferentiated Cel	I Туре				
		4/50 (8%)	4/50 (8%)			14/50 (28%)	6/50 (12%)	
verall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%	Total	20/100 (20%)	Mean 20%	SD 11.31%
All Organs: Mesothelioma: Benign, Mal								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Osteoma		0/50 (00/)	4/50 (20/)			0/50 (09/)	0/50 /00/\	
Novemble Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
verall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female		
#All Organs: Osteosarcoma or Osteoma									
		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%	
*Adrenal Cortex: Adenoma									
		1/50 (2%)	2/50 (4%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Adrenal Cortex: Plasma Cell Tumor Malignar	nt	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Adrenal Medulla: Pheochromocytoma Benign		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comple									
		0/49 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Maligna	nnt	0/40 (00%)	1/40 /00/			0/50 (00/)	0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	1/49 (2%)	SD 1.44%	Total	0/50 (0%)	0/50 (0%)	SD 0%	
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%) 1/49 (2%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Bone Marrow: 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%			
*Bone Marrow: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
*Bone Marrow: Plasma Cell Tumor Mali		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Bone: Hemangiosarcoma		0/50 (001)									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Bone: Osteoma		0/50 /(00/)	4/50 (001)			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%			

^{*:} 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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Bone: Osteosarcoma												
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Bone: Osteosarcoma or Osteoma												
		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%				
*Brain: Meningioma Benign		0/50 (00()	0/50 (0%)			0/50 (00/)	0/50 (0%)					
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/				
Overali 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, Maligr												
		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: Schwannoma Malignant		0/50 (00/)	0/50 /00//			0/50 (00)	4/50 (00/)					
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	1/50 (2%)	00 4 440/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 60

			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/48 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Esophagus: Squamous Cell Carcinoma	ı							
		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	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		7/50 (14%)	8/50 (16%)			9/50 (18%)	5/50 (10%)	
Overall Incidence	Total	15/100 (15%)	Mean 15%	SD 1.41%	Total	14/100 (14%)	Mean 14%	SD 5.66%
#Harderian Gland: Carcinoma								
		2/50 (4%)	2/50 (4%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
		9/50 (18%)	10/50 (20%)			10/50 (20%)	6/50 (12%)	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 1.41%	Total	16/100 (16%)	Mean 16%	SD 5.66%
#Harderian Gland: 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Heart: 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%
*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%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (001)	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 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: Colon/Rect Leiomyosarcoma	tum:	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%

^{*:} 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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Mean 0%

SD 0%

Report Date: 03/22/2010

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Duodenum: 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% #Intestine Small: Duodenum: 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: 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 (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: 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: Ileum: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/100 (0%)

Total

Mean 0%

Total

0/100 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Small: Ileum: 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%
fIntestine Small: Jejunum: 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%
#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%
fintestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	00.00		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Leiomyosarcoma								
		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%
fintestine Small: Site Unspec Adenoma	ified:							
		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%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Intestine Small: Site Unspecified: Carcinoma												
		3/50 (6%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Uns Carcinoma or Adenoma	•											
		3/50 (6%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Uns Hemangiosarcoma	pecified:											
		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 Uns Leiomyosarcoma	pecified:											
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Uns Polyp Adenomatous	pecified:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Islets, Pancreatic: Adenoma												
		2/50 (4%)	4/50 (8%)			0/49 (0%)	1/48 (2%)					
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	1/97 (1.03%)	Mean 1.04%	SD 1.47%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%	Total	0/49 (0%) 1/97 (1.03%)	1/48 (2%) Mean 1.04%	SD 1.47%
*Kidney: Renal Tubule: 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%
*Kidney: Renal Tubule: Carcinoma								
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%
*Kidney: Renal Tubule: Carcinoma or 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%
*Kidney: Renal Tubule: Hemangioma			(05.3)					
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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
*Kidney: Renal Tubule: 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%				
*Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Kidney: Renal Tubule: Sarcoma												
	T	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Fibrous Histiocytoma												
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hemangioma												
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Hemangiosarcoma		0.50 (001)	0/50 /46:			0(50 (00))	4/50 (00/)					
Overall Incidence	Total	3/50 (6%)	2/50 (4%)	SD 1.41%	Total	0/50 (0%)	1/50 (2%) Mean 1%	SD 1.41%				
	Total	5/100 (5%)	Mean 5%		Total	1/100 (1%)						

^{*:} 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: GAVAGE

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Report Date: 03/22/2010

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female			
*Liver: Hepatoblastoma									
		3/50 (6%)	3/50 (6%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma									
		32/50 (64%)	24/50 (48%)			14/50 (28%)	13/50 (26%)		
Overall Incidence	Total	56/100 (56%)	Mean 56%	SD 11.31%	Total	27/100 (27%)	Mean 27%	SD 1.41%	
*Liver: Hepatocellular Carcinoma									
		26/50 (52%)	16/50 (32%)			5/50 (10%)	3/50 (6%)		
Overall Incidence	Total	42/100 (42%)	Mean 42%	SD 14.14%	Total	8/100 (8%)	Mean 8%	SD 2.83%	
*Liver: Hepatocellular Carcinoma	or Hepatobl	astoma							
		27/50 (54%)	18/50 (36%)			5/50 (10%)	3/50 (6%)		
Overall Incidence	Total	45/100 (45%)	Mean 45%	SD 12.73%	Total	8/100 (8%)	Mean 8%	SD 2.83%	
*Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma							
•	•	41/50 (82%)	33/50 (66%)			17/50 (34%)	15/50 (30%)		
Overall Incidence	Total	74/100 (74%)	Mean 74%	SD 11.31%	Total	32/100 (32%)	Mean 32%	SD 2.83%	
*Liver: Hepatocellular Carcinoma		•	lastoma			47/50 (0.45)	45/50 (000)		
	-	41/50 (82%)	33/50 (66%)	05 44 040/	-	17/50 (34%)	15/50 (30%)	00.000/	
Overall Incidence	Total	74/100 (74%)	Mean 74%	SD 11.31%	Total	32/100 (32%)	Mean 32%	SD 2.83%	

^{*:} 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: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Liver: Hepatocholangiocarcinoma	ı			,				
		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: Hepatocholangioma								
		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%
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Ito 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%
*Liver: Plasma Cell Tumor Maligna								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Liver: Sarcoma								
• " " " "	T	0/50 (0%)	0/50 (0%)	00.00/		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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female					
*Lung: 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%			
*Lung: Alveolar/Bronchiolar Ade	enoma										
		7/50 (14%)	7/50 (14%)			0/50 (0%)	3/50 (6%)				
Overall Incidence	Total	14/100 (14%)	Mean 14%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%			
*Lung: Alveolar/Bronchiolar Card	cinoma	44/50 (000)	0/50 /400/			4/50 (00()	4/50 (00()				
O	T-1-1	11/50 (22%)	6/50 (12%)	OD 7.070/	T-1-1	4/50 (8%)	1/50 (2%)	OD 4 0 40/			
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 7.07%	Total	5/100 (5%)	Mean 5%	SD 4.24%			
*Lung: Alveolar/Bronchiolar Card	cinoma or Alv										
		16/50 (32%)	13/50 (26%)			4/50 (8%)	4/50 (8%)				
Overall Incidence	Total	29/100 (29%)	Mean 29%	SD 4.24%	Total	8/100 (8%)	Mean 8%	SD 0%			
*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%			
*Lung: Fibrous Histiocytoma		0/50 (00/)	0/50 (0%)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%			
Overali incidence	Total	0/100 (0%)	Mean 0%	3D 0%	Total	0/100 (0%)	IVIEATI U%	3D 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*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	0/100 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*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	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (00)	0.750 (001)			(201)	2/52 (224)	
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: Hemangioma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Lymph Node: 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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node: Plasma Cell Tumor Malignaı	nt							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Lymph Node: 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%
#Lymph Node, Bronchial: 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%
Lymph Node, Mandibular: Fibrous Histiocytoma						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%
Lymph Node, Mandibular: 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%
Lymph Node, Mandibular: Mast Cell Tumor Malignant		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%
Jveran incluence	างเลเ	0/100 (0%)	Wear 0%	SD 0%	างเลเ	0/100 (0%)	เทษสก บ%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date: 03/22/2010

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female					
#Lymph Node, Mandibular: Plasma Cell Tumor Malignant												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Lymph Node, Mesenteric 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, Mesenteric Hemangioma	::											
	-	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/				
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%				
#Lymph Node, Mesenteric Plasma Cell Tumor Mali			•••••									
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Mammary Gland: Adenoacanthoma		0/50 (001)	0/50 (00)			0(50 (00))	0/50 (00)					
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	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%				

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

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

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Mammary Gland: Adenoma 0/50 (09/) 0/50 (09/) 0/50 (09/)												
		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 (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%				
#Mammary Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			(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%				
		0/100 (0%)		3D 0%	ı Olai	2/100 (2%)	IVIEdII 2%	3D 0%				
#Mammary Gland: Fibroadenoma			- ()									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	CD 00/	Tatal	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
Overall incidence		, ,		SD 0%	Total	0/100 (0%)						
#Mammary Gland: Fibroma, Fibroadenoma c	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%				
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	Adenoma										
		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%				

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female						
#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													
		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: Hemangiosarcoma			- ()										
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#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: Mast Cell Tumor Maligna	ant												
		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 Papilloma Squamous or	, 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%					

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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	0/50 (0%) 0/50 (0%) nce Total 0/100 (0%) Mean 0% SD 0% Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%) 0/50 (0%) nce Total 0/100 (0%) Mean 0% SD 0% noma noma nce						Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcino		ynx, Tooth, Gingiva):						
Overall Incidence	Total	` '	` '	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
- 1	,		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma								
						0/49 (0%)	1/48 (2%)	00 / 100/
Overall Incidence					Total	1/97 (1.03%)	Mean 1.04%	SD 1.47%
*Ovary: Cystadenoma						4/40 (99/)	2/49 /40/)	
Overall Incidence					Total	4/49 (8%) 6/97 (6.19%)	2/48 (4%) Mean 6.16%	SD 2.83%
*Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Benign							
Overall Incidence					Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories Tumor Incidence for Select

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

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
Ordinalosa Sell Famor Mangham		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
3,		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma				
		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma				
.		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Leiomyosarcoma				
• • • • • • • • • • • • • • • • • • • •		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma				
		0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Plasma Cell Tumor Malignant** 0/49 (0%)1/48 (2%)**Overall Incidence** Total 1/97 (1.03%) Mean 1.04% SD 1.47% *Ovary: Teratoma Benign 0/49 (0%)0/48 (0%)**Overall Incidence** Total 0/97 (0%) Mean 0% SD 0% *Ovary: **Teratoma Malignant** 0/49 (0%)0/48 (0%)Overall Incidence Total 0/97 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** 0/49 (0%)0/48 (0%)**Overall Incidence** Total 0/97 (0%) Mean 0% SD 0% *Pancreas: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% *Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/48 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/97 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: METHYLCELLULOSE

Route: GAVAGE

Length of Study: CHRONIC

Page: 79

			Male				Female	
Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distali Adenoma	s or Unspeci	fied Site:						
		0/50 (0%)	0/48 (0%)			1/49 (2%)	2/49 (4%)	
verall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/98 (3.06%)	Mean 3.06%	SD 1.44%
Pituitary Gland: Pars Distali Carcinoma	s or Unspeci							
		0/50 (0%)	0/48 (0%)			0/49 (0%)	0/49 (0%)	
verall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distali Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)			1/49 (2%)	2/49 (4%)	
verall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/98 (3.06%)	Mean 3.06%	SD 1.44%
Pituitary Gland: Pars Interm Adenoma								
		0/50 (0%)	0/48 (0%)			0/49 (0%)	0/49 (0%)	
verall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/50 (0%)	0/48 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

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

Vehicle: METHYLCELLULOSE

			Male				Female	
*Prostate: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%				
*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 (00/)			0/40 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
	101a1	0/100 (0%)		30 0%		0/96 (0%)	Wiedii 0%	
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyoma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

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

Vehicle: METHYLCELLULOSE

			Male				Female	
#Skeletal Muscle: Sarcoma								
		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%
Skin: Basal Cell Adenoma or	r Basosquamous	Tumor Benign						
	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin:		umor Benign, or Trichoep	oithelioma					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin:	or Rasosquamou	s Tumor (malignant or N0	ns)					
Basar och oarchiona (or Basosquamou	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:								
		oma, Basosquamous Tum	nor (benign, maligna	nt or				
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} 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

ence for Selected Control Animal Group

Route: GAVAGE

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Report Date: 03/22/2010

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, 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: Basosquamous Tumor	· Benign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Fibroma		0/50 (00/)	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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or Fil 1/50 (2%) 1/100 (1%)	orous Histiocytoma 0/50 (0%) Mean 1%	SD 1.41%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%			
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			3/50 (6%)	2/50 (4%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 1.41%			
#Skin: Fibrosarcoma, Sarcom	a, Myxosarcoma	, or Fibrous Histiocytoma				E/EO /400/\	2/50 /(50/.)				
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Fibrous Histiocytoma								
Overall Institutes	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Granular Cell Tumor Benig	n							
		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: 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%
#Skin: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 85

			Male				Female	
#Skin: Myxosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Neurofibrosarcoma or Sch	wannoma (m	alignant or NOS)						
ricar on brosar coma or con	wamioma (iii	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Neurofibrosarcoma, Neuro	,	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#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%)	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%
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
#Skin: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)	OD 004	Takal	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%
#Skin: Squamous Cell Carcino or Carcinoma	ma, Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant	or NOS),				
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 Papillon Overall Incidence	na 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 Papillon		······	iviean 076	JD 070	Total		inean 076	35 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%
#Skin: Squamous Cell Papillon	na, Papilloma, S	Squamous Cell Carcinoma	or Keratoacanthoma	1		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 Papillon	na, Papilloma, o	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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Trichoepithelioma		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: 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%
#Skin: Sebaceous Gland: Carcinoma								
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 or Adenoma	•••••	0/50 (0%)				0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Meningioma 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%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (00/)			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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Spleen: Hemangioma		252 (22)	2(7-2)			(20)	2/22 (22)	
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%
*Spleen: Hemangiosarcoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Spleen: Mast Cell Tumor Malignant	t	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%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Plasma Cell Tumor Maligna	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Mast Cell Tumor Malignant	t	0/50 (00/)	0/50 (09/)			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%
#Stomach, Forestomach: Squamous Cell Carcinoma		(00)	(00)			(20)	(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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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(0%)

SD 0%

Mean 0%

0/46

(0%)

0/47

0/93 (0%)

Total

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1
Length of Study: CHRONIC

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

Vehicle: METHYLCELLULOSE

			Male				Female					
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 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, 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 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 (0%)	0/50 (0%)		Total	0/50 (0%)	0/50 (0%)	CD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
Testes: Adenoma		0/50 (0%)	1/50 (2%)									
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%								
Thymus: Thymoma Benign												

SD 0%

Total

(0%)

0/45

0/89 (0%)

(0%)

0/44

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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	
*Thymus: Thymoma Malignant		0/45 (0%)	0/44 (0%)			0/47 (0%)	0/46 (0%)	
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/93 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/45 (00/)	0/44 (00/)			0(47 (00())	0/40 /00/	
Overall Incidence	Total	0/45 (0%) 0/89 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/93 (0%)	0/46 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma	II:							
		0/50 (0%)	1/49 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Ce Carcinoma	II:							
Occupil by all laws a	T-1-1	0/50 (0%)	1/49 (2%)	OD 4 440/	Tatal	1/50 (2%)	0/50 (0%)	OD 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:							
		0/50 (0%)	2/49 (4%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.04%	SD 2.89%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Tissue NOS: 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%
#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: Plasma Cell Tumor Malig								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tissue NOS: 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%
#Tongue: Fibroma								
		0/50 (0%)	1/50 (2%)	00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Strain: B6C3F1 Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
#Tongue: Squamous Cell Carcino	ma									
Owner Haller at James	Taral	0/50 (0%)	0/50 (0%)	00,007	Taral	0/50 (0%)	0/50 (0%)	00, 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Tongue: Squamous Cell Carcino	ma or Papillom	•								
		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 Papillon										
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	0/30 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Urinary Bladder: Hemangioma										
		0/50 (0%)	0/50 (0%)	OD O		0/50 (0%)	0/50 (0%)	22. 22/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Hemangiosarcoma										
		0/50 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	05.00		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Urinary Bladder: Plasma Cell Tumor Mal	ignant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Urinary Bladder: 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%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus:					
Polyp Stromal Overall Incidence		Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
#Uterus:			` '		
Sarcoma Stromal			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
#Uterus:					
Schwannoma Malignant			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Male			Female	
#Vagina: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

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

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	058812307	10/04/01	728	50(1)	39(698)	52.9	Formamide
Battelle Columbus Laboratory	052000506	02/10/04	730	50(1)	32(691)	51.1	Ginseng
Battelle Columbus Laboratory	059501106	08/09/01	728	50(1)	40(702)	52.3	5-(Hydroxymethyl)-2-furfural
					Female		
Battelle Columbus Laboratory	058812307	10/03/01	727	50(5)	38(692)	64.7	Formamide
Battelle Columbus Laboratory	052000506	02/09/04	729	50(5)	38(711)	63.9	Ginseng
Battelle Columbus Laboratory	059501106	08/08/01	727	50(5)	39(694)	64.4	5-(Hydroxymethyl)-2-furfural

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 97
Report Date: 03/22/2010

Species: MICE Strain: B6C3F1

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

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

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 98

			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: Hist	iocytic, Lym	phocytic, Mixed, NOS, o	· Undifferentiated Cel	I Туре						
		2/50 (4%)	4/50 (8%)	2/50 (4%)		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%		
#All Organs: Mesothelioma: Benign, Mal					•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignant		0/50 /00/	0/50 /00/	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%		
#All Organs: Osteoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 99

			Male			Female				
#All Organs: Osteosarcoma or Osteoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Adrenal Cortex: Adenoma										
		2/50 (4%)	1/50 (2%)	5/49 (10%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	8/149 (5.37%)	Mean 5.4%	SD 4.28%	Total	0/149 (0%)	Mean 0%	SD 0%		
Adrenal Cortex: Plasma Cell Tumor Maligna										
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%		
Adrenal Medulla: Pheochromocytoma Benign		0/50 (0%)	0/50 (0%)	0/49 (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%		
Adrenal Medulla: Pheochromocytoma Comple	ex	0/50 (00/)	0/50 (00/)	0/40 (00/)		0(50 (00))	0(50 (00))	0(50 (00))		
	.	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%		
Adrenal Medulla: Pheochromocytoma Maligna	ant									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 03/22/2010

Page: 100

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

Length of Study: CHRONIC

			Male				Female						
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS													
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)					
verall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
Bone Marrow: 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%					
Bone Marrow: Hemangiosarcoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)					
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%					
Bone Marrow: Plasma Cell Tumor Mali	gnant												
		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%					
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		0/50 (00/)	0/50 /000	0/50 (000)		0/50 (00)	0/50 /00/	0/50 (00/)					
warali ingidanga	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	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%					

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female				
#Bone: Osteosarcoma					,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Bone: Osteosarcoma or Osteoma											
Verall 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%		
Brain: Meningioma Benign											
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%		
Brain: Meningioma Malignant				- 1	4						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 SD 0%	(0%)	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	wean 0%	SD 0%		
Brain: Meningioma: Benign, Maligr	nant, NOS										
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%		
Brain: 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%		

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 102

			Male				Female	
Clitoral/Preputial Gland:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial 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%
Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 /00/	0/50 (000)	0/50 (00%)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overali incidence		0/150 (0%)	wean 0%	3D 0%	ı olal	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: 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%
Clitoral/Preputial Gland: 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%
Clitoral/Preputial Gland: 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 103

			Male		Female					
#Esophagus: Squamous Cell Carcinoma	ı									
		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										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma										
		6/50 (12%)	11/50 (22%)	11/50 (22%)		4/50 (8%)	7/50 (14%)	7/50 (14%)		
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 5.77%	Total	18/150 (12%)	Mean 12%	SD 3.46%		
#Harderian Gland: Carcinoma		2/50 (4%)	1/50 (2%)	3/50 (6%)		4/50 (8%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 2%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%		
#Harderian Gland: Carcinoma or Adenoma										
		7/50 (14%)	12/50 (24%)	13/50 (26%)		8/50 (16%)	7/50 (14%)	7/50 (14%)		
Overall Incidence	Total	32/150 (21.33%)	Mean 21.33%	SD 6.43%	Total	22/150 (14.67%)	Mean 14.67%	SD 1.15%		
#Harderian Gland: 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%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 104

			Male			Female					
Heart: Hemangioma											
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				-1			. ()				
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%			
#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%			
fintestine Large: Cecum: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Intestine Large: Cecum: Leiomyoma											
-		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/Rect Leiomyosarcoma	um:										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
Intestine Small: Duodenum: 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%
Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Duodenum: 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%
fintestine 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	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: 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%
fintestine 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 106

			Male			Female			
#Intestine Small: Ileum: Polyp Adenomatous									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) 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%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Intestine Small: Jejunum: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
fIntestine Small: Site Unspec Adenoma	ified:								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male		Female								
#Intestine Small: Site Unspecified: 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%					
#Intestine Small: Site Unspe Carcinoma or Adenoma	ecified:												
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%					
#Intestine Small: Site Unspo Hemangiosarcoma	ecified:												
		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 Unspo Leiomyosarcoma	ecified:												
		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 Unspo Polyp Adenomatous	ecified:												
		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%					

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female	
Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Kidney: Renal Tubule: Adenoma		0/00 (553)	(0.1)			(40)	(24)	(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%
Kidney: Renal Tubule: Carcinoma						0/50 (00/)	0/50 (00)	0/50 (001)
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%
Kidney: Renal Tubule: Carcinoma or Adenoma				•••••				
Overall 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%
Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} 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: GAVAGE Vehicle: WATER **Page:** 109

			Male				Female				
*Kidney: Renal Tubule: 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%			
Kidney: Renal Tubule: Plasma Cell Tumor Malig	ınant										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Kidney: Renal Tubule: 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%			
Liver: Fibrous Histiocytoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Hemangioma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Liver: Hemangiosarcoma											
		1/50 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: GAVAGE

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatoblastoma								
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	24/50 (48%) 91/150 (60.67%)	34/50 (68%) Mean 60.67%	33/50 (66%) SD 11.02%	Total	6/50 (12%) 41/150 (27.33%)	21/50 (42%) Mean 27.33%	14/50 (28%) SD 15.01%
*Liver: Hepatocellular Carcinoma		45/50 (200V)	44/50 (200/)	44/50 (220()		4/50 (00/)	2/50 /49/)	2/50 (40/)
Overall Incidence	Total	15/50 (30%) 40/150 (26.67%)	14/50 (28%) Mean 26.67%	11/50 (22%) SD 4.16%	Total	4/50 (8%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	2/50 (4%) SD 2.31%
Liver: Hepatocellular Carcinoma	or Hepatob							
Overall Incidence	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%	Total	4/50 (8%) 9/150 (6%)	2/50 (4%) Mean 6%	3/50 (6%) SD 2%
*Liver: Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma 33/50 (66%)	39/50 (78%)	39/50 (78%)		9/50 (18%)	23/50 (46%)	14/50 (28%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 6.93%	Total	46/150 (30.67%)	Mean 30.67%	SD 14.19%
*Liver: Hepatocellular Carcinoma,	Hepatocell			20/50 /700/\		0/50 (48%)	22/50 /469/\	45/50 /200/
Overall Incidence	Total	34/50 (68%) 112/150 (74.67%)	39/50 (78%) Mean 74.67%	39/50 (78%) SD 5.77%	Total	9/50 (18%) 47/150 (31.33%)	23/50 (46%) Mean 31.33%	15/50 (30%) SD 14.05%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 111

			Male				Female	
Liver: Hepatocholangiocarcinom	a							
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%
Liver: Hepatocholangioma								
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%
Liver: Ito Cell Tumor Benign		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%
Liver: Ito 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%
_iver: Plasma Cell Tumor Maligna	ant		•••••				•••••	
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%
Liver: 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%

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 112

		Male				Female				
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
lenoma										
	10/50 (20%)	9/50 (18%)	10/50 (20%)		4/50 (8%)	6/50 (12%)	2/50 (4%)			
Total	29/150 (19.33%)	Mean 19.33%	SD 1.15%	Total	12/150 (8%)	Mean 8%	SD 4%			
ırcinoma										
	6/50 (12%)	3/50 (6%)	7/50 (14%)		2/50 (4%)	1/50 (2%)	1/50 (2%)			
Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%			
ırcinoma or Al			16/50 (32%)		5/50 (10%)	7/50 (1/1%)	3/50 (6%)			
Total	44/150 (29.33%)	Mean 29.33%	SD 4.62%	Total	15/150 (10%)	Mean 10%	SD 4%			
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Total	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
	······									
	0/50 (0%)	0/50 /09/	0/50 (09/)		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%)			
	Total Total Trotal Total	Total 0/150 (0%) Ilenoma 10/50 (20%) Total 29/150 (19.33%) Ircinoma 6/50 (12%) Total 16/150 (10.67%) Ircinoma or Alveolar/Bronchiolar Adeno 16/50 (32%) Total 44/150 (29.33%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% Henoma 10/50 (20%) 9/50 (18%) Total 29/150 (19.33%) Mean 19.33% Incinoma 6/50 (12%) 3/50 (6%) Total 16/150 (10.67%) Mean 10.67% Incinoma or Alveolar/Bronchiolar Adenoma 16/50 (32%) 12/50 (24%) Total 44/150 (29.33%) Mean 29.33% 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%	O/50 (0%)	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Idenoma	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 113

			Male				Female	
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Plasma Cell Tumor Maligi	nant							
		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: Sarcoma		0/50 (00/)	0/50 /00/	0/50 (0%)		0/50 (00)	0/50 (00/)	0/50 (00)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	טט ט% u%
Lymph Node: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)	T	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 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 114

			Male				Female	
#Lymph Node: Plasma Cell Tumor Malignar	nt							
		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: Sarcoma								
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	5D 0%
Lymph Node, Bronchial: 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%
		` '			10tai	0/150 (0%)	iviean 0%	
Lymph Node, Mandibular: 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, 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		0/50 /(00/)	4/50 (000)	0/50 (00%)		0/50 /00/	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
overali incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 115

			Male				Female				
#Lymph Node, Mandibular: Plasma Cell Tumor Malignant											
		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%			
Lymph Node, Mesenteric: Fibrous Histiocytoma											
		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%			
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%			
Lymph Node, Mesenteric: Hemangiosarcoma											
	T	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%			
Lymph Node, Mesenteric: Plasma Cell Tumor Malign	ant										
		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: Adenoacanthoma											
		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%			

^{*:} 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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 116

			Male				Female	
#Mammary 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%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Mammary Gland: Carcinoma								
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%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
Mammary Gland: Carcinoma or Adenoma	1	0/50 (0%)	0/50 (00)	0/50 (00)		0/50 /400	4/50 (000)	4/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%
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	a 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%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%

^{*:} 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: GAVAGE Vehicle: WATER Page: 117

			Male				Female	
#Mesentery: Fibrosarcoma								
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%
#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		2.50						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Sarcoma		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%
Nose: 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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or Pa	ongue, Phar							
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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 118

			Male				Female			
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): 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%		
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva): Squamous, or Papilloma								
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%		
*Ovary: Choriocarcinoma										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Ovary: Cystadenoma	•••••					4/50 (00)	7/50 (4.40())	0/50 (00)		
Overall Incidence					Total	1/50 (2%) 11/150 (7.33%)	7/50 (14%) Mean 7.33%	3/50 (6%) SD 6.11%		
*Ovary: Fibrous Histiocytoma	•••••					(201)	(00)	(201)		
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
*Ovary: Granulosa Cell Tumor I	Benign									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male		Female	
Ovary: Granulosa Cell Tumor Malignant		0/50 (00)	0/50 (00/)	0/50 (05/2
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Hemangioma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Hemangiosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Luteoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

/AGE

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Report Date: 03/22/2010

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Ovary: Plasma Cell Tumor Malign	nant							
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Teratoma Benign								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Teratoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas:						•••••		
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%
Pancreas: Carcinoma								
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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

AVAGE

1/50

4/149 (2.68%)

(2%)

1/50

(2%)

Mean 2.69%

2/49

SD 1.2%

(4%)

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Report Date: 03/22/2010

Male **Female** *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/148 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 1/50 (2%)1/50 (2%)0/48 (0%)3/50 (6%)1/50 (2%)2/49 (4%)**Overall Incidence** Total 2/148 (1.35%) Mean 1.33% SD 1.15% 6/149 (4.03%) Mean 4.03% SD 2% Total *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 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% 0/149 (0%) Mean 0% SD 0% Total *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 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 Intermedia: 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 Intermedia: Carcinoma or Adenoma

Total

0/50

0/148 (0%)

(0%)

0/50

Mean 0%

(0%)

0/48

SD 0%

(0%)

Total

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male				Female	
*Prostate: Adenoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
	TOlai	0/150 (0%)		JD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				
*Prostate: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Salivary Glands: Carcinoma		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: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (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%

^{*:} 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: GAVAGE Vehicle: WATER Page: 123

			Male			Female				
#Seminal Vesicle: Adenoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%						
#Skeletal Muscle: Fibrosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skeletal Muscle: 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%		
#Skeletal Muscle: 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%		
Skeletal Muscle: Rhabdomyosarcoma										
•		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: Rhabdomyosarcoma or Rh	abdomyoma			- 1						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 **Toxicology Data Management System**

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Report Date: 03/22/2010

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male **Female #Skeletal Muscle:** Sarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% Total Total #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) #Skin:

Overall Incidence#Skin:

Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

NOS), or 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%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)

Total

^{*:} 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: 03/22/2010

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

Length of Study: CHRONIC

			Male				Female			
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 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%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Basosquamous Tumor	r Benign									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Fibroma			•••••					•••••		
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, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or F	ibrous Histiocytoma					•••••		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%		
Skin: Fibrosarcoma										
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%) 3/150 (2%)	3/50 (6%) Mean 2%	0/50 (0%) SD 3.46%		
Skin: Fibrosarcoma, Sarcom	na, Myxosarcoma	a, or Fibrous Histiocytom								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 126

			Male			Female				
#Skin: 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%		
#Skin: Granular Cell Tumor Benig	jn									
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 (00)	4/50 (001)	0(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%		
≴Skin: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
∕Skin: Liposarcoma					•••••					
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: Mast Cell Tumor Benign										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Vehicle: WATER

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Male **Female** #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: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** 1/150 (0.67%) Mean 0.67% SD 1.15% 2/150 (1.33%) Mean 1.33% SD 2.31% Total Total #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) (2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** 1/150 (0.67%) Mean 0.67% SD 1.15% Mean 1.33% SD 2.31% Total Total 2/150 (1.33%) #Skin: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) #Skin: Sarcoma 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% #Skin: **Schwannoma Malignant** 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** Total Mean 0.67% 2/150 (1.33%) Mean 1.33% SD 2.31% 1/150 (0.67%) SD 1.15% Total

^{*:} 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: 03/22/2010

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male					Female			
#Skin: 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%		
	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignant o	or NOS),							
or Carcinoma		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	(0%)	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
	10tai			3D 0%		1 Utai	0/130 (0%)	iviean 0%			
#Skin: Squamous Cell Papillor	ma	0/50 (00/)	0(50 (00))	0/50	(00()		0(50 (00))	0/50 (00/)	0(50 (00))		
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50	(0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%		
≇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%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	(0,0)	Total	0/150 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papillor	ma, Papilloma, S	quamous Cell Carcinoma	a or Keratoacanthoma	o/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 Papillor	ma, Papilloma, o	r 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%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 129

			Male				Female	
#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								
		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: 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%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma		0/50 (00/)	0/50 /00/	0/50 (00)		0/50 /00/	0/50 (00/)	0/40 (00/)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 130

			Male			Female				
*Spleen: Hemangioma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%		
Spleen: Hemangiosarcoma										
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 5/149 (3.36%)	0/50 (0%) Mean 3.39%	4/49 (8%) SD 4.25%		
Spleen: 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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
Spleen: Plasma Cell Tumor Malignar	nt									
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%		
Stomach, Forestomach: 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%		
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%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 131

			Male			Female					
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous											
		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%			
Stomach, Forestomach: Squamous Cell Papillor											
		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%			
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 or Adenoma	a										
		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%			
Testes: Adenoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%)							
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%							
Thymus: Thymoma Benign											
		0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)			
Overall Incidence	Total	0/137 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Imor Incidence for Selected Control Anima

Route: GAVAGE

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male			Female				
Thymus: Thymoma Malignant		0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)		
Overall Incidence	Total	0/137 (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: C-Cell: Carcinoma										
verall 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%		
hyroid Gland: C-Cell: 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%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%		
hyroid Gland: Follicular C Adenoma	Cell:									
overall Incidence	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%	Total	2/49 (4%) 3/146 (2.05%)	0/49 (0%) Mean 2.05%	1/48 (2%) SD 2.04%		
 Γhyroid Gland: Follicular C Carcinoma					•••••					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 133 Report Date: 03/22/2010

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

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	l:							
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%	Total	2/49 (4%) 3/146 (2.05%)	0/49 (0%) Mean 2.05%	1/48 (2%) SD 2.04%
Tissue 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%
Tissue NOS: Hemangiosarcoma		(45.7)	(05.)	(00)		(0.1)	(20)	0/20 (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: Plasma Cell Tumor Maligna								
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: 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%
Tongue: Fibroma								
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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 134

			Male				Female			
Tongue: Squamous Cell Carcinoma	a									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	0%)	Γotal	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
Tongue: Squamous Cell Carcinoma	a or Panillom	a Squamous								
Oquamous och ouromonic	a or r apinom	0/50 (0%)	0/50 (0%)	0/50 (0	0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Γotal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Tongue: Squamous Cell Papilloma							•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0	0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Γotal	0/150 (0%)	Mean 0%	SD 0%	
Tooth: Odontoma										
		0/50 (0%)	0/50 (0%)	,	0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Γotal	0/150 (0%)	Mean 0%	SD 0%	
Urinary Bladder: Hemangioma										
		1/50 (2%)	0/50 (0%)	,	0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		Γotal	0/149 (0%)	Mean 0%	SD 0%	
Urinary Bladder: Hemangiosarcoma										
		0/50 (0%)	0/50 (0%)	,	0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	٦	Γotal	0/149 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 135 Report Date: 03/22/2010

			Male			Female				
*Urinary Bladder: Plasma 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%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (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										
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%		
fUterus: Hemangioma										
Overall Incidence					Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%		
#Uterus: Hemangiosarcoma										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male		Female	
#Uterus: Leiomyoma		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Tot	` '	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jterus: Leiomyosarcoma				
verall Incidence	Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jterus: Polyp Stromal		2(72 (224)	2/22 / (22/)	(
verall Incidence	Tot	,	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Jterus: Sarcoma Stromal				
verall Incidence	Tot	()	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Iterus: Sarcoma Stromal or Polyp Stromal				
verall Incidence	Tot	0/50 (0%) al 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Jterus: Schwannoma Malignant				
overall Incidence	Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 137

	Male	F	Female
#Vagina: Liposarcoma Overall Incidence	Total	()	(0%) 0/50 (0%) an 0% SD 0%
#Vagina: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 0/150 (0%) Mea	(0%) 0/50 (0%) an 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: INHALATION Vehicle: AIR

Study Summary

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

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Sele

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#All Organs: Benign Tumors								
		36/50 (72%)	43/50 (86%)	33/50 (66%)		22/50 (44%)	34/50 (68%)	25/50 (50%)
		35/50 (70%)	28/50 (56%)	42/50 (84%)		26/50 (52%)	26/50 (52%)	24/50 (48%)
verall Incidence	Total	217/300 (72.33%)	Mean 72.33%	SD 11.27%	Total	157/300 (52.33%)	Mean 52.33%	SD 8.24%
All Organs: Malignant Tumors								
		30/50 (60%)	27/50 (54%)	36/50 (72%)		33/50 (66%)	26/50 (52%)	23/50 (46%)
		19/50 (38%)	22/50 (44%)	26/50 (52%)		29/50 (58%)	23/50 (46%)	27/50 (54%)
verall Incidence	Total	160/300 (53.33%)	Mean 53.33%	SD 11.98%	Total	161/300 (53.67%)	Mean 53.67%	SD 7.63%
#All Organs: Malignant and Benign T	umors							
		47/50 (94%)	48/50 (96%)	48/50 (96%)		42/50 (84%)	42/50 (84%)	41/50 (82%)
		43/50 (86%)	38/50 (76%)	47/50 (94%)		40/50 (80%)	37/50 (74%)	40/50 (80%)
verall Incidence	Total	271/300 (90.33%)	Mean 90.33%	SD 7.94%	Total	242/300 (80.67%)	Mean 80.67%	SD 3.72%
All Organs: Hemangioma								
		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%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
All Organs: Hemangiosarcoma								
		2/50 (4%)	0/50 (0%)	7/50 (14%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		4/50 (8%)	2/50 (4%)	4/50 (8%)		4/50 (8%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 4.8%	Total	18/300 (6%)	Mean 6%	SD 3.1%

^{*:} 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:								
Hemangiosarcoma or He	emangioma	0/50 (40/)	4/50 (00/)	7/50 (4.40/)		4/50 (00/)	4/50 (00/)	E/EO (400/)
		2/50 (4%) 4/50 (8%)	1/50 (2%) 2/50 (4%)	7/50 (14%) 5/50 (10%)		4/50 (8%) 5/50 (10%)	1/50 (2%) 2/50 (4%)	5/50 (10%) 2/50 (4%)
S	T-1-1	` ,	, ,	, ,	T-1-1	, ,	,	` ,
verall Incidence	Total	21/300 (7%)	Mean 7%	SD 4.52%	Total	19/300 (6.33%)	Mean 6.33%	SD 3.44%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	6/300 (2%)	Mean 2%	SD 1.26%
‡All Organs: Malignant Lymphoma: F	Histiocytic, Lym	2/50 (4%)	2/50 (4%)	2/50 (4%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
#All Organs: Malignant Lymphoma: H Overall Incidence	Histiocytic, Ly m Total				Total	17/50 (34%) 15/50 (30%) 72/300 (24%)	7/50 (14%) 13/50 (26%) Mean 24%	8/50 (16%) 12/50 (24%) SD 7.8%
Malignant Lymphoma: H Overall Incidence #All Organs:	Total	2/50 (4%) 0/50 (0%) 9/300 (3%)	2/50 (4%) 1/50 (2%)	2/50 (4%) 2/50 (4%)	Total	15/50 (30%)	13/50 (26%)	12/50 (24%)
Malignant Lymphoma: H	Total	2/50 (4%) 0/50 (0%) 9/300 (3%)	2/50 (4%) 1/50 (2%) Mean 3%	2/50 (4%) 2/50 (4%) SD 1.67%	Total	15/50 (30%) 72/300 (24%)	13/50 (26%) Mean 24%	12/50 (24%) SD 7.8%
Malignant Lymphoma: H Overall Incidence HAll Organs:	Total	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%)	2/50 (4%) 1/50 (2%) Mean 3%	2/50 (4%) 2/50 (4%) SD 1.67%	Total	15/50 (30%) 72/300 (24%) 0/50 (0%)	13/50 (26%) Mean 24% 	12/50 (24%) SD 7.8% 0/50 (0%)
Malignant Lymphoma: H Overall Incidence #All Organs: Mesothelioma: Benign,	Total	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%) Mean 3%	2/50 (4%) 2/50 (4%) SD 1.67%	Total 	15/50 (30%) 72/300 (24%) 0/50 (0%) 0/50 (0%)	13/50 (26%) Mean 24%	12/50 (24%) SD 7.8%
Malignant Lymphoma: H Overall Incidence #All Organs:	Total Malignant, NOS	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%)	2/50 (4%) 1/50 (2%) Mean 3% 0/50 (0%) 0/50 (0%)	2/50 (4%) 2/50 (4%) SD 1.67% 1/50 (2%) 0/50 (0%)		15/50 (30%) 72/300 (24%) 0/50 (0%)	13/50 (26%) Mean 24% 0/50 (0%) 0/50 (0%)	12/50 (24%) SD 7.8% 0/50 (0%) 0/50 (0%)
Malignant Lymphoma: H Overall Incidence fAll Organs: Mesothelioma: Benign, Overall Incidence	Total Malignant, NOS Total	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	2/50 (4%) 1/50 (2%) Mean 3% 0/50 (0%) 0/50 (0%) Mean 0.33%	2/50 (4%) 2/50 (4%) SD 1.67% 1/50 (2%) 0/50 (0%) SD 0.82%		15/50 (30%) 72/300 (24%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	13/50 (26%) Mean 24% 0/50 (0%) 0/50 (0%) Mean 0%	12/50 (24%) SD 7.8% 0/50 (0%) 0/50 (0%) SD 0%
Malignant Lymphoma: H Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence	Total Malignant, NOS Total	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	2/50 (4%) 1/50 (2%) Mean 3% 0/50 (0%) 0/50 (0%) Mean 0.33%	2/50 (4%) 2/50 (4%) SD 1.67% 1/50 (2%) 0/50 (0%) SD 0.82%		15/50 (30%) 72/300 (24%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	13/50 (26%) Mean 24% 0/50 (0%) 0/50 (0%) Mean 0%	12/50 (24%) SD 7.8% 0/50 (0%) 0/50 (0%) SD 0%
Malignant Lymphoma: H Overall Incidence #All Organs: Mesothelioma: Benign, Overall Incidence	Total Malignant, NOS Total	2/50 (4%) 0/50 (0%) 9/300 (3%) 6 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	2/50 (4%) 1/50 (2%) Mean 3% 0/50 (0%) 0/50 (0%) Mean 0.33%	2/50 (4%) 2/50 (4%) SD 1.67% 1/50 (2%) 0/50 (0%) SD 0.82%		15/50 (30%) 72/300 (24%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	13/50 (26%) Mean 24% 0/50 (0%) 0/50 (0%) Mean 0%	12/50 (24%) SD 7.8% 0/50 (0%) 0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		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%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		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%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		4/49 (8%)	1/50 (2%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	1/49 (2%)	2/49 (4%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	14/297 (4.71%)	Mean 4.71%	SD 4.52%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Adrenal Cortex: Plasma Cell Tumor Maligna	nt							
		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%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female			
*Adrenal Medulla: Pheochromocytoma Benign										
		1/50 (2%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 2/294 (0.68%)	0/47 (0%) Mean 0.69%	1/47 (2%) SD 1.07%	Total	2/50 (4%) 6/298 (2.01%)	1/48 (2%) Mean 2.01%	0/50 (0%) SD 2.53%		
Adrenal Medulla: Pheochromocytoma Co										
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
O	T-1-1	0/50 (0%)	0/47 (0%)	0/47 (0%)	T-1-1	0/50 (0%)	0/48 (0%)	0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Ma	alignant	0/50 (00/)	0/50 (00/)	0/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)	0/50 (0%) 0/47 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%		
*Adrenal Medulla: Pheochromocytoma: B		. •								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		4/50 (8%)	0/50 (0%) 1/48 (2%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 2/294 (0.68%)	0/47 (0%) Mean 0.69%	1/47 (2%) SD 1.07%	Total	2/50 (4%) 7/298 (2.35%)	1/48 (2%) Mean 2.35%	0/50 (0%) SD 3.2%		
*Bone Marrow: Hemangioma										
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
Occupation of demand	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	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%		

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC Male **Female** *Bone Marrow: Hemangiosarcoma 0/48 (0%)0/50 (0%)2/50 (4%)0/50 (0%)0/49 (0%)1/50 (2%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 2/298 (0.67%) Mean 0.67% SD 1.63% Total 4/299 (1.34%) Mean 1.33% SD 1.63% *Bone Marrow: **Plasma Cell Tumor Malignant** 0/48(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0% #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% 2/300 (0.67%) Mean 0.67% SD 1.03% Total #Bone: Osteoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Bone: Osteosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/50

SD 1.03%

(0%)

0/50

0/300 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

2/300 (0.67%)

(0%)

1/50

Mean 0.67%

(2%)

Overall Incidence

^{*:} 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

Control Animal Groups Report Date: 03/22/2010
ATION
AIR

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			Male				Female	
#Bone:								
Osteosarcoma or Osteoma		4/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/30 (0%) SD 0%
		2/300 (0.07 /0)					ivicali 070	
*Brain: Meningioma Benign								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	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%
*Brain: Meningioma: Benign, Malig	jnant, NOS							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland:								
		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%)		0/43 (0%)	0/42 (0%)	0/46 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/264 (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%)		0/43 (0%)	0/42 (0%)	0/46 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/264 (0%)	Mean 0%	SD 0%
*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%)		0/43 (0%)	0/42 (0%)	0/46 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/264 (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%)		0/43 (0%)	0/42 (0%)	0/46 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/264 (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%)		0/43 (0%)	0/42 (0%)	0/46 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/264 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** *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%)1/43 (2%)0/42 (0%)0/46 (0%)1/264 (0.38%) **Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total Mean 0.39% SD 0.95% #Esophagus: **Squamous Cell Carcinoma** (0%) 0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 4/50 7/50 (14%)8/50 (16%)(8%)3/50 (6%)8/50 (16%)3/50 (6%)10/50 (20%)3/50 (6%)2/50 (4%)3/50 (6%)4/50 (8%)1/50 (2%)**Overall Incidence** Total 34/300 (11.33%) Mean 11.33% SD 6.28% Total 22/300 (7.33%) Mean 7.33% SD 4.68% #Harderian Gland: Carcinoma

4/50

3/50

SD 2.19%

(8%)

(6%)

Total

2/50

1/50

11/300 (3.67%)

(4%)

(2%)

5/50

0/50

(10%)

Mean 3.67%

(0%)

2/50

1/50

SD 3.44%

(4%)

(2%)

Total

3/50

1/50

18/300 (6%)

(6%)

(2%)

4/50

3/50

Mean 6%

(8%)

(6%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male **Female** #Harderian Gland: Carcinoma or Adenoma (10%)10/50 (20%)11/50 (22%)8/50 (16%)5/50 12/50 (24%)5/50 (10%)11/50 (22%)6/50 (12%)5/50 (10%)(8%)4/50 (8%)2/50 (4%)32/300 (10.67%) **Overall Incidence** Total 51/300 (17%) Mean 17% SD 5.18% Total Mean 10.67% SD 6.89% #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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Heart: Hemangiosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 2/300 (0.67%) Mean 0.67% SD 1.03% #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%)

SD 0%

Total

0/300 (0%)

Total

......

0/300 (0%)

Mean 0%

Overall Incidence

^{*:} 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 Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Large: Colon/Rect Leiomyosarcoma	tum:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum Carcinoma	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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	
fintestine 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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		4/50 (8%)	1/50 (2%)	2/50 (4%)		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	8/300 (2.67%)	Mean 2.67%	SD 3.01%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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: Site Unsp Carcinoma	pecified:							
		4/50 (8%)	1/50 (2%)	2/50 (4%)		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	8/300 (2.67%)	Mean 2.67%	SD 3.01%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	pecified:							
		4/50 (8%)	1/50 (2%)	2/50 (4%)		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	8/300 (2.67%)	Mean 2.67%	SD 3.01%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma Overall Incidence	pecified: Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	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%
#Intestine Small: Site Unsp 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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Site Unsp 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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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	
*Islets, Pancreatic: Adenoma								
		0/48 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	2/49 (4%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/296 (1.69%)	Mean 1.69%	SD 1.99%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
*Islets, Pancreatic: Carcinoma								
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%
*Islets, Pancreatic: Carcinoma or Adenoma								
		0/48 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	2/49 (4%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/296 (2.03%)	Mean 2.02%	SD 1.81%	Total	2/298 (0.67%)	Mean 0.67%	SD 1.04%
*Kidney: Renal Tubule: Adenoma								
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*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%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant							
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/49 (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%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male				Female	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	0/50 (0%) SD 0.82%
						•••••	
	1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Total	4/50 (8%) 9/298 (3.02%)	1/49 (2%) Mean 3.01%	1/49 (2%) SD 2.75%	Total	1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 1.63%
	1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/50 (0%) 3/298 (1.01%)	0/49 (0%) Mean 1%	0/49 (0%) SD 1.1%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	30/50 (60%)	34/50 (68%)	28/50 (56%)		19/50 (38%)	18/50 (36%)	14/50 (28%)
Total	` ,	, ,	` '	Total	` ,		14/50 (28%) SD 6.45%
	Total Total	0/50 (0%) Total 0/298 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/298 (0.34%) 1/50 (2%) 4/50 (8%) Total 9/298 (3.02%) 1/50 (2%) 0/50 (0%) Total 3/298 (1.01%) 30/50 (60%) 24/50 (48%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/298 (0%) Mean 0% 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/49 (0%) Total 1/298 (0.34%) Mean 0.33% 1/50 (2%) 0/50 (0%) 4/50 (8%) 1/49 (2%) Total 9/298 (3.02%) Mean 3.01% 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 3/298 (1.01%) Mean 1% 30/50 (60%) 34/50 (68%) 24/50 (48%) 21/49 (43%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) Total 0/298 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/49 (0%) Total 1/298 (0.34%) Mean 0.33% SD 0.82% 1/50 (2%) 0/50 (0%) 2/50 (4%) 4/50 (8%) 1/49 (2%) 1/49 (2%) Total 9/298 (3.02%) Mean 3.01% SD 2.75% 1/50 (2%) 1/50 (2%) 5D 2.75% 1/50 (2%) 1/50 (2%) 0/49 (0%) 0/49 (0%) Total 3/298 (1.01%) Mean 1% SD 1.1% 30/50 (60%) 34/50 (68%) 28/50 (56%) 24/50 (48%) 21/49 (43%) 33/49 (67%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) Total 0/298 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) Total 1/298 (0.34%) Mean 0.33% SD 0.82% Total 1/50 (2%) 4/50 (8%) 1/49 (2%) 1/49 (2%) 1/49 (2%) 1/49 (2%) 1/49 (2%) Total 1/50 (2%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) Total Total 3/298 (1.01%) Mean 1% SD 1.1% Total Total 30/50 (60%) 24/50 (48%) 21/49 (43%) 33/49 (67%) 24/50 (56%) 24/50 (48%) 21/49 (43%) 33/49 (67%) 28/50 (56%) 24/50 (68%) 21/49 (43%) 33/49 (67%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) Total 0/298 (0%) Mean 0% SD 0% Total 0/300 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 1/50 (2%) Total 1/298 (0.34%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Total 1/300 (0.33%) D 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) Total 9/298 (3.02%) Mean 3.01% SD 2.75% Total 4/300 (1.33%) Total 4/300 (1.33%) 1/50 (2%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%) Total 3/298 (1.01%) Mean 1% SD 1.1% Total 0/300 (0%) 30/50 (60%) 34/50 (68%) 28/50 (56%) 19/50 (2%) 24/50 (48%) 21/49 (43%) 33/49 (67%) 10/50 (20%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/298 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% 0/50 (0%) 0/50 (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%) 0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/298 (0.34%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% Mean 0.33% Mean 0.33% Total 9/298 (3.02%) Mean 3.01% SD 2.75% Total 4/300 (1.33%) Mean 1.33% Total 9/298 (3.02%) Mean 3.01% SD 2.75% Total 4/300 (1.33%) Mean 1.33% Total 3/298 (1.01%) Mean 1% SD 1.1% Total 0/300 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Liver: Hepatocellular Carcino	oma							
		15/50 (30%)	13/50 (26%)	20/50 (40%)		5/50 (10%)	10/50 (20%)	4/50 (8%)
		10/50 (20%)	10/49 (20%)	11/49 (22%)		3/50 (6%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	79/298 (26.51%)	Mean 26.48%	SD 7.62%	Total	33/300 (11%)	Mean 11%	SD 5.18%
*Liver:								
Hepatocellular Carcino	ma or Hepatob		44/50 (000/)	20/50 (400/)		F/F0 (400/)	40/50 (000/)	4/50 (00/)
		16/50 (32%) 10/50 (20%)	14/50 (28%) 10/49 (20%)	20/50 (40%) 11/49 (22%)		5/50 (10%) 3/50 (6%)	10/50 (20%) 4/50 (8%)	4/50 (8%) 7/50 (14%)
Overall Incidence	Total	81/298 (27.18%)	Mean 27.14%	SD 7.85%	Total	, ,	4/30 (6%) Mean 11%	SD 5.18%
		01/290 (27.10%)				33/300 (11%)		
*Liver: Hepatocellular Carcino	oma or Hepatoc	ellular Adenoma 38/50 (76%) 28/50 (56%)	40/50 (80%) 26/49 (53%)	40/50 (80%) 37/49 (76%)		24/50 (48%) 13/50 (26%)	25/50 (50%) 17/50 (34%)	16/50 (32%) 20/50 (40%)
Overall Incidence	Total	209/298 (70.13%)	Mean 70.1%	SD 12.24%	Total	115/300 (38.33%)	Mean 38.33%	SD 9.42%
	ma, Hepatocell	lular Adenoma, or Hepato		40/50 (90%)		24/50 (499/)	25/50 (500()	46/50 (220/)
*Liver: Hepatocellular Carcino	ma, Hepatocell	38/50 (76%)	41/50 (82%)	40/50 (80%) 37/49 (76%)		24/50 (48%) 13/50 (26%)	25/50 (50%) 17/50 (34%)	16/50 (32%) 20/50 (40%)
	ma, Hepatocell Total	•		40/50 (80%) 37/49 (76%) SD 12.59%	Total	24/50 (48%) 13/50 (26%) 115/300 (38.33%)	25/50 (50%) 17/50 (34%) Mean 38.33%	16/50 (32%) 20/50 (40%) SD 9.42%
Hepatocellular Carcino Overall Incidence *Liver:	Total	38/50 (76%) 28/50 (56%)	41/50 (82%) 26/49 (53%)	37/49 (76%)	Total	13/50 (26%)	17/50 (34%)	20/50 (40%)
Hepatocellular Carcino Overall Incidence	Total	38/50 (76%) 28/50 (56%)	41/50 (82%) 26/49 (53%)	37/49 (76%)	Total	13/50 (26%)	17/50 (34%)	20/50 (40%)
Hepatocellular Carcino Overall Incidence *Liver:	Total	38/50 (76%) 28/50 (56%) 210/298 (70.47%)	41/50 (82%) 26/49 (53%) Mean 70.43%	37/49 (76%) SD 12.59%	Total	13/50 (26%) 115/300 (38.33%)	17/50 (34%) Mean 38.33%	20/50 (40%) SD 9.42%

^{*:} 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	
*Liver: Hepatocholangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*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%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignan								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Mali	gnant							
	9	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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	
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Alveolar/Bronchiolar <i>A</i>	Adenoma							
		6/50 (12%)	13/50 (26%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
		8/50 (16%)	10/50 (20%)	10/50 (20%)		1/50 (2%)	3/50 (6%)	6/50 (12%)
Overall Incidence	Total	51/300 (17%)	Mean 17%	SD 6.42%	Total	14/300 (4.67%)	Mean 4.67%	SD 3.93%
*Lung: Alveolar/Bronchiolar 0	Carcinoma							
		8/50 (16%)	9/50 (18%)	12/50 (24%)		0/50 (0%)	3/50 (6%)	3/50 (6%)
		5/50 (10%)	7/50 (14%)	11/50 (22%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	52/300 (17.33%)	Mean 17.33%	SD 5.16%	Total	9/300 (3%)	Mean 3%	SD 2.76%
Lung: Alveolar/Bronchiolar C	Carcinoma or Al	veolar/Bronchiolar Adeno	oma					
		13/50 (26%)	19/50 (38%)	15/50 (30%)		1/50 (2%)	4/50 (8%)	5/50 (10%)
		13/50 (26%)	17/50 (34%)	20/50 (40%)		2/50 (4%)	5/50 (10%)	6/50 (12%)
Overall Incidence	Total	97/300 (32.33%)	Mean 32.33%	SD 5.99%	Total	23/300 (7.67%)	Mean 7.67%	SD 3.88%
*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%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Lung: **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%)0/300 (0%) Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 2/300 (0.67%) Mean 0.67% SD 1.03% *Lung: **Plasma 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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% *Lung: Sarcoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #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%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Malig	jnant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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	
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)	1/50 (2%)
Overall Incidence	Total	0/300 (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 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: 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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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	
#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%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	9/300 (3%)	Mean 3%	SD 2.76%
#Mammary Gland: Carcinoma or Adenom	a							
		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%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	9/300 (3%)	Mean 3%	SD 2.76%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Mammary Gland: Fibroma, Fibroadenom	na 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, or	Adenoma						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	5/50 (10%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	10/300 (3.33%)	Mean 3.33%	SD 3.5%

^{*:} 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	
#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%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	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%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.63%
#Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Nose: Mast Cell Tumor Malignant								
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Oral Cavity (Oral Mucos		rynx, 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%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Oral Cavity (Oral Mucos	. •	rynx, Tooth, Gingiva):						
•		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
		Squamous, or Papillom 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		Squamous, or Papillom		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Squamous Cell Carcino		Squamous, or Papillom		0/50 (0%) 0/50 (0%) SD 0.82%	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%
#Oral Cavity (Oral Mucos Squamous Cell Carcin Overall Incidence 'Ovary: Choriocarcinoma	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 0.33%	0/50 (0%) SD 0.82%
Squamous Cell Carcing Overall Incidence Ovary:	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/48 (0%)	0/50 (0%) SD 0.82% 0/49 (0%)
Squamous Cell Carcing Overall Incidence Ovary: Choriocarcinoma	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/48 (0%)	1/50 (2%) Mean 0.33% 0/48 (0%) 0/49 (0%)	0/50 (0%) SD 0.82% 0/49 (0%) 0/50 (0%)
Squamous Cell Carcing Overall Incidence Ovary: Choriocarcinoma	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	Total Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	1/50 (2%) Mean 0.33% 0/48 (0%)	0/50 (0%) SD 0.82% 0/49 (0%)
Squamous Cell Carcing Overall Incidence Ovary: Choriocarcinoma Overall Incidence	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/48 (0%)	1/50 (2%) Mean 0.33% 0/48 (0%) 0/49 (0%)	0/50 (0%) SD 0.82% 0/49 (0%) 0/50 (0%)
Squamous Cell Carcing Overall Incidence 'Ovary: Choriocarcinoma Overall Incidence 'Ovary:	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/48 (0%) 0/294 (0%) 3/50 (6%)	1/50 (2%) Mean 0.33% 0/48 (0%) 0/49 (0%) Mean 0% 5/48 (10%)	0/50 (0%) SD 0.82% 0/49 (0%) 0/50 (0%) SD 0%
Overall Incidence Ovary: Choriocarcinoma Overall Incidence	oma, Papilloma	Squamous, or Papillom 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/300 (0.33%) 0/50 (0%) 0/48 (0%) 0/294 (0%)	1/50 (2%) Mean 0.33% 0/48 (0%) 0/49 (0%) Mean 0%	0/50 (0%) SD 0.82% 0/49 (0%) 0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Fibrous Histiocytoma** 0/50 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/294 (0%) **Overall Incidence** Total Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/294 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/48 0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/294 (0%) Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/294 (0%) Mean 0% SD 0% *Ovary: Hemangioma 0/50 (0%)0/48 (0%)0/49 (0%)0/48 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/294 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
Ovary: Hemangiosarcoma				
nemangiosa coma		0/50 (0%)	0/48 (0%)	1/49 (2%)
		0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/294 (0.34%)	Mean 0.34%	SD 0.83%
Ovary: Leiomyosarcoma				
•		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/294 (0.34%)	Mean 0.34%	SD 0.83%
Ovary: Luteoma				
		1/50 (2%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	1/50 (2%)
verall Incidence	Total	2/294 (0.68%)	Mean 0.67%	SD 1.03%
Ovary: Plasma Cell Tumor Malignant				
•		0/50 (0%)	0/48 (0%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign				
-		0/50 (0%)	1/48 (2%)	0/49 (0%)
		0/48 (0%)	0/49 (0%)	1/50 (2%)
Overall Incidence	Total	2/294 (0.68%)	Mean 0.68%	SD 1.05%

^{*:} 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: 03/22/2010

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

Length of Study: CHRONIC

			Male				Female	
*Ovary: Teratoma Malignant								
						0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence					Total	0/48 (0%) 1/294 (0.34%)	0/49 (0%) Mean 0.33%	1/50 (2%) SD 0.82%
·····								
*Ovary: Tubulostromal Adenoma								
						0/50 (0%)	0/48 (0%)	0/49 (0%)
						0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence					Total	0/294 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
		0/48 (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%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
		1/48 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.35%	SD 0.85%	Total	0/298 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		1/48 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/296 (0.34%)	Mean 0.35%	SD 0.85%	Total	0/298 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Pituitary Gland: Pars Di	stalis or Unspec	ified Site:						
		1/46 (2%)	1/48 (2%)	0/50 (0%)		5/46 (11%)	8/50 (16%)	10/50 (20%)
		0/48 (0%)	0/47 (0%)	0/50 (0%)		4/50 (8%)	4/50 (8%)	6/49 (12%)
Overall Incidence	Total	2/289 (0.69%)	Mean 0.71%	SD 1.1%	Total	37/295 (12.54%)	Mean 12.52%	SD 4.73%
Pituitary Gland: Pars Di								
		0/46 (0%)	0/48 (0%)	0/50 (0%)		1/46 (2%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/47 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/289 (0%)	Mean 0%	SD 0%	Total	2/295 (0.68%)	Mean 0.7%	SD 1.08%
Pituitary Gland: Pars Dis Carcinoma or Adenom		inea Site.						
Carcinoma or Adenom Overall Incidence	Total	1/46 (2%) 0/48 (0%) 2/289 (0.69%)	1/48 (2%) 0/47 (0%) Mean 0.71%	0/50 (0%) 0/50 (0%) SD 1.1%	Total	6/46 (13%) 4/50 (8%) 39/295 (13.22%)	8/50 (16%) 5/50 (10%) Mean 13.21%	10/50 (20%) 6/49 (12%) SD 4.3%
Carcinoma or Adenom Overall Incidence *Pituitary Gland: Pars Int	Total	1/46 (2%) 0/48 (0%) 2/289 (0.69%)	0/47 (0%)	0/50 (0%)	Total	4/50 (8%)	5/50 (10%)	6/49 (12%)
Carcinoma or Adenom Overall Incidence	Total	1/46 (2%) 0/48 (0%) 2/289 (0.69%)	0/47 (0%)	0/50 (0%)	Total	4/50 (8%)	5/50 (10%) Mean 13.21%	6/49 (12%)
Carcinoma or Adenom Overall Incidence Pituitary Gland: Pars Int	Total	1/46 (2%) 0/48 (0%) 2/289 (0.69%)	0/47 (0%) Mean 0.71%	0/50 (0%) SD 1.1%	Total	4/50 (8%) 39/295 (13.22%)	5/50 (10%) Mean 13.21%	6/49 (12%) SD 4.3%
Carcinoma or Adenom Overall Incidence *Pituitary Gland: Pars Int Adenoma	Total	1/46 (2%) 0/48 (0%) 2/289 (0.69%) 0/46 (0%)	0/47 (0%) Mean 0.71% 0/48 (0%)	0/50 (0%) SD 1.1% 0/50 (0%)	Total Total	4/50 (8%) 39/295 (13.22%) 0/46 (0%)	5/50 (10%) Mean 13.21% 2/50 (4%)	6/49 (12%) SD 4.3% 2/50 (4%)
Carcinoma or Adenom Overall Incidence *Pituitary Gland: Pars Int Adenoma Overall Incidence	Total termedia: Total termedia:	1/46 (2%) 0/48 (0%) 2/289 (0.69%) 0/46 (0%) 1/48 (2%)	0/47 (0%) Mean 0.71% 0/48 (0%) 0/47 (0%)	0/50 (0%) SD 1.1% 0/50 (0%) 0/50 (0%)		4/50 (8%) 39/295 (13.22%) 0/46 (0%) 0/50 (0%)	5/50 (10%) Mean 13.21% 2/50 (4%) 0/50 (0%)	6/49 (12%) SD 4.3% 2/50 (4%) 1/49 (2%)
Carcinoma or Adenom Overall Incidence *Pituitary Gland: Pars Int Adenoma Overall Incidence *Pituitary Gland: Pars Int	Total termedia: Total termedia:	1/46 (2%) 0/48 (0%) 2/289 (0.69%) 0/46 (0%) 1/48 (2%)	0/47 (0%) Mean 0.71% 0/48 (0%) 0/47 (0%)	0/50 (0%) SD 1.1% 0/50 (0%) 0/50 (0%)		4/50 (8%) 39/295 (13.22%) 0/46 (0%) 0/50 (0%)	5/50 (10%) Mean 13.21% 2/50 (4%) 0/50 (0%)	6/49 (12%) SD 4.3% 2/50 (4%) 1/49 (2%)
Carcinoma or Adenom Overall Incidence *Pituitary Gland: Pars Int Adenoma Overall Incidence *Pituitary Gland: Pars Int	Total termedia: Total termedia:	1/46 (2%) 0/48 (0%) 2/289 (0.69%) 0/46 (0%) 1/48 (2%) 1/289 (0.35%)	0/47 (0%) Mean 0.71% 0/48 (0%) 0/47 (0%) Mean 0.35%	0/50 (0%) SD 1.1% 0/50 (0%) 0/50 (0%) SD 0.85%		4/50 (8%) 39/295 (13.22%) 0/46 (0%) 0/50 (0%) 5/295 (1.69%)	5/50 (10%) Mean 13.21% 2/50 (4%) 0/50 (0%) Mean 1.67%	6/49 (12%) SD 4.3% 2/50 (4%) 1/49 (2%) SD 1.97%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female	
*Prostate: Adenoma						
		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%		
*Prostate: Carcinoma or Adenoma						
		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%		
*Prostate: Hemangioma						
		0/49 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Carcinoma						
		0/49 (0%)	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%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total 0/299 (0%) Mean 0% SD 0%	
*Salivary Glands: Carcinoma or Adenoma						
		0/49 (0%)	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%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total 0/299 (0%) Mean 0% SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Salivary Glands: Mast Cell Tumor Malignan	t							
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Seminal Vesicle: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Occupation of James	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma o	r Rhabdomyoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	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%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, B	asosquamous T	umor Benign, or Trichoe	pithelioma					
, <u>-</u>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:			00)					
Basai Celi Carcinoma d	or Basosquamou	us Tumor (malignant or N 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:		oma, Basosquamous Tur	mor (benign, malignan	t or				
		oma, Basosquamous Tur 0/50 (0%) 0/50 (0%) 0/300 (0%)	nor (benign, malignan 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (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: Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom q Papilloma, Ke	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% a, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence Skin: Basal or Sq. Cell Carci	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 3), Basal Cell Adenom bithelioma 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% a,	Total Total	0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 1/50 (2%)	0/50 (0%) SD 0% 0/50 (0%)
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, S	Total Total noma, Carcinom or Papilloma, Ke Total	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% a, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Dverall Incidence Skin: Basal or Sq. Cell Carcin Adenoma, Papilloma, Section Science Skin:	Total Total noma, Carcinom or Papilloma, Ke Total	0/50 (0%) 0/50 (0%) 0/300 (0%) a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% B), Basal Cell Adenoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) SD 0% a, 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Fibroma, Fibrosarcoma	a. Sarcoma. Mv)	coma, Myxosarcoma, or F	ibrous Histiocytoma					
	., •a. ••a, <i>y</i> :	0/50 (0%)	2/50 (4%)	1/50 (2%)		8/50 (16%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	2/50 (4%)		6/50 (12%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	21/300 (7%)	Mean 7%	SD 6.16%
#Skin: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	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: Fibrosarcoma, Sarcom	a, Myxosarcom	a, or Fibrous Histiocytom	a					
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%) 2/50 (4%)		8/50 (16%) 6/50 (12%)	0/50 (0%) 2/50 (4%)	4/50 (8%) 1/50 (2%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 1.97%	Total	21/300 (7%)	Mean 7%	SD 6.16%
#Skin: Fibrous Histiocytoma								
		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%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Granular Cell Tumor Ben	nign							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: 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%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Hemangiosarcoma								
· ·		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 1.63%	Total	1/50 (2%) 3/300 (1%)	0/50 (0%) Mean 1%	0/50 (0%) SD 1.1%
#Skin: Liposarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
#Skin: Mast Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} 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: 03/22/2010

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

Length of Study: CHRONIC

			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%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%			
Skin: Neurofibrosarcoma or	r Schwannoma (m	valignant or NOS)									
Neuronbrosarcoma or	Scriwannonia (ii	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%			
Neurofibrosarcoma, N	leurofibroma, or S	Schwannoma (benign, ma	lignant or NOS)								
Neurofibrosarcoma, N Overall Incidence	leurofibroma, or \$ Total	Schwannoma (benign, ma 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	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%			
Overall Incidence #Skin:		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%)			
Overall Incidence		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%)			
Overall Incidence		0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (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%			
Overall Incidence #Skin: Osteosarcoma		0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%)	Total Total	0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%)			
Overall Incidence #Skin: Osteosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (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%) 0/300 (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%)			
Overall Incidence #Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (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%) 0/300 (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%)			
Overall Incidence #Skin: Osteosarcoma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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					Male						F	emale		
#Skin: Schwannoma Malignant														
_		,	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 ((0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300 (0%)		Mean	0%	SD 0%		Total	0/300 (0%)	Mea	า 0%	SD	0%
#Skin: Squamous Cell Carcinoma														
		0/50 ((0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50 ((0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300 (0%)		Mean	0%	SD 0%		Total	1/300 (0.	.33%)	Mean	0.33%	SD 0.	.82%
or Carcinoma Overall Incidence	Total	,	(0%) (0%)	0/50 0/50 Mean	(0%) (0%) 0%	0/50 0/50 SD 0%	(0%) (0%)	Total	0/50 0/50 1/300 (0.	(0%) (0%) .33%)	1/50 0/50 Mean	(2%) (0%) 0.33%	0/50 0/50 SD 0.	(0%) (0%) .82%
		0/300 (0/0)		IVICALI	0 70	00 070		i Otai		.0070)		0.0070	00 0.	.02 /0
					•••••					•••••			•••••	
#Skin: Squamous Cell Papilloma		0/50	00()	0/50	(00/)	0/50	(00/)			(00/)	0/50	(00/)	0/50	(00/)
		,	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
	Total	0/50	(0%) (0%)	0/50	(0%)	0/50	(0%) (0%)	Total	0/50 0/50	(0%)	0/50	(0%)	0/50	(0%)
	Total	,	` '		(0%)		` '	Total	0/50	(0%)		(0%)		(0%)
Squamous Cell Papilloma		0/50 (0/300 (0%)	` '	0/50	(0%)	0/50	` '	Total	0/50 0/50	(0%)	0/50	(0%)	0/50	(0%)
Squamous Cell Papilloma Overall Incidence #Skin:		0/50 (i 0/300 (0%) 	(0%)	0/50 Mean 0/50	(0%)	0/50 SD 0% 0/50	(0%)	Total	0/50 0/50 0/300 ((0%) 0%) (0%)	0/50 Mean	(0%) 0% (0%)	0/50 SD 0/50	(0%) 0% (0%)
Squamous Cell Papilloma Overall Incidence #Skin:		0/50 (i 0/300 (0%) 0/50 (i	(0%)	0/50 Mean	(0%) 0% (0%) (0%)	0/50 SD 0%	(0%)	Total	0/50 0/50 0/300 ((0%) 0%) (0%) (0%)	0/50 Mea	(0%) n 0% (0%) (0%)	0/50 SD	(0%) 0% (0%) (0%) (0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: INHALATION Strain: B6C3F1 Vehicle: AIR

Length of Study: CHRONIC

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			Male				Female	
#Skin:								
Squamous Cell Papillon	na, Papilloma, S	•						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin:								
Squamous Cell Papillon	na, Papilloma, o		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%)	0/50 (0%)
Overall Incidence	Total	0/300 (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%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: 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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: 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%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma								
		0/48 (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%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
_		0/48 (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%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		2/48 (4%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	0/49 (0%)	2/50 (4%)
		1/50 (2%)	1/49 (2%)	1/49 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	8/296 (2.7%)	Mean 2.71%	SD 2.08%	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Spleen: Mast Cell Tumor Malignar	nt							
		0/48 (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%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Spleen: Plasma Cell Tumor Maligr	nant							
_		0/48 (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%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Mast Cell Tumor Malignar	nt							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	ıa							
		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%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papillom	na Squamous						
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	5/300 (1.67%)	Mean 1.67%	SD 0.82%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
·		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	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	3/300 (1%)	1/50 (2%) Mean 1%	1/50 (2%) SD 1.1%
#Stomach, Glandular: Adenoma				•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Carcinoma or Adenoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Testes: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%				
*Thymus: Thymoma Benign								
-		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
Overall Incidence	Total	0/41 (0%) 0/256 (0%)	0/47 (0%) Mean 0%	0/47 (0%) SD 0%	Total	0/50 (0%) 0/292 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thymus: Thymoma Malignant								
		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/47 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/256 (0%)	Mean 0%	SD 0%	Total	0/292 (0%)	Mean 0%	SD 0%
'Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/47 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/256 (0%)	Mean 0%	SD 0%	Total	0/292 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		3/50 (6%)	0/49 (0%)	0/49 (0%)		3/50 (6%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	3/297 (1.01%)	Mean 1%	SD 2.45%	Total	6/299 (2.01%)	Mean 2%	SD 2.53%

^{*:} 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	
Thyroid Gland: Follicular C Carcinoma	Cell:							
		0/49 (0%)	` ,	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	` '	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
*Thyroid Gland: Follicular C Carcinoma or Adenoma	Cell:							
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	2/50 (4%)	0/50 (0%)
		3/50 (6%)	0/49 (0%)	0/49 (0%)		3/50 (6%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	3/297 (1.01%)		D 2.45%	Total	8/299 (2.68%)	Mean 2.67%	SD 2.42%
#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%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligr	nant							
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

^{*:} 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	
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: 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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous						
·	•	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#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%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

^{*:} 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	
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/300 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/47 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	1/296 (0.34%)	Mean 0.33%	SD 0.82%
Urinary Bladder: Plasma Cell Tumor Mal	ignant							
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/295 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male			Female	
EUterus: Adenoma				
Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Uterus: Carcinoma				
		0/50 (0%)	3/50 (6%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%
Uterus:				
Hemangioma				
·		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%
Uterus: Hemangiosarcoma				
Tioman grood to the		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Uterus: Leiomyoma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
tuterus:				
Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In address of	Total	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Uterus: Polyp Stromal				
		0/50 (0%)	3/50 (6%)	1/50 (2%)
		3/50 (6%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	10/300 (3.33%)	Mean 3.33%	SD 2.42%
tUterus: Sarcoma Stromal		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal				
		0/50 (0%)	3/50 (6%)	1/50 (2%)
		3/50 (6%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	10/300 (3.33%)	Mean 3.33%	SD 2.42%
Uterus: Schwannoma Malignant				
-		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%

^{*:} 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					
#Vagina: Liposarcoma	Total	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%			
#Vagina: Squamous Cell Papilloma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

Route: ORAL Vehicle: FEED Page: 188

Report Date: 03/22/2010

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059902704	07/29/02	729	50(1)	46(715)	50.0	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517406	N/A	N/A	0(0)	0(0)	N/A	Cresols
Southern Research Institute	059900706	05/12/03	729	50(1)	43(715)	48.3	Goldenseal root powder
Southern Research Institute	052000804	03/25/03	729	50(1)	45(712)	49.8	Milk thistle extract
					Female		
Southern Research Institute	059902704	07/29/02	732	50(5)	45(698)	50.3	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517406	08/20/02	728	50(5)	41(696)	51.8	Cresols
Southern Research Institute	059900706	05/12/03	732	50(5)	44(718)	51.9	Goldenseal root powder
Southern Research Institute	052000804	03/25/03	732	50(5)	40(714)	51.0	Milk thistle extract

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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			Male				Female	
#All Organs: Benign Tumors								
-		28/50 (56%) 21/50 (42%)		28/50 (56%)		16/50 (32%) 18/50 (36%)	16/50 (32%)	17/50 (34%)
verall Incidence	Total	77/150 (51.33%)	Mean 51.33%	SD 8.08%	Total	67/200 (33.5%)	Mean 33.5%	SD 1.91%
All Organs: Malignant Tumors								
		24/50 (48%) 29/50 (58%)		20/50 (40%)		22/50 (44%) 19/50 (38%)	20/50 (40%)	13/50 (26%)
verall Incidence	Total	73/150 (48.67%)	Mean 48.67%	SD 9.02%	Total	74/200 (37%)	Mean 37%	SD 7.75%
All Organs: Malignant and Benign T	umors							
		40/50 (80%) 39/50 (78%)		38/50 (76%)		31/50 (62%) 32/50 (64%)	29/50 (58%)	26/50 (52%)
verall Incidence	Total	117/150 (78%)	Mean 78%	SD 2%	Total	118/200 (59%)	Mean 59%	SD 5.29%
All Organs: Hemangioma								
		0/50 (0%) 2/50 (4%)		0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
All Organs: Hemangiosarcoma								
-		2/50 (4%) 3/50 (6%)		2/50 (4%)		3/50 (6%) 2/50 (4%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories Tumor

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** #All Organs: Hemangiosarcoma or Hemangioma 2/50 (4%)2/50 (4%)3/50 (6%)1/50 (2%)1/50 (2%)4/50 (8%)3/50 (6%)8/200 (4%) Mean 4% Overall Incidence Total 8/150 (5.33%) Mean 5.33% SD 2.31% Total SD 2.31% #All Organs: **Histiocytic Sarcoma** 0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 4/200 (2%) Mean 2% SD 1.63% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 2/50 (4%)1/50 (2%)5/50 (10%)7/50 (14%) 6/50 (12%) (12%)6/50 11/50 (22%)**Overall Incidence** Total 9/150 (6%) Mean 6% SD 5.29% Total 29/200 (14.5%) Mean 14.5% SD 5.26% **#All Organs:** Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% **#All Organs:** Mesothelioma: Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/50

0/200 (0%)

Total

(0%)

Mean 0%

SD 0%

Total

0/50

0/150 (0%)

.....

(0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% **#All Organs:** Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% *Adrenal Cortex: Adenoma 0/50 (0%)2/50 (4%)0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 2% Total 0/199 (0%) Mean 0% SD 0% *Adrenal Cortex: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Beni	gn							
		0/49 (0%) 1/49 (2%)		0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/197 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Com	plex							
		0/49 (0%) 0/49 (0%)		0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Malig	gnant							
		0/49 (0%) 0/49 (0%)		0/50 (0%)		1/49 (2%) 0/49 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	2/197 (1.02%)	Mean 1.02%	SD 1.18%
Adrenal Medulla: Pheochromocytoma: Ben	ign, Complex							
		0/49 (0%) 1/49 (2%)		0/50 (0%)		1/49 (2%) 0/49 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%	Total	2/197 (1.02%)	Mean 1.02%	SD 1.18%
Bone Marrow: Hemangioma								
-		0/50 (0%) 0/49 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Contract/Lab: All Laboratories

Strain: B6C3F1 Length of Study: CHRONIC

			Male				Female	
*Bone Marrow: Hemangiosarcoma								
-		0/50 (0%) 1/49 (2%)		0/50 (09	%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	0/199 (0%)	Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Maliç	gnant							
		0/50 (0%) 0/49 (0%)		0/50 (09	%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (09	%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)		0/50 (09	%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (09	%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Bone: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% *Brain: Meningioma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (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%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Brain: Meningioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FFFD

Vehicle: FEED

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			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 1/50 (2%)		0/50 (0%)		0/44 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/44 (0%) 0/47 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/190 (0.53%)	Mean 0.51%	SD 1.02%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)		0/50 (0%)		0/44 (0%) 0/47 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/190 (0.53%)	Mean 0.51%	SD 1.02%
*Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/44 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/44 (0%) 0/47 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** *Clitoral/Preputial Gland: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/44 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/47 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/190 (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%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Eye: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 5/50 (10%)7/50 (14%)7/50 (14%)6/50 5/50 (10%)(12%) 5/50 (10%)6/50 (12%)**Overall Incidence** Total 17/150 (11.33%) Mean 11.33% SD 2.31% Total 24/200 (12%) Mean 12% SD 1.63% #Harderian Gland: Carcinoma 1/50 (2%)2/50 (4%)2/50 (4%)1/50 (2%)(4%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 2% Total 7/200 (3.5%) Mean 3.5%

^{*:} 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: ORAL Vehicle: FEED

Length of Study: CHRONIC

e. OKAL ele: FEED **Page**: 197

			Male				Female	
Harderian Gland: Carcinoma or Adenoma								
		5/50 (10%) 5/50 (10%)		9/50 (18%)		9/50 (18%) 8/50 (16%)	7/50 (14%)	7/50 (14%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 4.62%	Total	31/200 (15.5%)	Mean 15.5%	SD 1.91%
#Harderian Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
'Heart: Hemangioma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: Mar2010 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma	ım:							
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		1/50 (2%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 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%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% #Intestine Small: Ileum: Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Ileum: **Polyp Adenomatous**

0/50

SD 0%

(0%)

0/50

0/50

0/200 (0%)

Total

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/50

0/150 (0%)

(0%)

(0%)

Mean 0%

Overall Incidence

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Small: Jejunum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 1/50 (2%)2/50 (4%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 3/150 (2%) Mean 2% SD 2% Total 1/200 (0.5%) Mean 0.5% SD 1% #Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (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%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Intestine Small: Site Unspecified: Adenoma 0/50 1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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			Male				Female	
#Intestine Small: Site Uns Carcinoma	specified:							
		2/50 (4%) 0/50 (0%)		2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Uns Carcinoma or Adenoma	•							
		3/50 (6%) 0/50 (0%)		2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Uns Hemangiosarcoma	specified:							
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Uns Polyp Adenomatous								
-		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 0%

SD 0%

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Islets, Pancreatic: Adenoma 1/50 (2%)0/49 (0%)0/50 (0%)1/50 (2%)1/48 (2%)0/49 (0%)0/49(0%)2/197 (1.02%) **Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total Mean 1.02% SD 1.18% *Islets, Pancreatic: Carcinoma 0/50 (0%)0/49(0%)2/50 (4%)0/50 (0%)(0%)0/49 (0%)0/49 (0%)Overall Incidence Total 0/148 (0%) Mean 0% SD 0% Total 2/197 (1.02%) Mean 1% SD 2% *Islets, Pancreatic: Carcinoma or Adenoma 1/50 (2%)0/49 2/50 (4%)1/50 (2%)1/48 (2%)(0%)0/49 0/49 (0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 4/197 (2.03%) Mean 2.02% SD 1.63% *Kidney: Renal Tubule: Adenoma 2/50 (4%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 1.15%

Total

0/200 (0%)

Total

1/150 (0.67%)

Mean 0.67%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Kidney: Renal Tubule: Carcinoma or Adenoma 3/50 (6%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 3.46% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% *Kidney: Renal Tubule: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: **Plasma Cell Tumor Malignant** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

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			Male				Female	
Liver: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
		2/50 (4%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatoblastoma								
-		0/50 (0%) 0/50 (0%)		1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
		21/50 (42%) 12/50 (24%)		22/50 (44%)		1/50 (2%) 3/50 (6%)	4/50 (8%)	3/50 (6%)
Overall Incidence	Total	55/150 (36.67%)	Mean 36.67%	SD 11.02%	Total	11/200 (5.5%)	Mean 5.5%	SD 2.52%

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Liver: **Hepatocellular Carcinoma** 15/50 (30%)8/50 (16%) 3/50 (6%)1/50 (2%)3/50 (6%)17/50 (34%)0/50 (0%)7/200 (3.5%) **Overall Incidence** Total 40/150 (26.67%) Mean 26.67% SD 9.45% Total Mean 3.5% SD 3% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 15/50 (30%)9/50 (18%)3/50 (6%)1/50 (2%)3/50 (6%)17/50 (34%)0/50 (0%)Mean 27.33% **Overall Incidence** Total 41/150 (27.33%) SD 8.33% Total 7/200 (3.5%) Mean 3.5% SD 3% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 32/50 (64%)26/50 (52%)4/50 (8%)4/50 6/50 (12%) 26/50 (52%)3/50 (6%)**Overall Incidence** Total 84/150 (56%) Mean 56% SD 6.93% Total 17/200 (8.5%) SD 2.52% Mean 8.5% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 32/50 (64%)4/50 (8%)4/50 26/50 (8%)6/50 (12%)26/50 (52%)3/50 (6%)**Overall Incidence** Total 84/150 (56%) Mean 56% SD 6.93% Total 17/200 (8.5%) Mean 8.5% SD 2.52% *Liver: Hepatocholangiocarcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** *Liver: Hepatocholangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Liver: Ito Cell Tumor Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Liver: **Ito Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Liver: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

icle: FEED

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			Male				Female	
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A	Adenoma							
		13/50 (26%) 1/50 (2%)		4/50 (8%)		1/50 (2%) 1/50 (2%)	5/50 (10%)	4/50 (8%)
Overall Incidence	Total	18/150 (12%)	Mean 12%	SD 12.49%	Total	11/200 (5.5%)	Mean 5.5%	SD 4.12%
Lung: Alveolar/Bronchiolar C	Carcinoma							
		3/50 (6%) 10/50 (20%)		6/50 (12%)		1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 7.02%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%
Lung: Alveolar/Bronchiolar C	Carcinoma or Al	veolar/Bronchiolar Adenc	oma					
		16/50 (32%) 11/50 (22%)		10/50 (20%)		2/50 (4%) 2/50 (4%)	5/50 (10%)	5/50 (10%)
Overall Incidence	Total	37/150 (24.67%)	Mean 24.67%	SD 6.43%	Total	14/200 (7%)	Mean 7%	SD 3.46%
Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: FEED

Strain: B6C3F1
Length of Study: CHRONIC

Male

Vehicle: FEED

Female

			Male				Female	
Lung: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Plasma Cell Tumor Maligr								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
		0/50 (0%) 1/50 (2%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% **#Lymph Node: Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Lymph Node, Bronchial: Hemangiosarcoma 0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (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%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Lymph Node, Mandibular: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Lymph Node, Mandibular: **Plasma Cell Tumor Malignant** 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Lymph Node, Mesenteric: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)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 0/200 (0%) Mean 0% SD 0% #Lymph Node, Mesenteric: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% #Lymph Node, Mesenteric: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% **#Mammary Gland:** Adenoacanthoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o	r Adenoma							
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, (Adenoma						
,		0/50 (0%) 0/50 (0%)		0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mesentery: **Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Mesentery: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)SD 1.15% Mean 0% Overall Incidence Total 1/150 (0.67%) Mean 0.67% Total 0/200 (0%) SD 0% #Mesentery: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Mesentery: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Nose: **Mast Cell Tumor Malignant** (2%)0/50 1/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

le: FEED

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			Male				Female	
#Oral Cavity (Oral Mucos Papilloma Squamous o		ynx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
•		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcin	oma, Papilloma (0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	•	0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	` '	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall Incidence *Ovary: Choriocarcinoma	•	0/50 (0%) 0/50 (0%)	Mean 0%	,	Total	0/50 (0%)	,	,
Overall Incidence *Ovary: Choriocarcinoma	•	0/50 (0%) 0/50 (0%)	Mean 0%	,	Total Total	0/50 (0%) 0/200 (0%) 0/48 (0%)	Mean 0%	SD 0%
Overall Incidence Ovary: Choriocarcinoma Overall Incidence	•	0/50 (0%) 0/50 (0%)	Mean 0%	,		0/50 (0%) 0/200 (0%) 0/48 (0%) 0/46 (0%)	Mean 0% 0/50 (0%)	SD 0% 0/49 (0%)
Overall Incidence *Ovary: Choriocarcinoma Overall Incidence *Ovary:	•	0/50 (0%) 0/50 (0%)	Mean 0%	,		0/50 (0%) 0/200 (0%) 0/48 (0%) 0/46 (0%)	Mean 0% 0/50 (0%)	SD 0% 0/49 (0%)

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

^{#:} Denominator is number of animals necropsied

Version: Mar2010 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male	Female	
*Ovary: Fibrous Histiocytoma			
		0/48 (0%) 0/50 (0%) 0/49 0/46 (0%)	(0%)
Overall Incidence	Total	0/193 (0%) Mean 0% SD 09	
*Ovary: Granulosa Cell Tumor Benign			
		2/48 (4%) 0/50 (0%) 0/49 0/46 (0%)	(0%)
Overall Incidence	Total	2/193 (1.04%) Mean 1.04% SD 2.08	
*Ovary: Granulosa Cell Tumor Malignant			
		1/48 (2%) 0/50 (0%) 0/49 0/46 (0%)	(0%)
Overall Incidence	Total	1/193 (0.52%) Mean 0.52% SD 1.04	.,-
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			
		3/48 (6%) 0/50 (0%) 0/49 0/46 (0%)	(0%)
Overall Incidence	Total	3/193 (1.55%) Mean 1.56% SD 3.12	2%
*Ovary: Hemangioma			
		0/48 (0%) 0/50 (0%) 0/49 0/46 (0%)	(0%)
Overall Incidence	Total	0/193 (0%) Mean 0% SD 0%	%

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

^{#:} Denominator is number of animals necropsied

Version: Mar2010 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male			Female	
Ovary: Hemangiosarcoma					
•			0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/193 (0%)	Mean 0%	SD 0%
Ovary: Leiomyosarcoma					
			0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/193 (0%)	Mean 0%	SD 0%
Ovary: Luteoma					
			0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/193 (0%)	Mean 0%	SD 0%
Ovary: Plasma Cell Tumor Malignant					
			0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/193 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign					
-			0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/193 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

nicle: FEED

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			Male	Female				
Ovary: Teratoma Malignant								
						0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/193 (0%)	Mean 0%	SD 0%
Ovary: Tubulostromal Adenoma								
						0/48 (0%) 0/46 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/193 (0%)	Mean 0%	SD 0%
Pancreas: Adenoma								
		0/50 (0%) 0/49 (0%)		1/49 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/49 (0%)		0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)		1/49 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.68%	SD 1.18%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/48 (0%)0/50 (0%)1/47 (2%)2/50 (4%)0/50 (0%)0/48 (0%)2/49 (4%)Mean 0% **Overall Incidence** Total 0/146 (0%) SD 0% Total 5/196 (2.55%) Mean 2.55% SD 1.93% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/48(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)Overall Incidence Total 0/146 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 0/48 (0%)0/50 (0%)1/47 (2%)2/50 0/50 (0%)(0%)0/48 2/49 (4%)**Overall Incidence** Total 0/146 (0%) Mean 0% SD 0% Total 5/196 (2.55%) Mean 2.55% SD 1.93% *Pituitary Gland: Pars Intermedia: Adenoma 0/48 (0%)0/50 (0%)1/47 (2%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 0/146 (0%) Mean 0% SD 0% Total 1/196 (0.51%) Mean 0.53% SD 1.06% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/48 (0%)0/50 (0%)1/47 (2%)0/50 (0%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 0/146 (0%) Mean 0% SD 0% Total 1/196 (0.51%) Mean 0.53%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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			Male					Female	
*Prostate: Adenoma		1/50 (2%)		0/50	(0%)				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Prostate: Carcinoma or Adenoma									
		1/50 (2%) 0/50 (0%)		0/50	(0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Prostate: Hemangioma									
-		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 (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	0/200 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)		0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

Mean 0%

(0%)

0/50

SD 0%

SD 0%

(0%)

0/50

Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Salivary Glands: **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%)0/200 (0%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle: Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)

SD 1.15%

0/50

SD 0%

(0%)

Total

Total

0/200 (0%)

0/50

0/50

0/200 (0%)

(0%)

(0%)

Total

Total

1/150 (0.67%)

0/50

0/50

0/150 (0%)

(0%)

(0%)

.....

Mean 0.67%

Mean 0%

Overall Incidence

#Skeletal Muscle: Myxosarcoma

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female #Skeletal Muscle:** Rhabdomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1%

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

^{#:} Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% 0/200 (0%) **Overall Incidence** Total 0/150 (0%) SD 0% Total Mean 0% SD 0% #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/150 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (0%)0/50 0/50 (0%)0/50 0/50 (0%)1/50 (2%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: **Basosquamous Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 0/150 (0%) SD 0% SD 0% Mean 0% Total 0/200 (0%) Mean 0%

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^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)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 0/200 (0%) Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 1/50 (2%)0/50 (0%)2/50 (4%)5/50 (10%) 3/50 (6%)3/50 (6%)3/50 (6%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 3.06% Total 13/200 (6.5%) Mean 6.5% SD 2.52% #Skin: **Fibrosarcoma** 0/50 (0%)0/50 (0%)1/50 (2%)4/50 (8%)1/50 (2%)0/50 (0%)3/50 (6%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 9/200 (4.5%) SD 3% Mean 4.5% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma (2%)0/50 2/50 (4%)5/50 3/50 (10%) (6%)2/50 (4%)3/50 (6%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 2% Total 13/200 (6.5%) Mean 6.5% SD 2.52% #Skin: **Fibrous Histiocytoma** 1/50 (2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 2% Total 1/200 (0.5%) Mean 0.5%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male			Female		
#Skin: Granular Cell Tumor Benig	gn							
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Hemangiosarcoma								
		0/50 (0%) 2/50 (4%)		1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
·		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

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Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)1/50 (2%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Skin: Osteosarcoma 0/50 (0%)0/50 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 0/200 (0%) Mean 0% SD 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)(4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 3/200 (1.5%) Mean 1.5%

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)(0%)(0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)(0%)0/50 0/50 **Overall Incidence** SD 0% 0/200 (0%) SD 0% Total 0/150 (0%) Mean 0% Total Mean 0% #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/200 (0%)

Mean 0%

SD 0%

Total

0/150 (0%)

Mean 0%

Overall Incidence

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% **#Skin: Sebaceous Gland:** Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (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%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

control Animal Groups Report Date: 03/22/2010

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			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)		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	1/200 (0.5%)	Mean 0.5%	SD 1%
#Spinal Cord: Meningioma Malignant								
		1/50 (2%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma			•••••					
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
		0/50 (0%) 2/50 (4%)		1/50 (2%)		2/50 (4%) 0/50 (0%)	1/48 (2%)	1/48 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	4/196 (2.04%)	Mean 2.04%	SD 1.63%

^{*:} 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: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Spleen: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/196 (0%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Spleen: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% #Stomach, Forestomach: **Mast Cell Tumor Malignant** 1/50 (2%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Forestomach: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (4%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% Total 1/200 (0.5%) Mean 0.5%

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

^{#:} Denominator is number of animals necropsied

Version: Mar2010 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
		2/50 (4%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		0/50 (0%) 1/50 (2%)		0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
Thymus: Thymoma Benign								
		0/41 (0%) 0/45 (0%)		0/44 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/130 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Mean 0.5%

SD 1%

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** *Thymus: **Thymoma Malignant** 0/41 (0%)0/44 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/45 (0%)0/49 (0%)Overall Incidence Total 0/130 (0%) Mean 0% SD 0% Total 0/197 (0%) Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/41 (0%)0/44(0%)0/49(0%)0/50 (0%)(0%)0/45 (0%)0/49 (0%)Mean 0% Overall Incidence Total 0/130 (0%) Mean 0% SD 0% Total 0/197 (0%) SD 0% *Thyroid Gland: C-Cell: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/48 0/50 (0%)(0%)0/48 0/50 (0%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Overall Incidence Total 0/148 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)1/50 (2%)1/50 (2%)0/48 (0%)0/50 (0%)0/48 (0%)0/50 (0%)

SD 1.15%

Total

1/198 (0.51%)

Total

1/148 (0.68%)

.....

Mean 0.67%

Overall Incidence

^{*:} 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: ORAL

Length of Study: CHRONIC

Vehicle: FEED

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			Male			Female		
*Thyroid Gland: Follicular Cel Carcinoma	II:							
		0/50 (0%) 0/48 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cel Carcinoma or Adenoma								
		0/50 (0%) 0/48 (0%)		1/50 (2%)		1/50 (2%) 0/50 (0%)	0/48 (0%)	0/50 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
Tissue NOS: Carcinoma								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (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%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tissue NOS: Plasma Cell Tumor Maligna								
		0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Tissue NOS:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Tongue: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% #Tongue: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (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%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Tooth: Odontoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% *Urinary Bladder: Hemangioma 0/50 (0%)0/49 (0%)0/49(0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/198 (0%) SD 0% *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Urinary Bladder: **Plasma Cell Tumor Malignant** 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0% *Urinary Bladder: Sarcoma 0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/198 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Version: Mar2010 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male			Female	
#Uterus: Adenoma					
Auerionia			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	,	,
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma					
			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma			•••••		
-			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
-			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyoma			•••••		
			0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} 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

Route: ORAL Vehicle: FEED Page: 236

Report Date: 03/22/2010

Strain: B6C3F1 Length of Study: CHRONIC

	Male	Female	
#Uterus: Leiomyosarcoma			
·		2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%) Mean 1%	SD 2%
#Uterus: Polyp Stromal			
		2/50 (4%) 0/50 (0%) 4/50 (8%)	2/50 (4%)
Overall Incidence	Total	8/200 (4%) Mean 4%	SD 3.27%
#Uterus: Sarcoma Stromal			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal			
		2/50 (4%) 0/50 (0%) 4/50 (8%)	2/50 (4%)
Overall Incidence	Total	8/200 (4%) Mean 4%	SD 3.27%
#Uterus: Schwannoma Malignant			
-		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%) Mean 0.5%	SD 1%

^{*:} 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: FEED Page: 237

	Male		Female
#Vagina: Liposarcoma		0/50 (0%)	/50 (0%) 0/50 (0%)
Overall Incidence	Total	(,	Mean 0% SD 0%
#Vagina: Squamous Cell Papilloma			/50 (0%) 0/50 (0%)
Overall Incidence	Total	(,	Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	052011406	09/04/02	729	50(1)	33(700)	55.6	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	729	50(1)	38(696)	54.1	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601506	08/22/01	729	50(1)	40(697)	54.0	Water disinfection byproducts (Dibromoacetonitrile)
					Female		
Southern Research Institute	052011406	09/04/02	735	50(5)	35(701)	64.3	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	734	50(5)	36(693)	63.0	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601506	08/22/01	731	50(5)	35(705)	60.9	Water disinfection byproducts (Dibromoacetonitrile)

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #All Organs: **Benign Tumors** 42/50 (84%)41/50 (82%)32/50 (64%)27/50 (54%)32/50 (64%)29/50 (58%)**Overall Incidence** Total 115/150 (76.67%) Mean 76.67% SD 11.02% Total 88/150 (58.67%) Mean 58.67% SD 5.03% #All Organs: **Malignant Tumors** 31/50 (62%)36/50 (72%)29/50 (58%)22/50 (44%)38/50 (76%)31/50 (62%)**Overall Incidence** Total 96/150 (64%) Mean 64% SD 7.21% 91/150 (60.67%) Mean 60.67% SD 16.04% Total #All Organs: **Malignant and Benign Tumors** 49/50 (98%)47/50 (94%)41/50 (82%)36/50 (72%)43/50 (86%)44/50 (88%)Overall Incidence Total 137/150 (91.33%) Mean 91.33% SD 8.33% Total 123/150 (82%) Mean 82% SD 8.72% #All Organs: Hemangioma 0/50 (0%)1/50 (2%)1/50 (2%)1/50 (2%)2/50 (4%)0/50 (0%)**Overall Incidence** Total Mean 1.33% SD 1.15% Total 3/150 (2%) Mean 2% SD 2% 2/150 (1.33%) **#All Organs:** Hemangiosarcoma 4/50 (8%)3/50 (6%)1/50 (2%)2/50 (4%)1/50 (2%)3/50 (6%)**Overall Incidence** Total 8/150 (5.33%) Mean 5.33% SD 3.06% Total 6/150 (4%) Mean 4% SD 2% **#All Organs:** Hemangiosarcoma or Hemangioma (6%) 4/50 (8%)4/50 (8%)2/50 (4%)3/50 3/50 (6%)3/50 (6%)**Overall Incidence** 10/150 (6.67%) Mean 6.67% SD 2.31% Mean 6% SD 0% Total Total 9/150 (6%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 240 Report Date: 03/22/2010

			Male			Female		
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	4/50 (8%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
All Organs: Malignant Lymphoma: Hist	iocytic, Lyn	nphocytic, Mixed, NOS, or	Undifferentiated Cel	I Type				
		2/50 (4%)	2/50 (4%)	0/50 (0%)		7/50 (14%)	18/50 (36%)	9/50 (18%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	34/150 (22.67%)	Mean 22.67%	SD 11.72%
#All Organs: Mesothelioma: Benign, Mal	lignant, NOS	S 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
All Organs: Osteosarcoma		4/50 (00/)	0/50 (0%)	0/50 (09/)		0/50 (09/)	0/50 /09/	0/50 (09/)
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%
JVGI all HICIUCHICC	ıvıaı	1/130 (0.07 /6)	IVICALI U.U <i>I /</i> 0	יוויטעס ווויו עס	ı Ulal	0/100 (0/0)	IVICALI U/0	٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #All Organs: Osteosarcoma or Osteoma 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 1/150 (0.67%) Mean 0.67% SD 1.15% Total *Adrenal Cortex: Adenoma 7/49 (14%)9/50 (18%)6/50 (12%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 22/149 (14.77%) Mean 14.76% SD 3.03% 0/149 (0%) Mean 0% SD 0% Total *Adrenal Cortex: **Plasma Cell Tumor Malignant** 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% *Adrenal Medulla: Pheochromocytoma Benign 0/49 (0%)0/50 (0%)1/49 (2%)0/49 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 1/148 (0.68%) Mean 0.68% SD 1.18% Total 0/149 (0%) Mean 0% SD 0% *Adrenal Medulla: **Pheochromocytoma Complex** 0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)1/50 (2%)0/50 (0%)Overall Incidence Total 0/148 (0%) Mean 0% SD 0% Total 1/149 (0.67%) Mean 0.67% SD 1.15% *Adrenal Medulla: **Pheochromocytoma Malignant** 0/49 (0%)0/50 (0%)0/49 (0%)0/49 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Mean 0.67% SD 1.15% Total 0/148 (0%) Total 1/149 (0.67%)

^{*:} 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: ORAL

Report Date: 03/22/2010

Page: 242

Species: MICE Strain: B6C3F1

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%) 0/50 (0%) 1/49 (2%) 0/49 (0%) 2/50 (4%) 0/50 (0%)												
Overall Incidence	Total	0/49 (0%) 1/148 (0.68%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/49 (0%) 2/149 (1.34%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%				
*Bone Marrow: Hemangioma												
Overall Incidence	Total	0/49 (0%) 0/149 (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 Marrow: Hemangiosarcoma												
Overall Incidence	Total	1/49 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.35%	0/50 (0%) SD 1.17%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Bone Marrow: Plasma Cell Tumor Mali												
Overall Incidence	Total	0/49 (0%) 0/149 (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: 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%				
#Bone: Osteoma												
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%				

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 243 Report Date: 03/22/2010

			Male				Female	
#Bone: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Brain: Meningioma Benign		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	0/30 (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	0/50 (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, Malig								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} 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: 244

Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/147 (0.68%)	0/48 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/147 (0.68%)	0/48 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%
*Clitoral/Preputial Gland: Hemangioma						(00)		2/17
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/147 (0%)	0/48 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/140 (0%)	0/43 (0%) Mean 0%	0/47 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 245

			Male				Female	
Esophagus: 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%
Eye: 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%
Harderian Gland: Adenoma								
overall Incidence	Total	6/50 (12%) 16/150 (10.67%)	5/50 (10%) Mean 10.67%	5/50 (10%) SD 1.15%	Total	4/50 (8%) 11/150 (7.33%)	1/50 (2%) Mean 7.33%	6/50 (12%) SD 5.03%
Harderian Gland: Carcinoma		0/50 (0%)	0/50 /00/	0/50 (0%)		4/50 (00)	2/52 (48/)	0/50 (40/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	2/50 (4%) SD 1.15%
Harderian Gland: Carcinoma or Adenoma								
verall Incidence	Total	6/50 (12%) 16/150 (10.67%)	5/50 (10%) Mean 10.67%	5/50 (10%) SD 1.15%	Total	5/50 (10%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	8/50 (16%) SD 5.03%
Harderian Gland: 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

			Male				Female	
*Heart: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	10tai	0/150 (0%)		טט ט% 	Total	0/150 (0%)	wean 0%	3D 0%
Heart: 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 Large: Cecum: Carcinoma								
	.	1/50 (2%)	1/50 (2%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma or Adenoma		4/50 (20/)	4/50 (20/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Large: Cecum:	•••••							
• • •		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%
fintestine Large: Colon/Rect Leiomyosarcoma	um:							
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 247

			Male				Female	
#Intestine Small: Duodenum: Adenoma								
Occupation of document	T-1-1	1/50 (2%)	3/50 (6%)	1/50 (2%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: 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%
fintestine Small: Duodenum: Polyp Adenomatous								
S	Taral	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Hemangiosarcoma								
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	T	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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 248

			Male				Female	
#Intestine Small: Ileum: 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%
fintestine Small: Jejunum: 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%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Intestine Small: Jejunum: 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%
fintestine Small: Jejunum: 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%
fIntestine Small: Site Unspec Adenoma								
		1/50 (2%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 249

			Male				Female	
#Intestine Small: Site Uns Carcinoma	pecified:							
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 (2%) SD 2%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
		3/130 (270)	ivican 270	3D 270		2/130 (1.55/0)		
Intestine Small: Site Uns Carcinoma or Adenoma	•							
		1/50 (2%)	5/50 (10%)	1/50 (2%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 4.62%	Total	3/150 (2%)	Mean 2%	SD 2%
Intestine Small: Site Uns Hemangiosarcoma	pecified:							
		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 Uns 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 Uns 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%
Islets, Pancreatic: Adenoma			(Pa)			(00)		
Overell Incidence	Tatal	3/49 (6%)	1/50 (2%)	1/50 (2%)	Tatal	1/49 (2%)	1/49 (2%)	1/49 (2%)
Overall Incidence	Total	5/149 (3.36%)	Mean 3.37%	SD 2.38%	Total	3/147 (2.04%)	Mean 2.04%	SD �%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Contract/Lab: All Laboratories

Strain: B6C3F1 Length of Study: CHRONIC

			Male				Female	
'Islets, Pancreatic: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/147 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma		2/40 (00/)	4/50 (00/)	4/50 (00)		4/40 (00/)	4/40 (00/)	4/40 (00/)
verall Incidence	Total	3/49 (6%) 5/149 (3.36%)	1/50 (2%) Mean 3.37%	1/50 (2%) SD 2.38%	Total	1/49 (2%) 3/147 (2.04%)	1/49 (2%) Mean 2.04%	1/49 (2%) SD �%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%	Total	0/150 (0%)	Mean 0%	SD 0%
(idney: Renal Tubule: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 251

			Male				Female	
Kidney: Renal Tubule: Hemangiosarcoma								
Normall Implications	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Malig	nant							
		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%
Kidney: Renal Tubule: Sarcoma		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%) SD 0%		0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
overali incidence	ıolai	0/150 (0%)	Mean 0%	3D 0%	Total	0/150 (0%)	Mean 0%	3D 0%
Liver: Fibrous Histiocytoma								
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
-		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
Liver: Hemangiosarcoma								
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/149 (2.01%)	Mean 2.01%	SD 2%

^{*:} 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: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 252

			Male			Female			
Liver: Hepatoblastoma		0/40 (004)	0/50 (00/)						
Overall Incidence	Total	17/50 (34%) 22/150 (14.67%)	4/50 (8%) Mean 14.67%	1/50 (2%) SD 17.01%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Liver: Hepatocellular Adenoma									
	.	36/50 (72%)	27/50 (54%)	29/50 (58%)		14/49 (29%)	27/50 (54%)	19/50 (38%)	
verall Incidence	Total	92/150 (61.33%)	Mean 61.33%	SD 9.45%	Total	60/149 (40.27%)	Mean 40.19%	SD 12.86%	
Liver: Hepatocellular Carcinoma									
		14/50 (28%)	19/50 (38%)	24/50 (48%)		8/49 (16%)	14/50 (28%)	10/50 (20%)	
Overall Incidence	Total	57/150 (38%)	Mean 38%	SD 10%	Total	32/149 (21.48%)	Mean 21.44%	SD 5.97%	
Liver: Hepatocellular Carcinoma	or Hepatob	olastoma							
	-	25/50 (50%)	21/50 (42%)	24/50 (48%)		8/49 (16%)	14/50 (28%)	10/50 (20%)	
Overall Incidence	Total	70/150 (46.67%)	Mean 46.67%	SD 4.16%	Total	32/149 (21.48%)	Mean 21.44%	SD 5.97%	
Liver: Hepatocellular Carcinoma		ellular Adenoma							
		42/50 (84%)	34/50 (68%)	37/50 (74%)		17/49 (35%)	31/50 (62%)	27/50 (54%)	
Overall Incidence	Total	113/150 (75.33%)	Mean 75.33%	SD 8.08%	Total	75/149 (50.34%)	Mean 50.23%	SD 14.04%	
Liver: Hepatocellular Carcinoma,				37/50 (74%)		17/49 (35%)	31/50 (62%)	27/50 (54%)	
Overall Incidence	Total	118/150 (78.67%)	Mean 78.67%	SD 11.72%	Total	75/149 (50.34%)	Mean 50.23%	SD 14.04%	
		` ,				` ,			

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 253

			Male			Female				
'Liver: Hepatocholangiocarcinoma	1									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Liver: Hepatocholangioma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Liver: Ito Cell Tumor Benign										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	2/50	(40/)		0/49 (0%)	0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 SD 2.31%	(4%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Liver: Plasma Cell Tumor Maligna	ınt									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Liver: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 254

			Male		Female				
*Lung: 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%	
Lung: Alveolar/Bronchiolar Ade	enoma								
		15/50 (30%)	4/50 (8%)	6/50 (12%)		1/50 (2%)	2/50 (4%)	3/50 (6%)	
Overall Incidence	Total	25/150 (16.67%)	Mean 16.67%	SD 11.72%	Total	6/150 (4%)	Mean 4%	SD 2%	
Lung: Alveolar/Bronchiolar Car	cinoma	3/50 (6%)	12/50 (24%)	4/50 (8%)	•••••	2/50 (4%)	6/50 (12%)	6/50 (12%)	
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 9.87%	Total	14/150 (9.33%)	Mean 9.33%	SD 4.62%	
Lung: Alveolar/Bronchiolar Car	cinoma or Al	veolar/Bronchiolar Adeno 16/50 (32%)	ma 15/50 (30%)	10/50 (20%)		2/50 (4%)	8/50 (16%)	9/50 (18%)	
Overall Incidence	Total	41/150 (27.33%)	Mean 27.33%	SD 6.43%	Total	19/150 (12.67%)	Mean 12.67%	SD 7.57%	
Lung: Fibrosarcoma					•••••				
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%	
veran incidence	างเลเ	1/100 (0.07%)	ivieari U.07%	1.10%		0/150 (0%)	iviean u%	עט עס 0%	
Lung: Fibrous Histiocytoma									
O II I I I	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

^{*:} 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: 255

			Male			Female				
Lung: 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%		
		0/150 (0%)		30 0%				3D 0%		
Lung: Plasma Cell Tumor Malig	ınant									
		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: Sarcoma			- /							
S 11 June 1 June 2 .	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node: 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%		
overali incidence	10tai	0/150 (0%)		SD 0%		0/150 (0%)	wean 0%	5D 0%		
Lymph Node: 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: 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%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

			Male					Female	
#Lymph Node: Plasma Cell Tumor Malignar	nt	0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	(070)	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Bronchial: Hemangiosarcoma		0/50 (09/)	0/50 (0%)	0/50	(00/)		0/50 (0%)	0/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Mandibular: 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%	(070)	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 257

			Male				Female	
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	ınt							
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%) 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: 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%
#Lymph Node, Mesenteric: 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%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	ınt							
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: Adenoacanthoma								
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%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 258

			Male			Female			
#Mammary Gland: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Mammary Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	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%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%	
Mammary Gland: Fibroadenoma									
		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: Fibroma, Fibroadenoma c	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%	
Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, or	Adenoma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%	

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Page: 259

Report Date: 03/22/2010

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male **Female** #Mesentery: **Fibrosarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% SD 3.46% #Mesentery: Hemangioma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mesentery: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Nose: **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% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

Overall Incidence

^{*:} 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: ORAL

Page: 260

Report Date: 03/22/2010

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
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%
Oral Cavity (Oral Mucosi Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva):						
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%
Ovary: Choriocarcinoma								
Overall Incidence					Total	0/50 (0%) 1/147 (0.68%)	0/47 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Ovary: Cystadenoma								
Overall Incidence					Total	1/50 (2%) 4/147 (2.72%)	2/47 (4%) Mean 2.75%	1/50 (2%) SD 1.3%
Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Granulosa Cell Tumor E	3enian							
Overall Incidence	g				Total	0/50 (0%) 1/147 (0.68%)	0/47 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} 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: 261

Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)0/47 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/147 (0%) Mean 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/47 (0%)1/50 (2%)**Overall Incidence** Total 1/147 (0.68%) Mean 0.67% SD 1.15% *Ovary: Hemangioma 0/50 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/147 (0%) Mean 0% SD 0% *Ovary: Hemangiosarcoma 0/50 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/147 (0%) Mean 0% *Ovary: Leiomyosarcoma 0/50 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/147 (0%) Mean 0% SD 0% *Ovary: Luteoma 0/50 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/147 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 262

			Male			Female			
*Ovary: Plasma Cell Tumor Malign	ant								
Overall Incidence					Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	
*Ovary: Teratoma Benign									
Overall Incidence					Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	
*Ovary: Teratoma Malignant									
Overall Incidence					Total	0/50 (0%) 0/147 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	
*Ovary: Tubulostromal Adenoma									
Overall Incidence					Total	0/50 (0%) 1/147 (0.68%)	0/47 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
*Pancreas: Adenoma									
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	
*Pancreas:									
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 1/146 (0.68%)	1/49 (2%) Mean 0.68%	0/49 (0%) SD 1.18%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male		Female				
Pancreas: Carcinoma or Adenoma									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	1/49 (2%)	0/49 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	Mean 0.68%	SD 1.18%	
Pituitary Gland: Pars Dista Adenoma	llis or Unspec	ified Site:							
		0/49 (0%)	1/50 (2%)	0/49 (0%)		3/48 (6%)	4/48 (8%)	2/48 (4%)	
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	9/144 (6.25%)	Mean 6.25%	SD 2.08%	
Pituitary Gland: Pars Dista Carcinoma	llis or Unspec								
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/48 (0%)	0/48 (0%)	0/48 (0%)	
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%	
Pituitary Gland: Pars Dista Carcinoma or Adenoma	llis or Unspec	ified Site:							
		0/49 (0%)	1/50 (2%)	0/49 (0%)		3/48 (6%)	4/48 (8%)	2/48 (4%)	
verall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	9/144 (6.25%)	Mean 6.25%	SD 2.08%	
Pituitary Gland: Pars Inter Adenoma	media:								
		0/49 (0%)	1/50 (2%)	0/49 (0%)		0/48 (0%)	0/48 (0%)	0/48 (0%)	
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/144 (0%)	Mean 0%	SD 0%	
Pituitary Gland: Pars Inter Carcinoma or Adenoma	media:								
		0/49 (0%)	1/50 (2%)	0/49 (0%)		0/48 (0%)	0/48 (0%)	0/48 (0%)	
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/144 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *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 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Prostate: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma 0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: Carcinoma or Adenoma 0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Salivary Glands: **Mast Cell Tumor Malignant** 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/149 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

> Route: ORAL Vehicle: WATER

Length of Study: CHRONIC Male Female

			Male				Female		
#Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (09/)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
#Skeletal Muscle: Fibrosarcoma									
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%	
#Skeletal Muscle: 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%	
#Skeletal Muscle: Myxosarcoma									
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%	
#Skeletal Muscle: Rhabdomyosarcoma									
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%	
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomvoma							•••••	
,		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%	

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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

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Report Date: 03/22/2010

Species: MICE

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male	Female				
#Skeletal Muscle: 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%
#Skin: Basal Cell Adenoma or	Basosquamou	s Tumor Benign						
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, B	asosquamous 1	Гumor Benign, or Trichoe						
		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								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant or N	OS)					
	-	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli	Basal Cell Aden	noma, Basosquamous Tur	nor (benign, maligna	nt or				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma											
Adenoma, Papilloma, S	Sq Papilloma, Ke	,				0/50 (00/)	0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin: Basosquamous Tumor	r Benign		•••••								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
#Skin: Fibroma	•••••		•••••								
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%			
#Skin:	a Sarcoma Myy	coma, Myxosarcoma, or F	ibrous Histiocytoma				•••••	•••••			
r ibroma, r ibrosarcom	a, oarcoma, wy	0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	4/50 (8%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%			
#Skin: Fibrosarcoma											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 5/150 (3.33%)	0/50 (0%) Mean 3.33%	4/50 (8%) SD 4.16%			
#Skin: Fibrosarcoma, Sarcom	na, Myxosarcom	a, or Fibrous Histiocytom	a				•••••	•••••			
	,,	0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	4/50 (8%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male				Female	
#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: Granular Cell Tumor Benig	n				•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Hemangioma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Skin: Liposarcoma								
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: Mast Cell Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 03/22/2010

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			Male					Female	
‡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: Neurofibrosarcoma or Sch	wannoma (m	nalignant or NOS)							
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma, Neuro	fibroma, or \$	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Osteosarcoma		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 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50	(0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin: Schwannoma Malignant		- (OC)	(00)	- /	(201)				
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	0/50	(0%)	Tatal	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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male				Female	
#Skin: Squamous Cell Carcinoma	ı							
		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 Carcinoma or Carcinoma	ı, Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papilloma		0/50 (0%)	4/50 (00)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (0%)
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%
	10tai	1/130 (0.07 /6)			10tai			
Skin: Squamous Cell Papilloma	or Papilloma	a 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papilloma,	Papilloma,	•				0(50 (00))	0/50 (00/)	0/50 (00/)
Verall Incidence	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	2D 0%
Skin: Squamous Cell Papilloma,	Papilloma,	or Keratoacanthoma 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
		17130 (0.0778)		OD 1.1070	iotai	0/100 (0/0)	WCarr 070	OD 070

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 271

			Male				Female	
#Skin: Trichoepithelioma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	10tai	0/150 (0%)	Mean 0%	3D 0%		0/150 (0%)		
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Sebaceous 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%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
	-	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%
Spinal Cord: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma								
	-	0/49 (0%)	0/50 (0%)	0/50 (0%)	-	0/48 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/145 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male				Female	
*Spleen: Hemangioma								
Overall Incidence	Total	0/49 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/48 (0%) 0/145 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
Spleen: Hemangiosarcoma			•••••					•••••
overall Incidence	Total	2/49 (4%) 4/149 (2.68%)	1/50 (2%) Mean 2.69%	1/50 (2%) SD 1.2%	Total	1/48 (2%) 2/145 (1.38%)	1/49 (2%) Mean 1.37%	0/48 (0%) SD 1.19%
Spleen: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 0/145 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
Spleen: Plasma Cell Tumor Maligna	nt							
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 0/145 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%
Stomach, Forestomach: 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%
Stomach, Forestomach: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

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

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female #Stomach**, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% 2/150 (1.33%) Mean 1.33% SD 1.15% Total **#Stomach**, Forestomach: **Squamous Cell Papilloma** 0/50 (0%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #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 or Adenoma

*Testes: Adenoma

Overall Incidence

0/50 (0%) 1/50 (2%) 1/50 (2%) **Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15%

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

*Thymus: Thymoma Benign

0/49 (0%)0/46 (0%)0/44 (0%)0/46 (0%)0/49 (0%)0/46 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/139 (0%) Total 0/141 (0%)

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

^{*:} 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: 274

Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thymus: Thymoma Malignant								
		0/49 (0%)	0/46 (0%)	0/44 (0%)		0/46 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/139 (0%)	Mean 0%	SD 0%	Total	0/141 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malignan	it, NOS	0/49 (0%)	0/46 (0%)	0/44 (0%)		0/46 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/139 (0%)	Mean 0%	SD 0%	Total	0/141 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma			•••••					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
*Thyroid Gland: Follicular Cell Adenoma								
		1/50 (2%)	3/50 (6%)	3/50 (6%)		1/50 (2%)	3/50 (6%)	1/49 (2%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%	Total	5/149 (3.36%)	Mean 3.35%	SD 2.3%
*Thyroid Gland: Follicular Cell Carcinoma	:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 275

			Male				Female	
Thyroid Gland: Follicular Ce Carcinoma or Adenoma	ell:							
		1/50 (2%)	3/50 (6%)	3/50 (6%)		1/50 (2%)	3/50 (6%)	1/49 (2%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%	Total	5/149 (3.36%)	Mean 3.35%	SD 2.3%
Tissue NOS: 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%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Malign:	ant							
		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%
fTissue NOS: 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%
Tongue: Fibroma				2(22)		(201)	0/50 (00)	(001)
Overell In elden ee	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 276

			Male				Female	
₹Tongue: 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%	Tota	l 0/150 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma o	or Papillom	a 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%	Tota	0/150 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Papilloma				- /	(224)	- (aay)	0.700 (001)	
		0/50 (0%)	0/50 (0%)	,	(0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tota	l 0/150 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		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%	Tota	l 0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/49 (0%)	0/50 (0%)	0/50 ((0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Tota	l 0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)	0/50 ((0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Tota	l 0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 277

			Male				Female	
Urinary Bladder: Plasma Cell Tumor Mal	ignant							
O	T-1-1	0/49 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	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%
Urinary Bladder: Sarcoma		2/42 (221)	2/52 (221)	2(52)		2(72)	2/22 (224)	2/20 (00)
Overall Incidence	Total	0/49 (0%) 0/149 (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%
Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
:Uterus:								
Hemangiosarcoma						0/50 (09/)	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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Report Date: 03/22/2010

	Male			Female	
#Uterus: Leiomyoma			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: Leiomyosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	1/50 (2%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	1/50 (2%) 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					
Overall Incidence		Total	1/50 (2%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	1/50 (2%) SD 1.15%
#Uterus: Schwannoma Malignant			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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: WATER

Male			Female	
#Vagina: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} 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

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059902806	10/03/02	728	50(1)	37(682)	53.5	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700308	06/25/02	730	50(1)	34(702)	54.2	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500306	04/26/04	729	50(1)	34(694)	54.6	Methyl trans-styryl ketone
					Female		
Battelle Columbus Laboratory	059902806	10/02/02	727	50(1)	31(692)	60.8	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700308	06/24/02	729	50(1)	33(693)	60.9	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500306	04/26/04	731	50(1)	37(709)	64.6	Methyl trans-styryl ketone

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female	
#All Organs: Benign Tumors								
		41/50 (82%)	40/50 (80%)	37/50 (74%)		27/50 (54%)	39/50 (78%)	33/50 (66%)
Overall Incidence	Total	118/150 (78.67%)	Mean 78.67%	SD 4.16%	Total	99/150 (66%)	Mean 66%	SD 12%
All Organs: Malignant Tumors								
		26/50 (52%)	27/50 (54%)	37/50 (74%)		31/50 (62%)	31/50 (62%)	42/50 (84%)
verall Incidence	Total	90/150 (60%)	Mean 60%	SD 12.17%	Total	104/150 (69.33%)	Mean 69.33%	SD 12.7%
All Organs: Malignant and Benign To	umors	48/50 (96%)	45/50 (90%)	49/50 (98%)		44/50 (88%)	46/50 (92%)	48/50 (96%)
Overall Incidence	Total	142/150 (94.67%)	Mean 94.67%	SD 4.16%	Total	138/150 (92%)	Mean 92%	SD 4%
All Organs: Hemangioma		2/50 (4%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
All Organs: Hemangiosarcoma								
		5/50 (10%)	6/50 (12%)	6/50 (12%)		7/50 (14%)	1/50 (2%)	5/50 (10%)
Overall Incidence	Total	17/150 (11.33%)	Mean 11.33%	SD 1.15%	Total	13/150 (8.67%)	Mean 8.67%	SD 6.11%
All Organs: Hemangiosarcoma or He	emangioma				•••••			
		7/50 (14%)	6/50 (12%)	7/50 (14%)		8/50 (16%)	1/50 (2%)	5/50 (10%)
Overall Incidence	Total	20/150 (13.33%)	Mean 13.33%	SD 1.15%	Total	14/150 (9.33%)	Mean 9.33%	SD 7.02%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ntrol Animal Groups Report Date: 03/22/2010

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			Male				Female	
#All Organs: Histiocytic Sarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%
#All Organs: Malignant Lymphoma: His	tiocytic, Lym			I Туре				
Overall Incidence	Total	0/50 (0%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	4/50 (8%) SD 4.16%	Total	9/50 (18%) 43/150 (28.67%)	14/50 (28%) Mean 28.67%	20/50 (40%) SD 11.02%
#All Organs: Mesothelioma: Benign, Ma		3		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%
#All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (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%
#All Organs: Osteosarcoma								0/50 (00)
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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 283

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	ı							
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%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	6/49 (12%) 18/149 (12.08%)	6/50 (12%) Mean 12.08%	6/50 (12%) SD 0.14%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Cortex: Plasma Cell Tumor Maligna	ant							
Overall Incidence	Total	0/49 (0%) 0/149 (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%
Adrenal Medulla: Pheochromocytoma Benig	n	0/40 /00/	0/50 (00/)	0/40 (00/)		0/50 (00)	0/50 (40/)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Adrenal Medulla: Pheochromocytoma Comp								
Overall Incidence	Total	0/49 (0%) 0/148 (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%
Adrenal Medulla: Pheochromocytoma Maligr	nant							
Overall Incidence	Total	0/49 (0%) 1/148 (0.68%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

SD 0%

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS											
		0/49 (0%)	1/50 (2%)	0/49 (0%	,	0/50 (0%)	2/50 (4%)	1/50 (2%)			
verall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%			
Bone Marrow: Hemangioma											
	+	0/50 (0%)	0/50 (0%)	0/50 (0%	,	0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Bone Marrow: Hemangiosarcoma		4/50 (00)	4/50 (00/)	0/50 (00	4)	4/50 (00/)	0/50 (00/)	4/50 (004)			
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0% SD 1.15%	%) Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%			
		,									
Bone Marrow: Plasma Cell Tumor Maliç	gnant	0/50 (001)	2/22 (221)	0.170 (00		2/52 (224)	0/50 (004)	2 (22 ()			
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%			
	10tai	0/130 (0/6)			10tai	0/130 (0 /8)					
Bone: Hemangiosarcoma		0/50 (001)	2/22 (221)	0.170 (00		2/52 (224)	0/50 (004)	2 (22 ()			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	%) Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
	ı viai	0/100 (0%)	IVIEAN U%	JU U%	ı olal	0/150 (0%)	IVIEAN U%	0% U.			
#Bone: Osteoma											
		0/50 (0%)	0/50 (0%)	0/50 (0%	6)	0/50 (0%)	0/50 (0%)	0/50 (0%)			

SD 0%

Total

0/150 (0%)

Total

0/150 (0%)

Overall Incidence

^{*:} 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: 03/22/2010

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female** #Bone: Osteosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)SD 2% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% #Bone: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% SD 2% *Brain: Meningioma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Brain: **Meningioma Malignant** (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Brain: Meningioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Brain: **Schwannoma Malignant** (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 1/150 (0.67%) Mean 0.67% SD 1.15% 0/150 (0%) Total

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Report Date: 03/22/2010

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			Male				Female	
Clitoral/Preputial Gland: Adenoma								
Normall Implications	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangioma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/48 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female	
#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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		10/50 (20%)	7/50 (14%)	2/50 (4%)		3/50 (6%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 8.08%	Total	13/150 (8.67%)	Mean 8.67%	SD 3.06%
#Harderian Gland: Carcinoma		2/52 (191)	2/52 (221)			(20)	2/22 (124)	0.750 (001)
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
		3/130 (2%)				` ,		
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%)	7/50 (14%)	3/50 (6%)		3/50 (6%)	8/50 (16%)	4/50 (8%)
Overall Incidence	Total	22/150 (14.67%)	Mean 14.67%	SD 9.02%	Total	15/150 (10%)	Mean 10%	SD 5.29%
#Harderian Gland: Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 288

			Male				Female		
Heart: Hemangioma									
• • • • • • • • • • • • • • • • • • •	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Heart: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Intestine Large: Cecum: Carcinoma		0/50 (631)	0/50 (051)	4/50 (00%)		0/50 (00)	0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	1/50 (2%) SD 1.15%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Overali incidence		1/150 (0.67%)	Mean 0.67%	עכ	Total	0/150 (0%)	wiean 0%	3D 0%	
fintestine Large: Cecum: Carcinoma or Adenoma		2/72 (224)	2(72 (22))			2/22 (22/)	(00)	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%	
		1/150 (0.6/%)			10tai	0/150 (0%)	iviean 0%	3D 0%	
#Intestine Large: Cecum: Leiomyoma									
		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/Rect Leiomyosarcoma	um:								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 289

			Male				Female	
#Intestine Small: Duodenum: 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%
fintestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Duodenum: Leiomyosarcoma		0/20 (05:)	0.50	2/20 (05)		2/22 (22)	2/52 (22/2	(50)
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine 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	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (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%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

Page: 290

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
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%) 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 Small: Jejunum: 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%
fIntestine Small: Jejunum: Hemangiosarcoma								
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%
Intestine Small: Jejunum: 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: Site Unspec Adenoma								
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%

^{*:} 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: 291

Report Date: 03/22/2010

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Intestine Small: Site Unspe Carcinoma	cified:							
O	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	T-1-1	0/50 (0%)	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: Site Unspe Carcinoma or Adenoma	cified:							
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Site Unspe Hemangiosarcoma	cified:							
		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%
fIntestine Small: Site Unspe 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 Unspe 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%
Islets, Pancreatic: Adenoma					•			
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 292

			Male				Female	
Islets, Pancreatic: 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%
slets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		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%
Kidney: Renal Tubule: Adenoma								
	T-1-1	0/50 (0%)	0/50 (0%)	1/48 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
	.	0/50 (0%)	0/50 (0%)	0/48 (0%)	.	0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangioma			0. To (0.5.)			0/20	(00)	
N	T-1-1	0/50 (0%)	0/50 (0%)	0/48 (0%)	T-1-1	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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 293

			Male				Female	
*Kidney: Renal Tubule: Hemangiosarcoma								
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: Plasma Cell Tumor Maligi	nant				•••••			
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: Sarcoma								
overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%
iver: Fibrous Histiocytoma		- (a)	(00)	(201)	•••••	2/22 (22)	(00)	(201)
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%
iver: Hemangioma					•••••			
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%
iver: Hemangiosarcoma		4/50 (00/)	4/50 (00)	(/50 (00))		0(50 (40))	4/50 (00)	4/50 (004)
Overall Incidence	Total	1/50 (2%) 6/150 (4%)	1/50 (2%) Mean 4%	4/50 (8%) SD 3.46%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 294

			Male				Female	
*Liver: Hepatoblastoma								
		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Liver: Hepatocellular Adenoma								
-		33/50 (66%)	35/50 (70%)	31/50 (62%)		22/50 (44%)	31/50 (62%)	30/50 (60%)
Overall Incidence	Total	99/150 (66%)	Mean 66%	SD 4%	Total	83/150 (55.33%)	Mean 55.33%	SD 9.87%
Liver: Hepatocellular Carcinoma								
		14/50 (28%)	17/50 (34%)	28/50 (56%)		3/50 (6%)	8/50 (16%)	23/50 (46%)
Overall Incidence	Total	59/150 (39.33%)	Mean 39.33%	SD 14.74%	Total	34/150 (22.67%)	Mean 22.67%	SD 20.82%
*Liver: Hepatocellular Carcinoma o								
•	•	15/50 (30%)	19/50 (38%)	29/50 (58%)		3/50 (6%)	9/50 (18%)	23/50 (46%)
Overall Incidence	Total	63/150 (42%)	Mean 42%	SD 14.42%	Total	35/150 (23.33%)	Mean 23.33%	SD 20.53%
Liver: Hepatocellular Carcinoma o								
		40/50 (80%)	41/50 (82%)	45/50 (90%)		22/50 (44%)	32/50 (64%)	38/50 (76%)
Overall Incidence	Total	126/150 (84%)	Mean 84%	SD 5.29%	Total	92/150 (61.33%)	Mean 61.33%	SD 16.17%
*Liver: Hepatocellular Carcinoma,	Hepatocell	ular Adenoma, or Hepatol 40/50 (80%)	olastoma 41/50 (82%)	45/50 (90%)		22/50 (44%)	32/50 (64%)	38/50 (76%)
Overall Incidence	Total	126/150 (84%)	Mean 84%	SD 5.29%	Total	92/150 (61.33%)	Mean 61.33%	SD 16.17%
JVGI GII IIICIUCIICC	i Ulai	120/130 (04/0)	IVICALL 04/0	GD 3.2370	iotal	32/130 (01.33/8)	Mean 01.55/6	GD 10.1770

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 295

			Male				Female	
*Liver: Hepatocholangiocarcinoma	ı							
		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: Hepatocholangioma								
		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	1/150 (0.67%)	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	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Plasma Cell Tumor Maligna	ınt							
		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: 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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 296

			Male				Female	
*Lung: 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%
₋ung: Alveolar/Bronchiolar Ade	noma							
		6/50 (12%)	10/50 (20%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	24/150 (16%)	Mean 16%	SD 4%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Lung: Alveolar/Bronchiolar Card	cinoma	5/50 (10%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	3/50 (6%)	3/50 (6%)
verall Incidence	Total	18/150 (12%)	Mean 12%	SD 2%	Total	10/150 (6.67%)	Mean 6.67%	SD 1.15%
∟ung: Alveolar/Bronchiolar Card	cinoma or Al	veolar/Bronchiolar Adeno 11/50 (22%)	ma 15/50 (30%)	14/50 (28%)		5/50 (10%)	5/50 (10%)	4/50 (8%)
Overall Incidence	Total	40/150 (26.67%)	Mean 26.67%	SD 4.16%	Total	14/150 (9.33%)	Mean 9.33%	SD 1.15%
_ung: Fibrosarcoma								
N	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Taral	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%
Lung: Fibrous Histiocytoma								
	T	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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 297

			Male				Female	
Lung: Hemangiosarcoma								
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Overall Incidence	Total	0/150 (0%)	Mean 0%	3D 0%	Total	1/150 (0.67%)		
Lung: Plasma Cell Tumor Malig	ınant							
		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%
Lung: Sarcoma								
N	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tarat	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: Fibrous Histiocytoma				-4				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	1/50 (2%)	0/50 (0%) SD 1.15%
	10tai	0/150 (0%)		3D 0%	Total	1/150 (0.67%)	Mean 0.67%	
Lymph Node: 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%
Lymph Node: Hemangiosarcoma								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 298

Report Date: 03/22/2010

			Male				Female	
#Lymph Node: Plasma Cell Tumor Malignar	nt	0(50 (00))	0/50 (00%)	0/50 (00/)		0/50 (00.)	0/50 (00/)	0/50 /05/
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: 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								
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%
_ymph Node, Mandibular: Fibrous Histiocytoma								
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%
Lymph Node, Mandibular: 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%
Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 0%

Total

0/150 (0%)

Mean 0%

SD 0%

Total

0/150 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 299

			Male				Female		
#Lymph Node, Mandibular: Plasma Cell Tumor Malignant									
	T	0/50 (0%)	0/50 (0%)	0/50 (0%)	T ()	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: Fibrous Histiocytoma									
		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%	
Lymph Node, Mesenteric: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Lymph Node, Mesenteric: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	ant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Mammary Gland: Adenoacanthoma									
		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%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 300

Report	Date:	03/22/	2010
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			Male				Female	
#Mammary 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%
	10lai	` '				` ,		SD 0%
#Mammary Gland: Carcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%
#Mammary Gland: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%
#Mammary Gland: Fibroadenoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or Ad								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Carc		r Adenoma				0(50 (40))	0/50 (00/)	0/50 (40/)
O	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	2/50 (4%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 301

			Male				Female		
Mesentery: Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Mesentery: Hemangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Mesentery: Hemangiosarcoma		0/50 /(0%)	4/50 /00/	0/50 (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%	
		1/150 (0.6/%)				0/130 (0%)	Weatt 0%		
Mesentery: Sarcoma									
Overall Incidence	Tatal	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%)	Tatal	1/50 (2%)	0/50 (0%)	0/50 (0%) SD 1.15%	
	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%		
Nose: Mast Cell Tumor Malign	nant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Oral Cavity (Oral Mucos Papilloma Squamous o									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 302

			Male				Female	
Oral Cavity (Oral Mucos		/nx, Tooth, Gingiva):						
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%
Oral Cavity (Oral Mucos	a, Tongue, Phary							
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%
Ovary: Choriocarcinoma								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Ovary: Cystadenoma						2/50 (4%)	3/50 (6%)	1/49 (2%)
verall Incidence					Total	6/149 (4.03%)	Mean 4.01%	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	Benign							
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 303

	Male	Female				
Ovary: Granulosa Cell Tumor Malignant		0/50 (00%)	0/50 (00/)	0/40 (00/)		
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
vary: Granulosa Cell Tumor: Benign, Malignant, NOS						
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
ovary: Hemangioma						
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
vary: Hemangiosarcoma						
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
vary: Leiomyosarcoma						
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
Dvary: Luteoma						
verall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 304

			Male				Female	
*Ovary: Plasma Cell Tumor Malign	ant					0/50 (00/)	0/50 (00/)	0/40 (00/)
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%
*Ovary: Teratoma Malignant					••••••	0/50 (00)	(201)	2/12
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/149 (0%)	Mean 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								
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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 305

			Male				Female	
Pancreas: Carcinoma or Adenoma	ı							
		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%
Pituitary Gland: Pars Dis Adenoma								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		4/49 (8%)	5/50 (10%)	5/47 (11%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	14/146 (9.59%)	Mean 9.6%	SD 1.28%
Pituitary Gland: Pars Dis Carcinoma	talis or Unspec	ified Site: 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec							
O	Tatal	1/50 (2%)	0/50 (0%)	0/49 (0%)	Tatal	4/49 (8%)	5/50 (10%)	5/47 (11%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	14/146 (9.59%)	Mean 9.6%	SD 1.28%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/47 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/146 (0.68%)	Mean 0.67%	SD 1.15%
Pituitary Gland: Pars Inte Carcinoma or Adenoma	rmedia:							
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/47 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/146 (0.68%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 306 Report Date: 03/22/2010

			Male				Female	
*Prostate: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Prostate: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Prostate: Hemangioma			•••••					
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			•••••					
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								
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: 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%

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 307 Report Date: 03/22/2010

			Male				Female	
#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						•••••	•••••	
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%
Skeletal Muscle: Hemangiosarcoma		2(22)					(20)	(50)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Skeletal Muscle: Myxosarcoma								
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%
Skeletal Muscle: Rhabdomyosarcoma								
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%
Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma							
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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 308

			Male				Female					
#Skeletal Muscle: 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%				
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Adenoma, Bas	sosquamous T	umor Benign, or Trichoep	oithelioma									
,	•	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 or	Basosquamou	us Tumor (malignant or NO	OS) 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, Ba NOS), or Trichoepithelior		oma, Basosquamous Tur	nor (benign, malignan	t or								
		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%				

^{*:} 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: 03/22/2010

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma											
•		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: Basosquamous Tumor											
	-	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: Fibroma											
	-	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: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	coma, Myxosarcoma, or F	•	4/50 (20%)		0/50 /00/	4/50 (00/)	4/50 (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%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%			
				3D 1.1370		2/130 (1.3370)					
Skin: Fibrosarcoma											
		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%			
#Skin:		a, or Fibrous Histiocytom	a					4/50 (00)			
		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%			

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Liposarcoma

Overall Incidence

Overall Incidence

Mast Cell Tumor Benign

#Skin:

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: **Granular Cell Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% #Skin: Hemangiosarcoma 1/50 (2%)2/50 (4%)1/50 (2%)1/50 (2%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% Total 3/150 (2%) Mean 2% SD 2% #Skin:

0/50

SD 0%

0/50

SD 0%

(0%)

(0%)

Total

Total

0/50

0/50

1/150 (0.67%)

0/150 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0.67%

0/50

1/50

SD 0%

SD 1.15%

(0%)

(2%)

Total

Total

0/50

0/150 (0%)

0/50

0/150 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 311

			Male				Female	
#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: Neurofibrosarcoma or Sch								
		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%
#Skin: Neurofibrosarcoma, Neuro	fibroma, or \$	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 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%
Skin: Osteosarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
≇Skin: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Schwannoma Malignant	•••••							
		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%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

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

Route: SKIN Vehicle: ETHANOL

			Male		,		Female	
#Skin: Squamous Cell Carcinom		0/50 (0%)	0/50 (0%)	,	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tot	al 0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant o	or NOS),				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (SD 0%	(0%) Tot	0/50 (0%) al 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Squamous Cell Papilloma	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%	Tot	al 0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a or Papilloma	0/50 (0%)	0/50 (0%)	0/50 (······································	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tot	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, S	•			(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 (SD 0%	0%) Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, o		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 (SD 0%	0%) Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

Route: SKIN

Page: 313

Report Date: 03/22/2010

Species: MICE Strain: B6C3F1 Vehicle: ETHANOL Length of Study: CHRONIC

			Male			0/50 (0%) 0/50 (0%) 0/50 (0%) Il 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) Il 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%)		
#Skin: Trichoepithelioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 ^o 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 ^o SD 0%	Total	` '	` '	` ,
Skin: Sebaceous Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 ^o SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 ^o SD 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%) Mean 0%	SD 0%	%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Fibrous Histiocytoma								(00)
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0 ^o SD 0%	%) Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Mean 0.67%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN Vehicle: ETHANOL

			Male			Female 0/50 (0%) 0/50 (0%) 0/49 (09) 0/149 (0%) Mean 0% SD 0%		
*Spleen: Hemangioma		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	` '	` ,	` '
Spleen: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%) 7/148 (4.73%)	1/50 (2%) Mean 4.75%	3/48 (6%) SD 2.38%	Total	5/50 (10%) 7/149 (4.7%)	0/50 (0%) Mean 4.69%	2/49 (4%) SD 5.03%
Spleen: Mast Cell Tumor Malignant								
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%
Spleen: Plasma Cell Tumor Malignai	nt							
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%
Stomach, Forestomach: 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%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 /02/	0/50 (0%)	1/50 (20/)		0/50 (09/)	0/50 (0%)	0/50 (08/)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 1.15%

Total

0/150 (0%)

Mean 0%

SD 0%

Total

1/150 (0.67%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

0/49

0/140 (0%)

(0%)

0/47

Mean 0%

(0%)

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC Male **Female #Stomach**, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 1/50 0/50 (0%)0/50 (0%)4/50 (8%) 1/50 (2%)(2%)1/50 (2%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 4.62% Total 3/150 (2%) Mean 2% SD 0% **#Stomach**, Forestomach: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 3.46% 3/150 (2%) Mean 2% SD 0% Total #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 or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 0/150 (0%) *Testes: Adenoma 2/50 (4%)2/50 (4%)0/50 (0%)**Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 2.31% *Thymus: Thymoma Benign

0/44

SD 0%

(0%)

Total

0/50

0/147 (0%)

(0%)

0/47

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 316

						Female		
*Thymus: Thymoma Malignant		0/49 (0%)	1/47 (2%)	0/44 (0%)		0/50 (0%)	1/47 (2%)	0/50 (0%)
Overall Incidence	Total	1/140 (0.71%)	Mean 0.71%	SD 1.23%	Total	1/147 (0.68%)	Mean 0.71%	SD 1.23%
*Thymus: Thymoma: Benign, Maligna	int, NOS	•••••	•••••					
Overall Incidence	Total	0/49 (0%) 1/140 (0.71%)	1/47 (2%) Mean 0.71%	0/44 (0%) SD 1.23%	Total	0/50 (0%) 1/147 (0.68%)	1/47 (2%) Mean 0.71%	0/50 (0%) SD 1.23%
*Thyroid Gland: C-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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						0/50 (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	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: Follicular Cel Adenoma	ll:							
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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: Follicular Cel Carcinoma	II:							
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%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 317

			Male				Female	
Thyroid Gland: Follicular C Carcinoma or Adenoma	ell:							
	T	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
#Tissue NOS: 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%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
‡Tissue NOS: Plasma Cell Tumor Maligr	nant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Sarcoma								
		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%
Tongue: Fibroma		(650)	(05)	2/20 (00)				
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	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 318

			Male				Female	
‡Tongue: Squamous Cell Carcinor	ma							
		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 Carcinor	ma or Papillom	a 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 Papillom	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%
Tooth: Odontoma								
	-	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%
Urinary Bladder: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		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%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female 0/50 (0%) 0/49 (0%) Mean 0% SD 0% 0/50 (0%) 0/49 (0%) Mean 0.67% SD 1.15% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15% 0/50 (0%) 0/50 (0%) Mean 0% SD 0%		
*Urinary Bladder: Plasma Cell Tumor Malignant 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)									
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Sarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)			
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	, ,	` '	
#Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	, ,		
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/150 (0.67%)	, ,	` ,	
#Uterus: Hemangioma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma									
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male		Female				
tUterus: Leiomyoma		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (00/)				
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%			
Iterus: Leiomyosarcoma							
verall Incidence	Total	` '	` '	` '			
Jterus: Polyp Stromal							
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	` '			
Iterus: Sarcoma Stromal							
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%			
Iterus: Sarcoma Stromal or Polyp Stromal							
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%			
Uterus: Schwannoma Malignant							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 321 Report Date: 03/22/2010

Male				
#Vagina: Liposarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Vagina: Squamous Cell Papilloma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied