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%)

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male		Total 7/150 (4.67%) Mean 4.67% SD 3.06%  7/50 (14%) 18/50 (36%) 9/50 (18%  Total 34/150 (22.67%) Mean 22.67% SD 11.72%  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%			
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` ,	` '
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	<b>S</b> 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	` ,	` '	` '
All Organs: Mesothelioma: Malignant		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (09/)	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	` '	, ,	` '
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	יוו עכ	ı Ulal	0/100 (0/0)	IVICALI U/0	٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male		Female				
#All Organs: Osteosarcoma or Osteoma									
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
Adrenal Cortex:									
Overall Incidence	Total	7/49 (14%) 22/149 (14.77%)	9/50 (18%) Mean 14.76%	6/50 (12%) SD 3.03%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Cortex: Plasma Cell Tumor Malignal	nt								
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Pheochromocytoma Benign									
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%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Adrenal Medulla: Pheochromocytoma Comple	ex								
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
Adrenal Medulla: Pheochromocytoma Maligna	ant								
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	

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

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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	
Adrenal Medulla: Pheochromocytoma: Be	nign, Complex	•						
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 Malig	gnant	0/40 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00)	0(50 (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%
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%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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% 1/150 (0.67%) Mean 0.67% SD 1.15% Total \*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** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Brain: Meningioma: Benign, Malignant, NOS

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

1/50

(0%)

(2%)

Mean 0%

Mean 0.67%

0/50

0/50

SD 0%

SD 1.15%

(0%)

(0%)

Total

Total

0/50

0/150 (0%)

0/50

0/150 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

**Overall Incidence** 

**Overall Incidence** 

**Schwannoma Malignant** 

\*Brain:

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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/)
verall 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 246

			Male				Female	
*Heart: Hemangioma								
• "' ''	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*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		4/50 (631)	4/50 (OS)	0/50 (001)		0/50 (001)	0.150 (001)	0/50 (00/)
Overall Incidence	Total	1/50 (2%)	1/50 (2%)	0/50 (0%) SD 1.15%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		2/150 (1.33%)	Mean 1.33%		Total	0/150 (0%)	wean 0%	5D 0%
fIntestine Large: Cecum: Carcinoma or Adenoma		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%
#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%

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 247

			Male				Female	
#Intestine Small: Duodenum: Adenoma								
• "' ''	<b>-</b>	1/50 (2%)	3/50 (6%)	1/50 (2%)	<b>T</b>	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								
2	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								
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>T</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 248

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 249

			Male			Total 2/150 (1.33%) Mean 1.33% SD 1.15%  1/50 (2%) 2/50 (4%) 0/50 (0%)  Total 3/150 (2%) Mean 2% SD 2%  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%  Total 0/150 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%		
#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	` '	` ,	` '
Intestine Small: Site Uns Carcinoma or Adenoma	•							
Overall Incidence	Total	1/50 (2%) 7/150 (4.67%)	5/50 (10%) Mean 4.67%	1/50 (2%) SD 4.62%	Total	` '	` ,	` '
Intestine Small: Site Uns Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		` '	` ,	` ,
Intestine Small: Site Uns Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` '	` '
Intestine Small: Site Uns Polyp Adenomatous								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	( ,
Islets, Pancreatic: Adenoma							(20)	
Overall 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 �%

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

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

Species: MICE

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 250

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	0/30 (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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 251

			Male				Female	
Kidney: Renal Tubule: Hemangiosarcoma								
Normall Implications	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%
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%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	ı Olai	0/150 (0%)		3D 0%		0/130 (0%)		
Liver: Fibrous Histiocytoma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>T</b>	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%

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 252

			Male			Female			
Liver: Hepatoblastoma		47/50 (0.40)	1/52 (00/)	4/52 (224)		0/40 (00/)	0/50 (00/)	2(52 (224)	
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									
	<b>.</b>	36/50 (72%)	27/50 (54%)	29/50 (58%)	<b></b>	14/49 (29%)	27/50 (54%)	19/50 (38%)	
Overall 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,		lular Adenoma, or Hepatol	blastoma						
Overall Incidence	Total	46/50 (92%) 118/150 (78.67%)	35/50 (70%) Mean 78.67%	37/50 (74%) SD 11.72%	Total	17/49 (35%) 75/149 (50.34%)	31/50 (62%) Mean 50.23%	27/50 (54%) SD 14.04%	
		` ,				,			

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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%	

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 255

			Male			Female				
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%	10tai	0/150 (0%)	Mean 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										
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 257

			Male				Female				
‡Lymph Node, Mandibular: Plasma Cell Tumor Malignar	nt										
		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%		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%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Mesenteric: Hemangioma											
		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%		
Lymph Node, Mesenteric: Hemangiosarcoma											
		0/50 (0%)	0/50 (0%)		(0%)		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: 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%		
Mammary Gland: Adenoacanthoma											
		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%		Total	0/150 (0%)	Mean 0%	SD 0%		

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: 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%	

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 03/22/2010

Page: 259

			Male			Female				
Mesentery: Fibrosarcoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	3/50 (6%) 3/150 (2%)	0/50 (0%) Mean 2%	0/50 (0%) SD 3.46%		
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										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Mesentery: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%		
Nose: Mast 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%		
Oral Cavity (Oral Mucosa, Papilloma Squamous or	, Tongue, Phary	/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%		

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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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	<b>g</b>				Total	0/50 (0%) 1/147 (0.68%)	0/47 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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%	

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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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%				

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Select

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 264 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	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	,			
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/49 (0%) 1/149 (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%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2% SD 1.15%	s) 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	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	b) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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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			remaie			
#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							•••••	
<b>,</b>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

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

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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%			

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Skin: Basal or Sq. Cell Carci	inoma, Carcinon	na, Basosq. Tumor (M or I	3), Basal Cell Adenon	1а,				
Adenoma, Papilloma, S	Sq Papilloma, Ke	eratoacanthoma, Trichoep				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%

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 268

			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										
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			(00)	(20)						
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%		

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 269

			Male				Female	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%)		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, Neuro	fibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)	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: Osteosarcoma												
O II I I I	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%				
≇Skin: Sarcoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%				
#Skin: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				

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

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

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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

Route: ORAL

Length of Study: CHRONIC

Vehicle: WATER

Page: 270

			Male			Female			
#Skin: Squamous Cell Carcinon	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%	
Skin: Squamous Cell Carcinon or Carcinoma	na, 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 Papillom	a	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Squamous Cell Papillom	a or Papilloma	o/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Squamous Cell Papillom	a, Papilloma, S	Squamous Cell Carcinom 0/50 (0%)	a or Keratoacanthom 1/50 (2%)	<b>a</b> 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 Papillom		or Keratoacanthoma 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 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%		
	10181	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										
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)		
verall Incidence	Total	0/150 (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										
	<b>-</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	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%		

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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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%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 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

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 275

			Male			Female			
*Thyroid Gland: Follicular C Carcinoma or Adenoma	ell:								
Overall In aldeman	Tatal	1/50 (2%)	3/50 (6%)	3/50 (6%)	Tatal	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									
		0/50 (0%)	0/50 (0%)	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									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

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 Carcinom	a									
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%		
	ı vlai	0/130 (0%)		3D 0%	10tai	0/150 (0%)				
Tongue: Squamous Cell Carcinom	a or Papillom	a Squamous								
		0/50 (0%)	0/50 (0%)	0/50 (09	,	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%		
fTongue: Squamous Cell Papilloma	1	0/50 (0%)	0/50 (0%)	0/50 (0º	2/1	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
#Tooth: Odontoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 <sup>4</sup> SD 0%	%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Urinary Bladder: Hemangioma										
		0/49 (0%)	0/50 (0%)	0/50 (09	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Hemangiosarcoma		0/40 (00%)	0/50 (00/)	0/50 /0/	20	0/50 (00)	0/50 /00/	0/50 (00/)		
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/50 (0°	,	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		

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

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

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: 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 (221)	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%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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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 (004)	
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 279

Report Date: 03/22/2010

Route: ORAL
Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #Vagina: Liposarcoma 0/50 (0%)0/50 (0%) 0/50 (0%) 0/150 (0%) SD 0% **Overall Incidence** Total Mean 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%

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

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