**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 96

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

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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%)

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%
						0/130 (0 /6)		
#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%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

**Page:** 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/)		2/52 (221)	0(50 (00))	0(50 (00))
S	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (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%
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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

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%)**Overall 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%)**Overall 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%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% ...... \*Bone Marrow: **Plasma Cell Tumor Malignant** 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% #Bone: 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% #Bone:

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%)

Osteoma

**Overall Incidence** 

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
#Bone: 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%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/50 (09/)	0/50 /09/\	0/50 /00/)		0/50 (09/)	0/50 (00/)	0/50 /09/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
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, 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%
Brain: Schwannoma Malignant		0/50 (00/)	0/50 /00/	0/50 /02/)		0/50 /00/	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overali incidence	Total	0/150 (0%)	Mean 0%		Total	0/150 (0%)	iviean 0%	SD 0%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female			
Clitoral/Preputial 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%		
Clitoral/Preputial Gland: Carcinoma										
	<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%		
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%		
Overall incluence		0/150 (0%)	wean 0%	3D 0%	TOTAL	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%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female		
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%	
						0/130 (0/8)			
Heart: Hemangiosarcoma							. ()		
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%	
		, ,				0/130 (0%)			
#Intestine Large: Cecum: Carcinoma									
	<b>T</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)	<b>+</b>	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: Carcinoma or Adenoma		0(50 (00))	0/50 (00/)	4(50 (00))		0(50 (00))	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
	ı olal	1/150 (0.67%)				0/130 (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

**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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 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%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: 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%) 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%	) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Small: Site Unspec	ified:							
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: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female	
#Intestine Small: Site Unspec Carcinoma	ified:							
		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 Unspec Carcinoma or Adenoma	ified:							
		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 Unspec Hemangiosarcoma	ified:							
		0/50 (0%)	0/50 (0%)	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 Unspec Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Site Unspec 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%)	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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 108

			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								
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 (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%
*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%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 109

			Male		Total 0/150 (0%) Mean 0% SD 0%  0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%  0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)				
Kidney: Renal Tubule: Hemangiosarcoma									
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		` ,	0/50 (0%)	` '	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%		0/150 (0%)	Mean 0%	SD 0%	
Kidney: Renal Tubule: Plasma Cell Tumor Malig	ınant								
		0/50 (0%)	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%)		` '	` ,	, ,	
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%	

<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:** 110

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%	

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 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%		

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 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%	

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: WATER Page: 113

Report Date: 03/22/2010

Length of Study: CHRONIC

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 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% \*Lung: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% ..... #Lymph Node: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)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% #Lymph Node: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/150 (0%) Mean 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 Mean 0% SD 0% 0/150 (0%) Mean 0% SD 0% 0/150 (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** 

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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

			Male				Female					
#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			- /									
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lymph Node, Mesenteric: Hemangiosarcoma												
	<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%				
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%				

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 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%		

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%

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

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

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcino		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%) 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%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 119 Report Date: 03/22/2010

	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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

			Male				Female	
Ovary: Plasma Cell Tumor Maligna	ant					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%
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					•••••	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%
Ovary: Tubulostromal Adenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
Pancreas: 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%
Pancreas: Carcinoma		0/50 (0%)	0/50 /00/\	0/50 (00/)		0/40 (09/)	0/50 (0%)	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%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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** 

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%	

<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: 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

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 03/22/2010

Page: 125

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									
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: 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%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: WATER

Page: 127

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

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 128

Report Date: 03/22/2010

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male					Female	
#Skin: Squamous Cell Carcino	oma								
		0/50 (0%)	0/50 (0%)	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 Ulai	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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%		

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

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

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 132

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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 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%

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

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

Species: MICE

Strain: B6C3F1

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

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 135 Report Date: 03/22/2010

			Male				Female	
*Urinary Bladder: Plasma Cell Tumor Mali	gnant							
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%

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

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

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 136

	Male	Female					
tUterus: Leiomyoma			0/50 /00/	0/50 (00/)	0/50 /00/		
Overall Incidence	т	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Jterus: Leiomyosarcoma							
verall Incidence	Т	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Jterus: Polyp Stromal			2/22 (221)	2/22 (22)	(50)		
verall Incidence		otal	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Jterus: Sarcoma Stromal							
verall Incidence		otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Iterus: Sarcoma Stromal or Polyp Stromal							
verall Incidence	т	otal	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Jterus: Schwannoma Malignant							
Overall Incidence	Ti	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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

	Male		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%) Me	(0%) 0/50 (0%) an 0% SD 0%

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

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