Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 03/22/2010

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Study Summary

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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

#All Organs:

#All Organs:

#All Organs:

#All Organs:

#All Organs: Osteoma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

#All Organs: Osteosarcoma

Mesothelioma: Malignant

Toxicology Data Management System

Contract/Lab: All Laboratories

Mesothelioma: Benign, Malignant, NOS

......

Total

Total

Total

Total

Total

Total

1/50

1/150 (0.67%)

0/50

5/150 (3.33%)

0/50

0/150 (0%)

0/50

0/150 (0%)

0/50

0/150 (0%)

0/50

0/150 (0%)

(0%)

Mean 0%

Mean 0%

(0%)

0/50

Species: MICE

Length of Study: CHRONIC

Histiocytic Sarcoma

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

SD 0%

0/50

SD 0%

(0%)

Male **Female** (2%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)1/50 (2%)Mean 0.67% SD 1.15% Total 5/150 (3.33%) Mean 3.33% SD 2.31% Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type (0%)1/50 (2%)4/50 (8%)9/50 (18%)14/50 (28%)20/50 (40%)Mean 3.33% SD 4.16% 43/150 (28.67%) Mean 28.67% SD 11.02% Total (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

0/150 (0%)

2/50

3/150 (2%)

(4%)

Total

Total

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Mean 0%

Mean 2%

(2%)

1/50

SD 0%

SD 2%

(0%)

0/50

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male		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% 0/50 (0%) 0/50 (0%) 0/50 (0 Total 0/150 (0%) Mean 0% SD 0% 1 0/50 (0%) 2/50 (4%) 0/50 (0 Total 2/150 (1.33%) Mean 1.33% SD 2.31%			Female				
#All Organs: Osteosarcoma or Osteoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		` '	` ,	` '				
Adrenal Cortex: Adenoma												
Overall Incidence	Total	6/49 (12%) 18/149 (12.08%)	6/50 (12%) Mean 12.08%	6/50 (12%) SD 0.14%	Total	` '	` '	` '				
Adrenal Cortex: Plasma Cell Tumor Maligna	ınt											
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	` '				
Adrenal Medulla: Pheochromocytoma Benigi	n	0/40 /00/	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (40/)	0/50 (00)				
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		` '	` '	0/50 (0%) SD 2.31%				
Adrenal Medulla: Pheochromocytoma Compl												
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	` '	` ,	` '				
Adrenal Medulla: Pheochromocytoma Malign	nant					0.75	(20)	(20)				
Overall Incidence	Total	0/49 (0%) 1/148 (0.68%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%				

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

SD 0%

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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

SD 0%

Total

0/150 (0%)

Total

0/150 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 285

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
*Brain: Meningioma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/30 (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, Maligr		•••••						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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 (001)	0/50 /00/	0.50		0/50 (00.)	4/50 (00/)	0/50 (00)
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Report Date: 03/22/2010

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

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			Male				Female	
#Esophagus: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		10/50 (20%)	7/50 (14%)	2/50 (4%)		3/50 (6%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	19/150 (12.67%)	Mean 12.67%	SD 8.08%	Total	13/150 (8.67%)	Mean 8.67%	SD 3.06%
#Harderian Gland: Carcinoma		2/52 (191)	2/52 (221)			2(72)	2/22 (124)	0.750 (001)
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
		3/130 (2%)				` ,		
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%)	7/50 (14%)	3/50 (6%)		3/50 (6%)	8/50 (16%)	4/50 (8%)
Overall Incidence	Total	22/150 (14.67%)	Mean 14.67%	SD 9.02%	Total	15/150 (10%)	Mean 10%	SD 5.29%
#Harderian Gland: Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 288

			Male				Female	
Heart: Hemangioma								
• • • • • • • • • • • • • • • • • • •	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Cecum: Carcinoma		0/50 (651)	0/50 (05.)	4/50 (00%)		0/50 (00.)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	1/50 (2%) SD 1.15%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overali incidence		1/150 (0.67%)	Mean 0.67%	עכ	Total	0/150 (0%)	wiean 0%	3D 0%
fintestine Large: Cecum: Carcinoma or Adenoma		2(72 (224)	2/22 (224)			2/52 (224)	2/22 (221)	2(-2)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/150 (0.6/%)			10tai	0/130 (0%)		3D 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyosarcoma	um:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 289

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

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			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
fIntestine Small: Jejunum: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male			Female 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%)			Female				
#Intestine Small: Site Unspe Carcinoma	cified:												
Occupation of decision	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)	T-1-1	` '	` '	, ,					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	l otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
Intestine Small: Site Unspe Carcinoma or Adenoma	cified:												
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
#Intestine Small: Site Unspe Hemangiosarcoma	cified:												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` '	` '					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
fIntestine Small: Site Unspe Leiomyosarcoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` '	` '					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
#Intestine Small: Site Unspe Polyp Adenomatous													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
Islets, Pancreatic: Adenoma					•								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 292

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Kidney: Renal Tubule: Adenoma								
	T-1-1	0/50 (0%)	0/50 (0%)	1/48 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
	.	0/50 (0%)	0/50 (0%)	0/48 (0%)	.	0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	0/149 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangioma			0. To (0.5.)			0/20	(00)	
N	T-1-1	0/50 (0%)	0/50 (0%)	0/48 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 293

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 294

			Male				Female	
*Liver: Hepatoblastoma								
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
	TOlai	0/100 (0.00%)		יייייייייייייייייייייייייייייייייייייי	10tai	1/150 (0.07%)		ו עכ 1.15%
*Liver: Hepatocellular Adenoma								
		33/50 (66%)	35/50 (70%)	31/50 (62%)		22/50 (44%)	31/50 (62%)	30/50 (60%)
Overall Incidence	Total	99/150 (66%)	Mean 66%	SD 4%	Total	83/150 (55.33%)	Mean 55.33%	SD 9.87%
*Liver: Hepatocellular Carcinoma		14/50 (28%)	17/50 (34%)	28/50 (56%)		3/50 (6%)	8/50 (16%)	23/50 (46%)
Overall Incidence	Total	59/150 (39.33%)	Mean 39.33%	SD 14.74%	Total	34/150 (22.67%)	Mean 22.67%	SD 20.82%
*Liver: Hepatocellular Carcinoma o	or Hepatob	lastoma						
•	•	15/50 (30%)	19/50 (38%)	29/50 (58%)		3/50 (6%)	9/50 (18%)	23/50 (46%)
Overall Incidence	Total	63/150 (42%)	Mean 42%	SD 14.42%	Total	35/150 (23.33%)	Mean 23.33%	SD 20.53%
*Liver: Hepatocellular Carcinoma o								
		40/50 (80%)	41/50 (82%)	45/50 (90%)		22/50 (44%)	32/50 (64%)	38/50 (76%)
Overall Incidence	Total	126/150 (84%)	Mean 84%	SD 5.29%	Total	92/150 (61.33%)	Mean 61.33%	SD 16.17%
*Liver: Hepatocellular Carcinoma, l	Hepatocell	lular Adenoma, or Hepatol	olastoma					
		40/50 (80%)	41/50 (82%)	45/50 (90%)		22/50 (44%)	32/50 (64%)	38/50 (76%)
Overall Incidence	Total	126/150 (84%)	Mean 84%	SD 5.29%	Total	92/150 (61.33%)	Mean 61.33%	SD 16.17%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 295

			Male				Female		
*Liver: Hepatocholangiocarcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocholangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver: Ito Cell Tumor Benign			- /					- / / / / / / / / / /	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Liver: Ito Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Liver: Plasma Cell Tumor Maligna	ınt								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
'Liver: Sarcoma	•••••								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 296

			Male				Female	
*Lung: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
₋ung: Alveolar/Bronchiolar Ade	noma							
		6/50 (12%)	10/50 (20%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	1/50 (2%)
verall Incidence	Total	24/150 (16%)	Mean 16%	SD 4%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Lung: Alveolar/Bronchiolar Card	cinoma	5/50 (10%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	3/50 (6%)	3/50 (6%)
verall Incidence	Total	18/150 (12%)	Mean 12%	SD 2%	Total	10/150 (6.67%)	Mean 6.67%	SD 1.15%
∟ung: Alveolar/Bronchiolar Card	cinoma or Al	veolar/Bronchiolar Adeno 11/50 (22%)	ma 15/50 (30%)	14/50 (28%)		5/50 (10%)	5/50 (10%)	4/50 (8%)
Overall Incidence	Total	40/150 (26.67%)	Mean 26.67%	SD 4.16%	Total	14/150 (9.33%)	Mean 9.33%	SD 1.15%
_ung: Fibrosarcoma								
N	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Taral	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma								
	T	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 297

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Report Date: 03/22/2010

			Male				Female	
#Lymph Node: Plasma Cell Tumor Malignar	nt	0(50 (00))	0/50 (00%)	0/50 (00/)		0/50 (00.)	0/50 (00/)	0/50 /05/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Bronchial: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
_ymph Node, Mandibular: Fibrous Histiocytoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Lymph Node, Mandibular: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 0%

Total

0/150 (0%)

Mean 0%

SD 0%

Total

0/150 (0%)

Mean 0%

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 299

			Male				Female	
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	ant							
	T	0/50 (0%)	0/50 (0%)	0/50 (0%)	T ()	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	ant							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 300

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 301

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 302

			Male				Female		
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Oral Cavity (Oral Mucos	a, Tongue, Phary								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Ovary: Choriocarcinoma									
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	
Ovary: Cystadenoma						2/50 (4%)	3/50 (6%)	1/49 (2%)	
verall Incidence					Total	6/149 (4.03%)	Mean 4.01%	SD 1.98%	
Ovary: Fibrous Histiocytoma									
Overall Incidence					Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%	
Ovary: Granulosa Cell Tumor	Benign								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 303

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
*Ovary: Plasma Cell Tumor Malign	ant					0/50 (00/)	0/50 (00/)	0/40 (00/)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
'Ovary: Teratoma Benign								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Teratoma Malignant					••••••	0/50 (00)	(201)	2/12
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/149 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 305

			Male				Female	
Pancreas: Carcinoma or Adenoma	ı							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dis Adenoma								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		4/49 (8%)	5/50 (10%)	5/47 (11%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	14/146 (9.59%)	Mean 9.6%	SD 1.28%
Pituitary Gland: Pars Dis Carcinoma	talis or Unspec	ified Site: 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec							
O	Tatal	1/50 (2%)	0/50 (0%)	0/49 (0%)	Tatal	4/49 (8%)	5/50 (10%)	5/47 (11%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	14/146 (9.59%)	Mean 9.6%	SD 1.28%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/47 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/146 (0.68%)	Mean 0.67%	SD 1.15%
Pituitary Gland: Pars Inte Carcinoma or Adenoma	rmedia:							
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/47 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/146 (0.68%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

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

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or B	asosquamous	Tumor Benign						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas	sosquamous T	umor Benign, or Trichoep	oithelioma					
,	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Basal Cell Carcinoma or	Basosquamou	us Tumor (malignant or NO	OS) 0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Basal Cell Carcinoma, Ba NOS), or Trichoepithelior		oma, Basosquamous Tur	nor (benign, malignan	t or				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	inoma, Carcinom Sq Papilloma, Ke	na, Basosq. Tumor (M or I eratoacanthoma, Trichoep	3), Basal Cell Adenon ithelioma	na,				
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Basosquamous Tumor								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Fibroma								
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	coma, Myxosarcoma, or F	•	4/50 (20%)		0/50 /00/	4/50 (00/)	4/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
				3D 1.1370		2/130 (1.3376)		
Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin:		a, or Fibrous Histiocytom	a					4/50 (00)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Liposarcoma

Overall Incidence

Overall Incidence

Mast Cell Tumor Benign

#Skin:

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

0/50

SD 0%

0/50

SD 0%

(0%)

(0%)

Total

Total

0/50

0/50

1/150 (0.67%)

0/150 (0%)

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

Mean 0.67%

0/50

1/50

SD 0%

SD 1.15%

(0%)

(2%)

Total

Total

0/50

0/150 (0%)

0/50

0/150 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 311

			Male				Female			
#Skin: Myxosarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
¢Skin: Neurofibrosarcoma or Sch										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%		
#Skin: Neurofibrosarcoma, Neuro	fibroma, or \$	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%		
Skin: Osteosarcoma										
O	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%		
≇Skin: Sarcoma										
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%		
#Skin: Schwannoma Malignant	•••••									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%		

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

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

Route: SKIN Vehicle: ETHANOL

			Male		,		Female	
#Skin: Squamous Cell Carcinom		0/50 (0%)	0/50 (0%)	,	0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tot	al 0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom or Carcinoma	na, Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant o	or NOS),				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (SD 0%	(0%) Tot	0/50 (0%) al 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Squamous Cell Papilloma	a	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tot	al 0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a or Papilloma	0/50 (0%)	0/50 (0%)	0/50 (······································	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Tot	` '	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, S	•			(00/)	0/50 /00()	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (SD 0%	0%) Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, o		0/50 (00/)	0/50	(00/)	0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (SD 0%	0%) Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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

Route: SKIN

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Report Date: 03/22/2010

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

			Male				Female	
#Skin: 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: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spinal Cord: Meningioma Malignant					•••••		•••••	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	SD 0%	%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Fibrous Histiocytoma								(00)
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0 SD 0%	%) Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Mean 0.67%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/22/2010

Route: SKIN Vehicle: ETHANOL

			Male				Female	
*Spleen: Hemangioma		0/50 /00/)	0/50 (00)	0/40 (00)		0/50 (00/)	0/50 (00/)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Spleen: Hemangiosarcoma								
Overall Incidence	Total	3/50 (6%) 7/148 (4.73%)	1/50 (2%) Mean 4.75%	3/48 (6%) SD 2.38%	Total	5/50 (10%) 7/149 (4.7%)	0/50 (0%) Mean 4.69%	2/49 (4%) SD 5.03%
Spleen: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Spleen: Plasma Cell Tumor Malignai	nt							
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Stomach, Forestomach: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 /02/	0/50 (0%)	1/50 (20/)		0/50 (09/)	0/50 (0%)	0/50 (08/)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

SD 1.15%

Total

0/150 (0%)

Mean 0%

SD 0%

Total

1/150 (0.67%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

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Report Date: 03/22/2010

Contract/Lab: All Laboratories

0/49

0/140 (0%)

(0%)

0/47

Mean 0%

(0%)

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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

0/44

SD 0%

(0%)

Total

0/50

0/147 (0%)

(0%)

0/47

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
*Thymus: Thymoma Malignant		0/49 (0%)	1/47 (2%)	0/44 (0%)		0/50 (0%)	1/47 (2%)	0/50 (0%)
Overall Incidence	Total	1/140 (0.71%)	Mean 0.71%	SD 1.23%	Total	1/147 (0.68%)	Mean 0.71%	SD 1.23%
*Thymus: Thymoma: Benign, Maligna	int, NOS	•••••	•••••					
Overall Incidence	Total	0/49 (0%) 1/140 (0.71%)	1/47 (2%) Mean 0.71%	0/44 (0%) SD 1.23%	Total	0/50 (0%) 1/147 (0.68%)	1/47 (2%) Mean 0.71%	0/50 (0%) SD 1.23%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						0/50 (00)	0/50 (00()	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: Follicular Cel Adenoma	ll:							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Thyroid Gland: Follicular Cel Carcinoma	II:							
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 317

			Male				Female	
Thyroid Gland: Follicular Ce Carcinoma or Adenoma	ell:							
• "		1/50 (2%)	0/50 (0%)	1/50 (2%)	.	0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%
#Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
‡Tissue NOS: Plasma Cell Tumor Malign:	ant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Tongue: Fibroma		0/50 (631)	0/50 (001)	0/50 (00%)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

^{#:} Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

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

	Male					Female			
#Tongue: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Tongue: Squamous Cell Carcinor	ma or Papillom	a Squamous							
•	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Tongue: Squamous Cell Papillom	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Tooth: Odontoma									
	-	1/50 (2%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
Urinary Bladder: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
Urinary Bladder: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 319

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male	Female			
tUterus: Leiomyoma		0/50 (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%	
Iterus: Leiomyosarcoma					
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Jterus: Polyp Stromal		(201)	(201)		
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	
Iterus: Sarcoma Stromal					
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Iterus: Sarcoma Stromal or Polyp Stromal					
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	
Uterus: Schwannoma Malignant					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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

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

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

^{#:} Denominator is number of animals necropsied