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:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/03/02 06/25/02 05/08/00	728 730 729	50 (1) 50 (1) 50 (1)	37(682) 34(702) 39(710)	53.5 54.2 52.6	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/02/02 06/24/02 05/08/00	727 729 732	50 (1) 50 (1) 50 (1)	31(692) 33(693) 33(674)	60.8 60.9 65.7	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male		Female	
#All Organs: Benign Tumors						
3		41/50 (82%)	40/50 (80%) 29	/50 (58%)	27/50 (54%) 39/50 (78%)	35/50 (70%)
Overall Incidence	Total	110/150 (73.33%)	` '	SD 13.32% Total	101/150 (67.33%) Mean 67.33%	SD 12.22%
#All Organs: Malignant Tumors						
9		26/50 (52%)	27/50 (54%) 27	[/] 50 (54%)	31/50 (62%) 31/50 (62%)	26/50 (52%)
Overall Incidence	Total	80/150 (53.33%)	` ,	SD 1.15% Total	88/150 (58.67%) Mean 58.67%	SD 5.77%
#All Organs:			•••••			•••••
Malignant and Benign Tu	ımors					
o o		48/50 (96%)	45/50 (90%) 42	/50 (84%)	44/50 (88%) 46/50 (92%)	47/50 (94%)
Overall Incidence	Total	135/150 (90%)		SD 6% Total	137/150 (91.33%) Mean 91.33%	SD 3.06%
#All Organs: Hemangioma					4.50 (001)	
		2/50 (4%)	0/50 (0%) 1/5	` '	1/50 (2%) 0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2% Total	3/150 (2%) Mean 2%	SD 2%
All Organs: Hemangiosarcoma						
J		5/50 (10%)	6/50 (12%) 0/5	60 (0%)	7/50 (14%) 1/50 (2%)	4/50 (8%)
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 6.43% Total	12/150 (8 ³ %) Mean 8%	SD 6%
All Organs: Hemangiosarcoma or He						
3	•	7/50 (14%)	6/50 (12%) 1/5	60 (2%)	8/50 (16%) 1/50 (2%)	6/50 (12%)
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 6.43% Total	15/150 (10%) Mean 10%	SD 7.21%

^{*:} 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:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%
#All Organs: Malignant Lymphoma: or Undifferentiated Cel	Histiocytic, Lyr							
		0/50 (0%)	1/50 (2%)	2/50 (4%)		9/50 (18%)	14/50 (28%)	10/50 (20%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	33/150 (22%)	Mean 22%	SD 5.29%
#All Organs: Mesothelioma: Benign,			0/50 (0%)	0/50 (0%)		0/50 (0%)	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: 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%
All Organs: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/30 (0%) Mean 0%	0/30 (0%) SD 0%	Total	3/150 (2%)	Mean 2%	0/30 (0%) SD 2%
veran incluence	IUIdl	0/130 (0%)	IVICALI U%	SD 0%	IUIAI	3/130 (270)	IVIEAL 270	3D 270

^{*:} 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:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Taral	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%
*Adrenal Cortex: Adenoma		6/49 (12%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	17/149 (11.41%)	Mean 11.41%	SD 1.23%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Malignar	nt	0/49 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		0/40 (00/)	0/50 (00/)	0(40 (00))	•••••	0/50 (00)	0/50 (404)	0/40 (00/)
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 2/149 (1.34%)	2/50 (4%) Mean 1.33%	0/49 (0%) SD 2.31%
*Adrenal Medulla: Pheochromocytoma Comple	•x	0/49 (0%)	0/50 (0%)	0/49 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

^{*:} 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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0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Adrenal Medulla: **Pheochromocytoma Malignant** 0/49 (0%)(2%)(0%)(0%)0/50 (0%)(0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 0/149 (0%) Mean 0% SD 0% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%)0/49 1/50 (2%)0/50 2/50 0/49 (0%)**Overall Incidence** SD 2.31% Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 2/149 (1.34%) Mean 1.33% *Bone Marrow: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% *Bone Marrow: Hemangiosarcoma (2%)(2%)0/49 (0%)(2%)(0%)(2%)1/50 1/50 0/50 1/49 2/149 (1.34%) SD 1.17% **Overall Incidence** Total Mean 1.33% SD 1.15% Total 2/149 (1.34%) Mean 1.35% *Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)0/49 (0%)0/50 0/50 0/49 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/149 Mean 0% SD 0% #Bone:

0/50

SD 0%

(0%)

Total

0/150 (0%)

Total

(0%)

0/150 (0%)

(0%)

Mean 0%

Hemangiosarcoma

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	
#Bone: 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%
#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	1	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: 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%
*Brain: Meningioma Benign		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Meningioma Malignant		0/50 (00/)	0/50 (0%)	0/40 (00/)		0/50 /00/	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} 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: 04/29/2009

SD 1.15%

Mean 0.67%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female *Brain: Meningioma: Benign, Malignant, NOS 0/50 (0%)(0%)(0%)(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% *Brain: Schwannoma Malignant 0/50 (0%)(0%)0/49 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/149 (0%) Mean 0% Total 1/150 (0.67%)Mean 0.67% SD 1.15% *Clitoral/Preputial Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/46 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% *Clitoral/Preputial Gland: Carcinoma (0%)(0%)0/50 (0%)(0%)0/46 (0%)0/50 0/50 0/50 0/150 (0%) Mean 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/146 (0%) SD 0% *Clitoral/Preputial Gland: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/46 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% *Clitoral/Preputial Gland: Hemangioma 0/50 (0%)(0%)0/50 (0%)(2%)0/50 (0%)0/46 (0%)

SD 0%

Total

1/146 (0.68%)

Mean 0%

Total

0/150 (0%)

Overall Incidence

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
Clitoral/Preputial Gland: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
verali ilicidence	····	0/130 (0/0)			ı olal	0/140 (070)	ivicali 070	
Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		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%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
, verum monuemoe	ı olu	0/100 (0/0)	Wicari 070	05 070	ı olul	0,140 (070)	Wicari 070	02 070
Esophagus: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 /00/	0/50 (00)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
, vorum moracnoc	ı olu	0/100 (0/0)	Wicari 070	05 070	ı olul	0/100 (0/0)	Wicari 070	00 070
Eye: Sarcoma								
hanall lunidanaa	Tatal	1/50 (2%)	0/50 (0%)	1/50 (2%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	3D 0%
Harderian Gland: Adenoma		•••••	•••••				•••••	•••••
		10/50 (20%)	7/50 (14%)	9/50 (18%)		3/50 (6%)	6/50 (12%)	9/50 (18%)
verall Incidence	Total	26/150 (17.33%)	Mean 17.33%	SD 3.06%	Total	18/150 (12%)	Mean 12%	SD 6%
Harderian Gland: Carcinoma		0/50 (40()	0/50 (00/)	0/50 (40/)		0/50 /00/	0/50 /40/	4/50 (00()
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 3/150 (2%)	2/50 (4%) Mean 2%	1/50 (2%) SD 2%
veran incluence	IUlai	4/130 (2.07/6)	IVICALI 2.0170	SD 2.31/0	i Ulai	J/100 (2/0)	IVICALI Z/0	3D 2/0

^{*:} 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

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Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
Intestine Large: Cecum: Carcinoma or Adenoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Intestine Large: Cecum: Leiomyoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Large: Colon/Rectum: Leiomyosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Duodenum: Adenoma				
		0/50 (0%)	0/50 (0%) 1/50 (2%	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.159	5% Total 1/150 (0.67%) Mean 0.67% SD 1.15%
ntestine Small: Duodenum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Duodenum: Leiomyosarcoma				0/10 /00/ 0/10 /00/ 0/10 /00/
		0/50 (0%)	0/50 (0%) 0/50 (0%	, , , , , , , , , , , , , , , , , , , ,
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Duodenum: Polyp Adenomatous 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Carcinoma 0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Intestine Small: Ileum: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Ileum: Polyp Adenomatous (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% #Intestine Small: Jejunum: Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 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: 04/29/2009

(2%)

SD 1.15%

1/50

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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

1/50

(2%)

SD 1.15%

0/50

Total

1/150 (0.67%)

(0%)

0/50

(0%)

Mean 0.67%

Total

0/50

1/150 (0.67%)

(0%)

0/50

(0%)

Mean 0.67%

Carcinoma or Adenoma

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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

#Intestine Small: Site Unspecified: Hemangiosarcoma O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyosarcoma O/50 (0%) O/50 (0%) O/50 (0%) Mean 0% Overall Incidence Total O/150 (0%) Mean 0% Overall Incidence Total O/150 (0%) O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0% SD 0% Overall Incidence Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 0.67% SD 1.15% Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) Mean 067% SD 1.15%				Male				Female	
Overall Incidence Total 0/50 (0%)		fied:							
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#Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Polyp Adenomatous 0/50 (0%) Overall Incidence Total 0/150 (0%) Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0.67% SD 1.15% Tislets, Pancreatic: Carcinoma 0/50 (0%) Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0.67% SD 0% Total 0/150 (0%) Mean 0.67% SD 0% Total 0/150 (0%) Mean 0.67% SD 0.750 (0%) Mean 0.67% SD 0.750 (0%) Tislets, Pancreatic: Carcinoma 0/50 (0%) Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%	Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified:	#Intestine Small: Site Unspecif								0/50 (00/)
#Intestine Small: Site Unspecified: Polyp Adenomatous 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma 0/50 (0%) 0/50 (0%) 1/49 (2%) Overall Incidence Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Islets, Pancreatic: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/149 (0%) 0/50 (0%) 0/49 (0%) Overall Incidence Total 0/149 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/49 (0%) Overall Incidence Total 0/149 (0%) 0/50 (0%) 1/49 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%) 0/50 (0%) 1/49 (2%) Overall Incidence 1 Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma 0/50 (0%) 0/50 (0%) 1/49 (2%) Overall Incidence 1 Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%	O	Tatal	, ,	` ,	` '	T-1-1	` '	` '	` ,
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Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Islets, Pancreatic: Adenoma Overall Incidence Total 1/149 (0.67%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Islets, Pancreatic: Carcinoma Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%) *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	#Intestine Small: Site Unspecif								
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Adenoma O/50 (0%) O/50 (0%) 1/49 (2%) Overall Incidence Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Islets, Pancreatic: Carcinoma O/50 (0%) O/50 (0%) O/50 (0%) Overall Incidence Total O/149 (0%) Mean 0% SD 0% Total O/150 (0%) O/50 (0%) Mean 0% SD 0% Total O/150 (0%) O/50 (0%) Mean 0% SD 0% Total O/150 (0%) I/50 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma O/50 (0%) O/50 (0%) I/49 (2%) O/50 (0%) I/50 (0%) I/50 (0%) O/50 (0%) I/50 (0%) Total O/150 (0%) I/50 (0%) O/50 (0%) I/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) I/49 (2%) O/50 (0%) I/50 (2%) O/50 (0%)	Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Islets, Pancreatic: Carcinoma Overall Incidence Total 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	•			•••••					
*Islets, Pancreatic: Carcinoma 0/50 (0%) 0/50 (0%) 0/49 (0%) Overall Incidence Total 0/149 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)			,	` ,	` ,		` '	` '	` '
Carcinoma 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%	Overall Incidence	Total	1/149 (0.67%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Carcinoma 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%	*Islets Pancreatic:								
O/50 (0%) O/50									
Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Islets, Pancreatic: Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)			0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Carcinoma or Adenoma 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	*Islate Paneroatie:					•••••			
	•		0/50 (00/)	0/50 (00/)	4/40 (00/)		0/50 (00/)	4/50 (00/)	0/50 (00/)
Overall Incidence Lotal 1/149 (0.67%) Mean 0.68% SD 1.18% Lotal 1/150 (0.67%) Mean 0.67% SD 1.15%			,	` ,	` '	-	` ,	` '	` '
	Overall Incidence	I otal	1/149 (0.67%)	Mean 0.68%	SD 1.18%	l otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (00/)	0/50 (0%)	0/40 (00/)		0/50 (00/)	0/50 (0%)	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%
Overall illicidence	TOtal	0/148 (0%)	IVICALI 070	30 0%	I Olai	0/149 (076)	IVICALI U/0	30 0/6
*Kidney: Renal Tubule: Carcinoma or Adenoma		2(-2)	- (((((((((((00)		- (·)	- ((((((((((
Occupation of days as	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%
*Kidney: Renal Tubule: Hemangioma								
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	0/48 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna	nt	0/50 (00/)	0/50 (09/)	0/49 (00/)		0/50 (09/)	0/50 (09/)	0/40 (09/)
Overall Incidence	Total	0/50 (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%
Overall incluence	IUlai	0/148 (0%)	IVICALI U70	3D 0%	Total	0/149 (070)	IVICALI U70	3D 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	
*Liver: Cholangiocarcinoma 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%
Overall illelidelide	I Olai	1/130 (0.07 /8)	iviean 0.07/6	30 1.13%	I Olai	0/130 (0/8)	Mean 076	
*Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*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%)	4/50 (20/)	0/50 (00/)		2/50 (49/)	4/50 (20/)	4/50 /00/)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%
*Liver: Hepatoblastoma		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Liver: Hepatocellular Adenoma	•	22/50 (669/)	25/50 (7700/)	49/50 (259/)		22/50 (449/)	24/50 (620()	24/50 (420/)
Overall Incidence	Total	33/50 (66%) 86/150 (57.33%)	35/50 (70%) Mean 57.33%	18/50 (36%) SD 18.58%	Total	22/50 (44%) 74/150 (49.33%)	31/50 (62%) Mean 49.33%	21/50 (42%) SD 11.02%

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

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Liver: Hepatocellular Carcinoma								
		14/50 (28%)	17/50 (34%)	20/50 (40%)		3/50 (6%)	8/50 (16%)	10/50 (20%)
Overall Incidence	Total	51/150 (34%)	Mean 34%	SD 6%	Total	21/150 (14%)	Mean 14%	SD 7.21%
.iver: Hepatocellular Carcinoma or					•••••			
riepatocentiai Garemonia or	Перагов	15/50 (30%)	19/50 (38%)	20/50 (40%)		3/50 (6%)	9/50 (18%)	10/50 (20%)
Overall Incidence	Total	54/150 (36%)	Mean 36%	SD 5.29%	Total	22/150 (14.67%)	Mean 14.67%	SD 7.57%
_iver: Hepatocellular Carcinoma or	Hepatoce	ellular Adenoma 40/50 (80%)	41/50 (82%)	35/50 (70%)	•••••	22/50 (44%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 6.43%	Total	83/150 (55.33%)	Mean 55.33%	SD 10.26%
Liver: Hepatocellular Carcinoma, H Hepatoblastoma	epatocell	ular Adenoma, or 40/50 (80%)	41/50 (82%)	35/50 (70%)		22/50 (44%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 6.43%	Total	83/150 (55.33%)	Mean 55.33%	SD 10.26%
.iver: Hepatocholangiocarcinoma		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: Hepatocholangioma	•••••	0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 /0%\
verall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Verali 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

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*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 Overall Incidence	ant Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Lung: Adenoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Lung: Alveolar/Bronchiolar Aden	oma	6/50 (12%)	10/50 (20%) 6/50 (12%)	1/50 (2%) 2/50 (4%) 4/50 (8%)
Overall Incidence	Total	22/150 (14.67%)	Mean 14.67% SD 4.62%	Total 7/150 (4.67%) Mean 4.67% SD 3.06%
Alveolar/Bronchiolar Aden Overall Incidence	Total	6/50 (12%) 22/150 (14.67%)		1/50 (2%) 2/50 (4%) 4/50 (8%) Total 7/150 (4.67%) Mean 4.67% SD 3.06%

^{*:} 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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: Alveolar/Bronchiolar Car	cinoma	E/EQ (400V)	0/50 /400/	2/50 /40/		4/50 (00/)	2/50 /00/)	0/50 (00/)
Overall Incidence	Total	5/50 (10%) 13/150 (8.67%)	6/50 (12%) Mean 8.67%	2/50 (4%) SD 4.16%	Total	4/50 (8%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	0/50 (0%) SD 4.16%
*Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv				•••••			
Overall Incidence	Total	11/50 (22%) 34/150 (22.67%)	15/50 (30%) Mean 22.67%	8/50 (16%) SD 7.02%	Total	5/50 (10%) 14/150 (9.33%)	5/50 (10%) Mean 9.33%	4/50 (8%) SD 1.15%
*Lung: Fibrosarcoma		0/50 (00/)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (/0//)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig	nant	0/50 (004)	0/50 (00)	0/50 (00/)		0/50 (004)	0/50 (001)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 325

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: 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: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
£Lymph Node: Hemangioma	•••••	0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Plasma Cell Tumor Malign	nant							•••••
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%

^{*:} 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:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#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%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Lymph Node, Mandibular: Hemangiosarcoma							(004)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt	(00)	(20)	2/22 (221)		(20)	(004)	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%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} 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	
_ymph Node, Mesenteric: Hemangioma								
-	-	0/50 (0%)	` '	0/50 (0%)	T	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
∟ymph Node, Mesenteric: Hemangiosarcoma		(22)	2/22 (22/)	2(-2 (22)		(22)	(00)	2(72 (22))
verall 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%
verali incidence	Total	0/150 (0%)	wean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	3D 0%
_ymph Node, Mesenteric: Plasma Cell Tumor Malignan	t	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
verali ilicidelice		` ,				` ,		
lammary Gland: Adenoacanthoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ciali molacinoc		0/100 (0/0)	Widaii 070		rotai	0/100 (0/0)	Wedit 070	0.00
lammary Gland: Adenoma		0(50 (00))	0/50 (00/)	2/52 (22/)		0/50 (00)	0(50 (00))	0/50 (001)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
eran meluence	ı Ulai	0/100 (0%)	IVIEAN U%	3D 0%	I Ulai	0/100 (0%)	IVIEdII U70	3D 0%
lammary Gland: Carcinoma								
	Tatal	1/50 (2%)	` '	1/50 (2%)	Tatal	2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%

^{*:} 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	
#Mammary Gland: Carcinoma or Adenoma	a							
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#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, Fibroadenom	a or Adenoma	0/50 (00)		(00)			(201)	(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%
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, o	or Adenoma						
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Mesentery: Fibrosarcoma					•••••			
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: 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%

^{*:} 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:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mesentery: 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%
#Mesentery: Sarcoma		0/50 (00/)	0/50 (00)	0/50 (001)		4/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Nose: Mast Cell Tumor Malignar	nt	0/50 (00()	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
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%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or F	ongue, 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%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom	ongue, 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%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom Papilloma	ongue, 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%

^{*:} 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: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male Female *Ovary: Choriocarcinoma 0/50 (0%)(0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Cystadenoma 2/50 (4%)3/50 1/49 (2%)**Overall Incidence** 6/149 (4.03%) SD 1.98% Total Mean 4.01% *Ovary: **Fibrous Histiocytoma** 0/50 (0%)(2%)0/49 (0%)1/50 **Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% *Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)1/49 (2%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.68% SD 1.18% **Granulosa Cell Tumor Malignant** 0/50 0/50 0/49 (0%)**Overall Incidence** Total 0/149 Mean 0% SD 0% *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS (0%)0/50 (0%)1/49 (2%)**Overall Incidence** SD 1.18% Total 1/149 (0.67%) Mean 0.68%

^{*:} 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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Total (0/50					
Total (0/50					
Total C		` '	,	,		0%)
Total 1	0/50 1/149 (0	` '	,	,		2%) 8%
Total (0/50 0/149 (0	` '	,	,		0%)
Total (0/50 0/149 (0	` '	,	,		0%)
	•••••	•••••	•••••			
Total (0/50 0/149 (0	` '	,	,		0%)
		•••••				
Total (0/50 0/149 (0	` '	,	,	,	0%)
	Total Total Total	O/50 Total 0/149 ((0/50 Total 1/149 ((0/50 Total 0/149 ((0/50 Total 0/149 ((0/50 Total 0/149 ((0/50 Total 0/149 ((0/50	O/50 (0%) Total 0/149 (0%) O/50 (0%) O/50 (0%) Total 0/149 (0%) O/50 (0%) Total 0/149 (0%) Total 0/149 (0%) O/50 (0%) O/50 (0%) O/50 (0%)	Total 0/149 (0%) Mean 0/50 (0%) 0/50 (Total 1/149 (0.67%) Mean 0/50 (0%) 0/50 (Total 0/149 (0%) Mean 0/50 (0%) 0/50 (Total 0/149 (0%) Mean 0/50 (0%) 0/50 (Total 0/149 (0%) Mean	Total 0/149 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 1/ Total 1/149 (0.67%) Mean 0.68% 0/50 (0%) 0/50 (0%) 0/ Total 0/149 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/ Total 0/149 (0%) Mean 0% 1/ 0/50 (0%) 0/50 (0%) 0/ Mean 0% 0/50 (0%) 0/50 (0%) 0/ Total 0/149 (0%) Mean 0%	Total 0/149 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 1/49 (2 Total 1/149 (0.67%) Mean 0.68% SD 1.1 0/50 (0%) 0/50 (0%) 0/49 (0 Total 0/149 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/49 (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

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	
*Ovary: Teratoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma			•••••					
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma		0/50 (00/)	0/50 (00()	0/40 /00/		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pituitary Gland: Pars Distalis o	or Unspecif	ied Site:	•••••					
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/50 (0%) Mean 0.67%	0/48 (0%) SD 1.15%	Total	4/49 (8%) 13/147 (8.84%)	5/50 (10%) Mean 8.83%	4/48 (8%) SD 1.01%

^{*:} 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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:						
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/50 (0%)	1/48 (2%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.69%	SD 1.2%
				•••••				
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma	or Unspecif							
		1/50 (2%)	0/50 (0%)	0/48 (0%)		4/49 (8%)	5/50 (10%)	5/48 (10%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	14/147 (9.52%)	Mean 9.53%	SD 1.2%
*Pituitary Gland: Pars Interme Adenoma	dia:							
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	dia:							
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	1/50 (2%)	0/48 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
*Prostate:								
Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (00/)	0/50 (09/)	0/50 (00/)				
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	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

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Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*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		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma			0/50 (0%)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)	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%				
#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%

^{*:} 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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#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%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Rhabdomyosarcoma			- ()					
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%
#Skeletal Muscle: Rhabdomyosarcoma or R	Rhabdomyom		0/50 (00/)	4/50 (20/)		0/50 (/0//)	0/50 (00/)	0/50 (09/)
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%
#Skeletal Muscle: Sarcoma		0/50 (00()	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Adenoma or Ba	asosquamou		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%

^{*:} 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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous [*]	Tumor Benign, or						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Totali illoluciloc	Total	0,100 (070)	MCail 070	OD 070	iotai	1,100 (0.01,70)	WCaii 0.07/0	OD 1.1070
Skin: Basal Cell Carcinoma NOS)	or Basosquamo							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin:								
Basal Cell Carcinoma, Tumor (benign, maligr	ant or NOS), or	Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, maligr		Trichoepithelioma		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%
Basal Cell Carcinoma,	Total Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma	0/50 (0%) Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan	Total Toma, Carcinonoma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%) na, Basosq. Tumor (M	0/50 (0%) Mean 0%	` '	Total 	` '	` '	` '
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan	Total Toma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% 0/50 (0%) Mean 0%	SD 0% /	Total	1/150 (0.67%) 0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15%
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) na, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% 0/50 (0%) Mean 0%	SD 0% (0%) SD 0%	Total	1/150 (0.67%) 0/50 (0%) 1/150 (0.67%)	Mean 0.67% 1/50 (2%) Mean 0.67%	SD 1.15% 0/50 (0%) SD 1.15%
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan verall Incidence	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%) ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0% 0/50 (0%) Mean 0%	SD 0% / / / / / / / / / / / / / / / / / /	Total	1/150 (0.67%) 0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15% 0/50 (0%)

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Fibroma (0%)(0%)(2%)(0%)(0%)0/150 (0%) **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or **Fibrous Histiocytoma** 0/50 (2%)0/50 (2%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #Skin: Fibrosarcoma 0/50 0/50 (0%)(0%)(2%)SD 0% SD 1.15% Overall Incidence Total 0/150 (0%) Mean 0% Total 1/150 (0.67%)Mean 0.67% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 2/150 (1.33%) Mean 1.33% SD 1.15% **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total Total 0/150 (0%) Mean 0% 0/150 (0%) Mean 0% SD 0% #Skin: **Granular Cell Tumor Benign** (0%)(0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 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			
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Hemangiosarcoma		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma							•••••	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or S	Schwannoma (r	malignant or NOS) 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%
#Skin: Neurofibrosarcoma, Nemalignant or NOS)	urofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%

^{*:} 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

Male Female #Skin: Osteosarcoma 0/50 (0%)(0%)0/50 (0%)(0%)(0%)0/150 (0%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total (0.67%)Mean 0.67% SD 1.15% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)(2%)(0%)1/50 0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% SD 2% #Skin: Squamous Cell Carcinoma (0%) (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 (0%)(2%)(0%)SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Skin: Squamous Cell Papilloma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0%

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ontrol Animal Groups I Page: 340

Report Date: 04/29/2009

Male Female #Skin: **Squamous Cell Papilloma or Papilloma** 0/50 (0%)(0%)(0%)0/50 (0%)(0%)0/150 (0%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 0/50 0/50 0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 0/50 0/50 (0%)(0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Skin: Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 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%)(0%)0/50 (0%)SD 0% SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% #Skin: Sebaceous Gland: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(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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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)				0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (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/)	0/40 /00/		0/50 (00()	4/50 (00)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) Mean 0.67%	0/49 (0%) SD 1.15%
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma	••••							
Overall Incidence	Total	3/50 (6%) 4/149 (2.68%)	1/50 (2%) Mean 2.67%	0/49 (0%) SD 3.06%	Total	5/50 (10%) 6/149 (4.03%)	0/50 (0%) Mean 4.01%	1/49 (2%) SD 5.28%
*Spleen: Mast Cell Tumor Malignant	:	0/50 (00/.)	0/50 (00/)	0/40 /00/		0/50 /00()	0/50 (0%)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/149 (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

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Spleen:								
Plasma Cell Tumor Malignar	nt	0/50 (0%)	0/50 (00/)	0/40 /00/)		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%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
·····								
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:		• • • • • • • • • • • • • • • • • • • •				•••••		•••••
Squamous Cell Carcinoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:								
Squamous Cell Carcinoma o	r Papillon	na Squamous						
-	-	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%
Stomach, Forestomach:					•••••			
Squamous Cell Papilloma								
equamous con i apinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%
Stomach, Glandular: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*T								
*Testes: Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)				
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%				
*Testes: Hemangiosarcoma		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%				
					•••••			
*Thymus: Thymoma Benign								
		0/49 (0%)	0/47 (0%)	0/47 (0%)		0/50 (0%)	0/47 (0%)	0/46 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	0/143 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/49 (0%)	1/47 (2%)	0/47 (0%)		0/50 (0%)	1/47 (2%)	0/46 (0%)
Overall Incidence	Total	1/143 (0.7%)	Mean 0.71%	SD 1.23%	Total	1/143 (0.7%)	Mean 0.71%	SD 1.23%

^{*:} 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:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female					
*Thymus: Thymoma: Benign, Malignant, NOS									
Overall Incidence	Total	0/49 (0%) 1/143 (0.7%)	1/47 (2%) 0/47 (0%) Mean 0.71% SD 1.23%	0/50 (0%) 1/47 (2%) 0/46 (0%) Total 1/143 (0.7%) Mean 0.71% SD 1.23%					
*Thyroid Gland: Adenoma	• • • • • • • • • • • • • • • • • • • •	0/50 (09/)	0/50 (00/) 0/40 (00/)	0/50 (0%) 0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%					
*Thyroid Gland: C-Cell: Carcinoma			2/72 (201)						
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%					
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •	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%					
*Thyroid Gland: Follicular Cell: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 3/50 (6%) Total 3/150 (2%) Mean 2% SD 3.46%					
*Thyroid Gland: Follicular Cell: Carcinoma		4/50 (00/)	0/50 (00/) 0/40 (00/)	0/50 (00/) 0/50 (00/)					
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) 0/49 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (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

Page: 345

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		1/50 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 3/50 (6%)			
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67% SD 1.15%	Total 3/150 (2%) Mean 2% SD 3.46%			
#Tissue NOS: Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%			
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			
#Tissue NOS: Plasma Cell Tumor Maligna	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%			
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			
#Tongue: Fibroma	•••••	0/50 (00/)	0/50 (00)	0/50 (001) 0/50 (001)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%			

^{*:} 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	
#Tongue: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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 Carcino			0/50 (0%)	0/50 (0%)		0/50 (0%)	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 Papillor Overall Incidence	na Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tooth: Odontoma Overall Incidence	Total	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%
*Urinary Bladder: Hemangioma Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} 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

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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

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

^{#:} Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male Female #Uterus: Leiomyoma 0/50 (0%)(0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% #Uterus: **Polyp Stromal** 0/50 (0%)1/50 (2%)4/50 (8%) **Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 4.16% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Sarcoma Stromal or Polyp Stromal 0/50 (0%)(2%)4/50 (8%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 4.16% **#Uterus:** Schwannoma Malignant (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0%

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

^{#:} Denominator is number of animals necropsied

Version: May2009 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

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			Male				Female	
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's 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%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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