**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/20/2010

Species: RATS Strain: F 344/N Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059902805	09/16/02	729	50(1)	21(676)	506.2	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/10/02	728	50(1)	25(680)	510.4	1,2-Dibromo-2,4-dicyanobutane
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
					Female		
Battelle Columbus Laboratory	059902805	09/17/02	730	50(1)	19(646)	341.0	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700307	07/11/02	729	50(1)	29(695)	337.8	1,2-Dibromo-2,4-dicyanobutane
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

Species: RATS

Strain: F 344/N

**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								
_		49/50 (98%)	46/50 (92%)	47/50 (94%)		37/50 (74%)	46/50 (92%)	43/50 (86%)
Overall Incidence	Total	142/150 (94.67%)	Mean 94.67%	SD 3.06%	Total	126/150 (84%)	Mean 84%	SD 9.17%
#All Organs: Malignant Tumors								
-		26/50 (52%)	23/50 (46%)	22/50 (44%)		19/50 (38%)	15/50 (30%)	12/50 (24%)
Overall Incidence	Total	71/150 (47.33%)	Mean 47.33%	SD 4.16%	Total	46/150 (30.67%)	Mean 30.67%	SD 7.02%
#All Organs: Malignant and Benign Tu	ımors	49/50 (98%)	50/50 (100%)	49/50 (98%)		44/50 (88%)	48/50 (96%)	45/50 (90%)
Overall Incidence	Total	148/150 (98.67%)	Mean 98.67%	SD 1.15%	Total	137/150 (91.33%)	Mean 91.33%	SD 4.16%
All Organs: 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%
All Organs: Hemangiosarcoma								
		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%
#All Organs: Hemangiosarcoma or He	mangioma						- 1	
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

Species: RATS

Strain: F 344/N

**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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				Total 1/150 (0.67%) Mean 0.67% SD 1.15%  0/50 (0%) 0/50 (0%) 0/50 (0  Total 0/150 (0%) Mean 0% SD 0%  12/50 (24%) 10/50 (20%) 8/50 (16  Total 30/150 (20%) Mean 20% SD 4%  0/50 (0%) 0/50 (0%) 0/50 (0  Total 0/150 (0%) Mean 0% SD 0%								
#All Organs: Histiocytic Sarcoma  1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)  1/50 (2%) 0/50 (0%) 0/50 (0%)												
	1/50 (2%)	1/50 (2%)	0/50 (0%)		` '	` '	` '					
	` ,				,	Mean 0.67%	SD 1.15%					
<b>-</b>	` '	` '	` '	<b>-</b>	` '	` ,	` ,					
lotal	0/150 (0%)	Mean 0%	SD 0%	l otal	0/150 (0%)	Mean 0%	SD 0%					
Total	ononuclear, or Undifferen 17/50 (34%) 45/150 (30%)	ntiated 17/50 (34%) Mean 30%	11/50 (22%) SD 6.93%	Total	` ,	,	` ,					
cytic, Lym			= =		0/50 (00)	0/50 (00/)	0/50 (00()					
Total	` ,	` '	` '	Total	` ,	` '	` ,					
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	` '	` ,	` '					
nant, NOS		1/50 (29/)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Total	` '	` '	` '	Total	` '	` ,	0/30 (0%) SD 0%					
	Total  Total  Cytic, Lym  Total  Total	0/50 (0%) Total 0/150 (0%)  nocytic, Mononuclear, or Undifferen 17/50 (34%) Total 45/150 (30%)  cytic, Lymphocytic, Mixed, NOS, or 0/50 (0%) Total 0/150 (0%)  Total 1/150 (0.67%)  nant, NOS 2/50 (4%)	0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%  nocytic, Mononuclear, or Undifferentiated 17/50 (34%) 17/50 (34%) Total 45/150 (30%) Mean 30%  cytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cel 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0%  0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67%  nant, NOS  2/50 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%  nocytic, Mononuclear, or Undifferentiated 17/50 (34%) 17/50 (34%) 11/50 (22%)  Total 45/150 (30%) Mean 30% SD 6.93%  cytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%  Total 1/150 (0.67%) Mean 0.67% SD 1.15%  nant, NOS  2/50 (4%) 1/50 (2%) 2/50 (4%)	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total  nocytic, Mononuclear, or Undifferentiated 17/50 (34%) 17/50 (34%) 11/50 (22%)  Total 45/150 (30%) Mean 30% SD 6.93% Total  cytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total  0/50 (0%) 1/50 (2%) 0/50 (0%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total  nant, NOS  2/50 (4%) 1/50 (2%) 2/50 (4%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  nocytic, Mononuclear, or Undifferentiated 17/50 (34%) 17/50 (34%) 11/50 (22%) 12/50 (24%)  Total 45/150 (30%) Mean 30% SD 6.93% Total 30/150 (20%)  cytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%)  nant, NOS 2/50 (4%) 1/50 (2%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0%  nocytic, Mononuclear, or Undifferentiated 17/50 (34%) 17/50 (34%) 11/50 (22%) 12/50 (24%) 10/50 (20%) Total 45/150 (30%) Mean 30% SD 6.93% Total 30/150 (20%) Mean 20%  cytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%  Total 0/150 (0%) 1/50 (2%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0%  nant, NOS  2/50 (4%) 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/50 (0%)					

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/20/2010

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	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%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#All Organs: Osteosarcoma								
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 or Osteoma						0/50 /00/\	0/50 (00()	4/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Adrenal Cortex: Adenoma								
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	3/50 (6%) Mean 2%	0/50 (0%) SD 3.46%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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

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

Species: RATS

Strain: F 344/N

# **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

			Male				Female	
Adrenal Medulla: Ganglioneuroma								
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%
Adrenal Medulla: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign		3/50 (6%)	5/50 (10%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 0%
Adrenal Medulla: Pheochromocytoma Comple	x	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%
Adrenal Medulla: Pheochromocytoma Maligna	nt							
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%
Adrenal Medulla: Pheochromocytoma: Benign	, Complex		E/E0 /400/\	E/EO /400/\		4/50 (20/)	4/50 (20/)	4/50 (20()
Overall Incidence	Total	3/50 (6%) 13/150 (8.67%)	5/50 (10%) Mean 8.67%	5/50 (10%) SD 2.31%	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 327

			Male			Female		
#Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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: Chondrosarcoma or Chond								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chordoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteoma				(00)				
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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 328

			Male					Female	male	
Brain: Astrocytoma Malignant		0/50 (0%)	4/50 /00/	0/50 //	00/)		0/50 (00/)	0/50 (09/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (i SD 1.15%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Ependymoma Benign										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 ( SD 0%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Ependymoma Malignant										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (i SD 0%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Glioma Malignant		0/50 (0%)	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 (i SD 0%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Granular Cell Tumor Benign										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 ( SD 0%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Brain: Medulloblastoma Mal										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (i SD 0%	0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 329

			Male				Female	
*Brain: Oligodendroglioma Benigi	n							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Oligodendroglioma Maligr								
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%
*Brain: Oligodendroglioma, Gliom	na, or Astroc	-	(0.00)	(0.1)		(2.3)	(20)	2/22 (224)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Brain: Osteosarcoma								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%
Brain: Schwannoma Malignant								
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%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%	Total	2/50 (4%) 11/150 (7.33%)	6/50 (12%) Mean 7.33%	3/50 (6%) SD 4.16%

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 330

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (00/)	0/50 (09/)		0/50 (00/)	0/50 (00/)	4/50 (20/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%	Total	2/50 (4%) 12/150 (8%)	6/50 (12%) Mean 8%	4/50 (8%) SD 4%
*Clitoral/Preputial Gland: 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%
*Clitoral/Preputial Gland: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Ear: Neural Crest Tumor					•••••			
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%
#Esophagus: 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%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 331

			Male				Female	
#Esophagus: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
‡Eye: Melanoma 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%
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 /00/	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		0/150 (0%)	Wear 0%	3D 0%	10tai	0/130 (0%)		
Harderian Gland: Carcinoma								
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%
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign								
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 332

			Male				Female	
*Heart: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Large: Colon/Recti Adenoma	um:							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
fIntestine Large: Colon/Rect	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%
fintestine Large: Colon/Rect Carcinoma or Adenoma	um:							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Intestine Large: Colon/Rect Hemangioma	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%
fintestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 333

			Male				Female	
fIntestine Small: Duodenum: 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%
fintestine Small: Ileum: Adenoma								
		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: Jejunum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Granular Cell Tumor Maligna	ant							
	<b>-</b>	1/50 (2%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: 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 Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Sveran incluence	Total	0/100 (0%)	Mean 0%	3D 0%	Total	0/150 (0%)	Mean 0%	3D 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 334

			Male				Female					
#Intestine Small: Site Unspecified: Adenoma												
		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: Site Uns Carcinoma	specified:											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Uns Carcinoma or Adenoma	specified:			0/50 (00()		0/50 (00/)	0/50 (00/)	(201)				
O	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	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: Site Uns Granular Cell Tumor Ma	•											
		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%				
#Intestine Small: Site Uns 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 Small: Site Uns Leiomyosarcoma	specified:											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				

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

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

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 335

			Male				Female	
Islets, Pancreatic:								
		3/50 (6%)	6/50 (12%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	12/150 (8%)	Mean 8%	SD 3.46%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
'Islets, Pancreatic: Carcinoma or Adenoma		2/50 (0%)	C/FO (400V)	2/50 (60()		4/50 (00()	0/50 (00/)	0/50 (40/)
Overall Incidence	Total	3/50 (6%) 12/150 (8%)	6/50 (12%) Mean 8%	3/50 (6%) SD 3.46%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
		` '						
Kidney: Pelvis and Transitio Carcinoma	nal Epitheliu							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transitio Carcinoma or Adenoma	nal Epitheliu	ım:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transitio Papilloma	nal Epitheliu							
		0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%) SD 0%		0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall Incidence	Total		Mean 0%		Total	0/150 (0%)		

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

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Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
Kidney: Renal Tubule: Adenoma										
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Kidney: Renal Tubule: Carcinoma			•••••							
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%		
Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 /00/	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%		
Kidney: Renal Tubule: 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%		
Kidney: Renal Tubule: Lipoma										
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%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%		
Kidney: Renal Tubule: Mesenchymal Tumor Benigi	n									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 337

			Male				Female					
*Kidney: Renal Tubule: Mesenchymal 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%				
Kidney: Renal Tubule: Nephroblastoma												
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%				
overali incidence	TOTAL	0/150 (0%)		טע סא	Total	0/150 (0%)	wiean 0%	3D 0%				
Kidney: Renal Tubule: Sarcoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
Liver: Cholangioma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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: Hepatocellular Adenoma		0/50 (631)	0/50 (05.)	4/50 (001)		0/50 (00.)	0/50 (00/)	0/50 (400)				
Overell In elden ee	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)	Tatal	0/50 (0%)	0/50 (0%)	2/50 (4%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%				

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 338

			Male		Female				
Liver: Hepatocellular Carcinom	ıa								
	<b>T</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)	<b>T</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinom	a or Hepatobl	astoma							
•	•	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Liver:  Hepatocellular Carcinom  Overall Incidence	a or Hepatoce	ellular Adenoma 0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	
*Liver:		ular Adenoma, or Hepatob 0/50 (0%)		1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	
*Liver: Ito Cell Tumor Benign									
Occupation of James	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%	
*Lung: Alveolar/Bronchiolar Ade									
	<b>-</b>	4/50 (8%)	1/50 (2%)	1/50 (2%)	<b>T</b>	0/50 (0%)	4/50 (8%)	0/50 (0%)	
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%	

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 339 Report Date: 03/20/2010

			Male				Female						
*Lung: Alveolar/Bronchiolar Carcinoma													
		1/50 (2%)	1/50 (2%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
Lung:		veolar/Bronchiolar Adeno											
		5/50 (10%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	4/50 (8%)	0/50 (0%)					
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 3.06%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%					
Lung: Fibrosarcoma					•••••								
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
Lung: Hemangiosarcoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
Lung: Squamous Cell Carcino	ma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%					
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%					

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mammary Gland: Adenolipoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% SD 2% #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 4/150 (2.67%) Mean 2.67% SD 1.15% Total

1/50

SD 1.15%

0/50

SD 3.06%

0/50

SD 0%

(2%)

(0%)

(0%)

Total

Total

Total

1/50

16/50

0/50

0/150 (0%)

7/150 (4.67%)

54/150 (36%)

(2%)

(32%)

(0%)

3/50

14/50

0/50

(6%)

(28%)

(0%)

Mean 4.67%

Mean 36%

Mean 0%

3/50

SD 2.31%

24/50 (48%)

SD 10.58%

SD 0%

0/50

(6%)

(0%)

*: Denominator is number of anir	mals with tissues examined microscopically

Total

Total

Total

0/50

1/150 (0.67%)

3/50

4/150 (2.67%)

0/50

0/150 (0%)

(0%)

(6%)

(0%)

0/50

1/50

0/50

Mean 0.67%

Mean 2.67%

Mean 0%

(0%)

(2%)

(0%)

......

#Mammary Gland:

**Overall Incidence** 

**Overall Incidence** 

#Mammary Gland: Fibroma

**Overall Incidence** 

#Mammary Gland: Fibroadenoma

Carcinoma or Adenoma

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 341

			Male				Female					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma												
		3/50 (6%)	1/50 (2%)	0/50 (0%)		16/50 (32%)	15/50 (30%)	25/50 (50%)				
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	Total	56/150 (37.33%)	Mean 37.33%	SD 11.02%				
Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, or	Adenoma										
		3/50 (6%)	1/50 (2%)	1/50 (2%)		17/50 (34%)	17/50 (34%)	26/50 (52%)				
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 2.31%	Total	60/150 (40%)	Mean 40%	SD 10.39%				
Mesentery: Fibrous Histiocytoma												
		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%				
Mesentery: Hemangiosarcoma		0/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (004)	0(50 (00))	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
	Total	0/150 (0%)	Mean 0%	3D 0%	Total	0/150 (0%)	wean 0%					
Mesentery: Lipoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	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: Schwannoma Malignant												
		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%				

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

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

Species: RATS

Strain: F 344/N

# **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	
Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Nose: Chondroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Nose: Squamous Cell Carcino	oma	0/50 (00%)	0/50 (00)	0/50 (0%)		0/40 (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	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phar							
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%
Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phar	ynx, Tooth, Gingiva):						
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%
#Oral Cavity (Oral Mucos	a, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma 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%

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: SKIN

Length of Study: CHRONIC

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Vehicle: ETHANOL
Venicie: ETHANOL

			Male			Female					
#Oral Mucosa: Squamous Cell Carcino	oma										
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 Mucosa: Squamous Cell Papillor	ma	0/50 (00/)	0/50 (00/)	0/50 (00/)		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%			
Ovary: Cystadenoma					•••••						
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Ovary: Granulosa Cell Tumor E	3enign					0/50 (0%)	0/50 (0%)	1/50 (2%)			
verall Incidence					Total	1/150 (0.67%)	Mean 0.67%	1/50 (2%) SD 1.15%			
Ovary: Granulosa Cell Tumor N	Malignant										
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%			
Ovary: Granulosa Cell Tumor:	Benign, Maligna	ant, NOS									
Overall Incidence					Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%			

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

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

**Toxicology Data Management System** 

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Report Date: 03/20/2010

Contract/Lab: All Laboratories

0/50

0/150 (0%)

(0%)

0/50

Mean 0%

(0%)

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Male **Female** \*Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% ..... \*Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% ..... \*Ovary: **Tubulostromal Adenoma** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% ..... \*Pancreas: Adenoma 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%) \*Pancreas: 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% \*Pancreas: Carcinoma or Adenoma

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

**Overall Incidence** 

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 345

			Male				Female					
*Pancreas: Mixed Tumor Benign												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Pancreas: Mixed 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%				
Parathyroid Gland: Adenoma												
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/43 (0%) 0/138 (0%)	0/46 (0%) Mean 0%	0/49 (0%) SD 0%				
Pituitary Gland: Pars Distal												
Overall Incidence	Total	35/49 (71%) 100/149 (67.11%)	32/50 (64%) Mean 67.14%	33/50 (66%) SD 3.84%	Total	22/50 (44%) 82/150 (54.67%)	35/50 (70%) Mean 54.67%	25/50 (50%) SD 13.61%				
Pituitary Gland: Pars Distal Carcinoma												
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Pituitary Gland: Pars Dista Carcinoma or Adenoma												
Overall Incidence	Total	35/49 (71%) 100/149 (67.11%)	32/50 (64%) Mean 67.14%	33/50 (66%) SD 3.84%	Total	22/50 (44%) 82/150 (54.67%)	35/50 (70%) Mean 54.67%	25/50 (50%) SD 13.61%				

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 03/20/2010

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspec	ified Site:						
Overall Incidence	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	10tai	0/149 (0/6)				0/130 (0 /6)	iviean 070	
*Pituitary Gland: Pars Interm Adenoma	nedia:							
		0/49 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:	0/40 (00/)	0/50 (00/)	4/50 (00/)		4/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Pituitary Gland: Pars Nervo Craniopharyngioma		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%
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report

Report Date: 03/20/2010

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			Male			Female           0/50 (0%) 0/50 (0%) 0/50 (0%)           0/150 (0%) Mean 0% SD 0%           0/50 (0%) 0/50 (0%) 0/50 (0%)           0/150 (0%) Mean 0% SD 0%           0/50 (0%) 0/50 (0%) 0/50 (0%)           0/150 (0%) Mean 0% SD 0%           0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)           0/150 (0%) Mean 0% SD 0%			Female			
*Salivary Glands: Carcinoma												
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	` ,	(/	` '				
Salivary Glands: Carcinoma or Adenoma	••••••											
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	` '	` ,	` '				
Salivary Glands: Sarcoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` '	` ,				
Salivary Glands: Schwannoma Malignant												
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	` '	` '	` '				
Seminal Vesicle: Adenoma			•••••					•••••				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%								
Skeletal Muscle: Fibrous Histiocytoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 348

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
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%
#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%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skeletal Muscle: Rhabdomyosarcoma or l	Rhabdomyoma	a 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 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: Basal Cell Adenoma or E	Basosquamous		(45.1)	(00)		(00)		(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%
#Skin: Basal Cell Adenoma, Ba	sosquamous T	<u> </u>	•	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/
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%

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC

# **Toxicology Data Management System**

**Page:** 349

Report Date: 03/20/2010

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

			Male		Female			
#Skin: Basal Cell Carcinoma								
Overell lesidenes	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	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%
#Skin: Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant or N	OS)					
		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%
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		oma, Basosquamous Tur 1/50 (2%)	nor (benign, maligna 0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinom	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 2/50 (4%) 7/150 (4.67%)	3), Basal Cell Adenon		Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
#Skin: Basal or Sq. Cell Carci	noma, Carcinom Sq Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 2/50 (4%) 7/150 (4.67%)	3), Basal Cell Adenon ithelioma 2/50 (4%) Mean 4.67%	na, 3/50 (6%) SD 1.15%		0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin: Fibroma	noma, Carcinom Sq Papilloma, Ke Total	na, Basosq. Tumor (M or Estatoacanthoma, Trichoep 2/50 (4%) 7/150 (4.67%)	3), Basal Cell Adenon ithelioma 2/50 (4%) Mean 4.67% 7/50 (14%)	na, 3/50 (6%) SD 1.15% 1/50 (2%)	Total	0/50 (0%) 2/150 (1.33%) 2/50 (4%)	1/50 (2%) Mean 1.33% 0/50 (0%)	1/50 (2%) SD 1.15% 1/50 (2%)
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin: Fibroma	noma, Carcinom Sq Papilloma, Ke	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep 2/50 (4%) 7/150 (4.67%)	3), Basal Cell Adenon ithelioma 2/50 (4%) Mean 4.67%	na, 3/50 (6%) SD 1.15%		0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence  #Skin: Fibroma Overall Incidence	noma, Carcinom Sq Papilloma, Ke Total Total	na, Basosq. Tumor (M or Estatoacanthoma, Trichoep 2/50 (4%) 7/150 (4.67%)	3), Basal Cell Adenon ithelioma 2/50 (4%) Mean 4.67% 7/50 (14%) Mean 6%	na, 3/50 (6%) SD 1.15% 1/50 (2%)	Total	0/50 (0%) 2/150 (1.33%) 2/50 (4%)	1/50 (2%) Mean 1.33% 0/50 (0%)	1/50 (2%) SD 1.15% 1/50 (2%)

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 350 Report Date: 03/20/2010

			Male				Female	
#Skin: Fibrosarcoma								
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		` ,				` ,		
#Skin: Fibrosarcoma Sarcoma	Myvosarcom	a, or Fibrous Histiocytom	_					
ribiosarcoma, Sarcoma,	Wyxosarcom	2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Fibrous Histiocytoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
≇Skin: Hemangioma								
S	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: 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%
#Skin: Keratoacanthoma		0/50 /00/					0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illelucite	ı Olai	7/130 (2.0//0)	IVIGAII 2.01 /0	OD 2.01/0	ı olal	0/100 (0/0)	IVICALI U70	JD 070

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 351

			Male				Female	
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor								
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: Neural Crest Tumor, Ma	lignant							
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: Neurofibroma or Schwa	nnoma benign			(00)		(00)	(20)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or S	Schwannoma (n	nalignant or NOS)						
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 352 Report Date: 03/20/2010

			Male				Female	
#Skin: Neurofibrosarcoma, Neurofi	broma, or	` •	•	0/50 (00/)		0/50 (00)	0/50 (00/)	4/50 /60/
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Skin: Sarcoma		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	0/50 (0%)	Mean 0%	SD 0%
≄Skin: Schwannoma Benign		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant		4/50 (00)	4/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00()	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	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
∜Skin: Squamous Cell Carcinoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (29/)	0/50 (09/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo		or NOS),				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)

SD 1.15%

Total

2/150 (1.33%)

Mean 1.33%

SD 1.15%

Total

1/150 (0.67%)

Mean 0.67%

**Overall Incidence** 

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

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

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

ed Control Animal Groups Report Date: 03/20/2010 SKIN

Page: 353

			Male				Female	
#Skin: Squamous Cell Papillom	a							
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%
#Skin: Squamous Cell Papillom	a or Papilloma	a	•••••					
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%
#Skin: Squamous Cell Papillom Overall Incidence	a, Papilloma, S	Squamous Cell Carcinom 1/50 (2%) 6/150 (4%)	a or Keratoacanthom 2/50 (4%) Mean 4%	<b>a</b> 3/50 (6%) SD 2%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
skin: Squamous Cell Papillom	a, Papilloma, o	or Keratoacanthoma	2/50 (4%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin:								
Trichoepithelioma								
Trichoepithelioma	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%
	Total	` '	, ,	,	Total	` '	` ,	` ,

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 354

			Male		Female           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)           0/150 (0%)         0/50 (0%)         0/50 (0%)			
Skin: Sebaceous Gland: Carcinoma or Adenoma						O/50 (0%) O/50 (0%) O/50 (0%)  Total O/150 (0%) Mean 0% SD 0%  O/50 (0%) O/50 (0%) O/50 (0%)  Total O/150 (0%) Mean 0% SD 0%  O/50 (0%) O/50 (0%) O/50 (0%)  Total O/150 (0%) Mean 0% SD 0%  Total O/150 (0%) O/50 (0%) O/50 (0%)  Total O/150 (0%) O/50 (0%) O/50 (0%)  O/50 (0%) O/50 (0%) O/50 (0%)  O/50 (0%) O/50 (0%) O/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	0/50 (0%)	` ,
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		` '	` ,	` ,
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (2.67%)	Mean 0.67%	SD 1.15%	Total	` '	` ,	` '
		, ,						
Spinal Cord: Glioma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (09/)	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	` '	` '	` '
		()						
Spleen: Fibrosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		` '	` ,	` ,
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: 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%

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

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

Species: RATS

Strain: F 344/N

# **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		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%  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%			
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	( ,
	10tai		iviean 0%	טט ט% 	I Olai		IVIEAN 0%	
Spleen: Leiomyosarcoma		0(50 (00))	0/50 (00/)	0/50 (00/)		0/50 (001)	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	` '	` '	` '
*Spleen: Sarcoma								
		1/50 (2%)	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%
#Stomach, Forestomach: Leiomyosarcoma			- /					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	` '
Stomach, Forestomach: 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%
#Stomach, Forestomach: Squamous Cell Carcinoma o								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for S

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 356

			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma								
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%
#Stomach, Glandular: 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%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Lipoma								
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, Glandular: 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%
Testes: Adenoma		20/50 /00%	07/50 /740/	27/50 (740/)				
Overall Incidence	Total	30/50 (60%) 104/150 (69.33%)	37/50 (74%) Mean 69.33%	37/50 (74%) SD 8.08%				

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

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

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/20/2010

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male		Female         0/49 (0%) 0/45 (0%) 1/50 (2%)         Total       1/144 (0.69%)       Mean 0.67%       SD 1.15%         O/49 (0%) 0/45 (0%) 0/50 (0%)         Total       0/144 (0%) 0/45 (0%) 0/50 (0%)         Total       0/144 (0%) 0/45 (0%) 0/50 (0%)         Total       0/144 (0%) 0/45 (0%) 1/50 (2%)         Total       1/144 (0.69%) 0/45 (0%) 1/50 (2%)         Mean 0.67% SD 1.15%			
*Testes: Hemangioma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
Thymus: Thymoma Benign								
		0/49 (0%)	0/49 (0%)	0/47 (0%)		` '	` '	` '
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.67%	SD 1.15%
Thymus: Thymoma Malignant								
		0/49 (0%)	0/49 (0%)	0/47 (0%)		` '	0/45 (0%)	` ,
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%		` '		
Thymus: Thymoma NOS								
Overall Incidence	Tatal	0/49 (0%)	0/49 (0%) Mean 0%	0/47 (0%)	Tatal	` '	` '	` '
	Total	0/145 (0%)		SD 0%		0/144 (0%)	wiean 0%	טט עא U%
Thymus: Thymoma: Benign, Malignant	t, NOS							
		0/49 (0%)	0/49 (0%)	0/47 (0%)		0/49 (0%)	0/45 (0%)	1/50 (2%)
Overall Incidence	Total	0/145 (0%)	Mean 0%	SD 0%		, ,	Mean 0.67%	SD 1.15%
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	10/50 (20%)	9/50 (18%)		6/50 (12%)	8/50 (16%)	7/50 (14%)
Overall Incidence	Total	29/150 (19.33%)	Mean 19.33%	SD 1.15%	Total	21/150 (14%)	Mean 14%	SD 2%

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 358 Report Date: 03/20/2010

			Male		Female				
Thyroid Gland: C-Cell: Carcinoma									
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
		3/130 (2/6)				0/130 (0 /8)			
Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		11/50 (22%)	12/50 (24%)	9/50 (18%)		6/50 (12%)	8/50 (16%)	7/50 (14%)	
verall Incidence	Total	32/150 (21.33%)	Mean 21.33%	SD 3.06%	Total	21/150 (14%)	Mean 14%	SD 2%	
Thyroid Gland: Follicular Cell: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
Гhyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
 Гhyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 2%	
Tissue NOS: Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

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

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

Species: RATS

Strain: F 344/N

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

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ilioi Allimai Groups

Page: 359

Mean 0.67%

SD 1.15%

Report Date: 03/20/2010

Male **Female #Tissue NOS:** Paraganglioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)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 Carcinoma** 0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(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% #Tongue: Squamous Cell Carcinoma or Papilloma Squamous 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% ...... #Tongue: Squamous Cell Papilloma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Tooth: **Adamantinoma 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% #Tooth: Odontoma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 1/50 (2%)0/50 (0%)

SD 0%

Total

1/150 (0.67%)

Mean 0%

Total

0/150 (0%)

**Overall Incidence** 

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

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

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

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

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

**Page:** 360

	Male					Female				
Urinary Bladder: Carcinoma or Papilloma				,						
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										
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%		
Urinary Bladder: Leiomyosarcoma		0/50 (00)	0/50 /00/	0/50 (0%)		0/50 (001)	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%		
Urinary Bladder: Papilloma										
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%		
Uterus: Adenoma		•••••								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Uterus: Carcinoma										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

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

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

Species: RATS

Strain: F 344/N

#### **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	
Uterus: Deciduoma Benign					
Overall Incidence	Т	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jterus: Hemangioma					
verall Incidence		otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Hemangiosarcoma					
verall Incidence		otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jterus: Leiomyosarcoma					
verall Incidence	Т	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Jterus: Polyp Stromal					
verall Incidence	Т	otal	5/50 (10%) 14/150 (9.33%)	2/50 (4%) Mean 9.33%	7/50 (14%) SD 5.03%
Jterus: Sarcoma					
verall Incidence	To	otal	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

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

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

Species: RATS

Strain: F 344/N

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

Tumor Incidence for Selected Control Animal Groups

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Report Date: 03/20/2010

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female			
#Uterus: Sarcoma Stromal						4/50 (001)	4/50 (00)	0/50 (00/)	
Overall Incidence					Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	
#Uterus: Sarcoma Stromal or Poly									
Overall Incidence					Total	6/50 (12%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	7/50 (14%) SD 4.16%	
#Uterus: Schwannoma Malignant									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Vagina: Polyp									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Adenoma						(20)			
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%	

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

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

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Length of Study: CHRONIC **Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 03/20/2010

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	Male					Female				
#Zymbal's Gland: Carcinoma										
		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%		
#Zymbal's Gland: Carcinoma or Adenoma										
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		

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

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