Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

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

Page: 242

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059500305	04/05/04	729	50(1)	27(683)	508.5	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/15/04	727	50(1)	23(651)	510.1	Pyrogallol
					Female		
Southern Research Institute	059500305	04/05/04	732	50(1)	30(685)	356.2	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903203	09/16/04	728	50(1)	29(670)	351.0	Pyrogallol

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 Page: 243 Report Date: 06/05/2013

			Male				Female			
#All Organs: Benign Tumors										
Overall Incidence	Total	46/50 (92%) 93/100 (93%)	47/50 (94%) Mean 93%	SD 1.41%	Total	47/50 (94%) 90/100 (90%)	43/50 (86%) Mean 90%	SD 5.66%		
#All Organs: Malignant Tumors										
Overall Incidence	Total	33/50 (66%) 55/100 (55%)	22/50 (44%) Mean 55%	SD 15.56%	Total	22/50 (44%) 34/100 (34%)	12/50 (24%) Mean 34%	SD 14.14%		
#All Organs: Malignant and Benign T	umors	40/50 (000)				40/50 (000/)	45/50 (000()			
Overall Incidence	Total	48/50 (96%) 97/100 (97%)	49/50 (98%) Mean 97%	SD 1.41%	Total	49/50 (98%) 94/100 (94%)	45/50 (90%) Mean 94%	SD 5.66%		
#All Organs: Hemangioma		0/50 (00/)				0/50 (00/)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Hemangiosarcoma or H	emangioma									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

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

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

Strain: 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 Page: 244

			Male				Female	Female		
#All Organs: Histiocytic Sarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Leukemia: Lymphocytic,	, Monocytic, Ma	ononuclear, or Undifferen	itiated							
	•	26/50 (52%)	11/50 (22%)			18/50 (36%)	8/50 (16%)			
Overall Incidence	Total	37/100 (37%)	Mean 37%	SD 21.21%	Total	26/100 (26%)	Mean 26%	SD 14.14%		
Overall Incidence	Total	phocytic, Mixed, NOS, or 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, N		3								
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignan	t									
Mesothelioma: Malignan		4/50 (8%)	2/50 (4%)			0/50 (0%)	0/50 (0%)			
	<b>t</b> Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
Mesothelioma: Malignan		` '	` '	SD 2.83%	Total	( ,	` ,	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: 245

			Male				Female			
#All Organs: Osteosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma or Osteoma		4/50 (00)	0/50 (00)			0/50 (00)	4/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%		
			ivicaii i /o							
*Adrenal Cortex: Adenoma										
	<b>.</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/	<b>T</b>	4/50 (8%)	1/50 (2%)	05 4040/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 4.24%		
*Adrenal Cortex: Carcinoma										
	<b>.</b>	1/50 (2%)	0/50 (0%)	05 4 440/	<b>T</b>	0/50 (0%)	0/50 (0%)	05.00/		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Benign										
		11/49 (22%)	4/50 (8%)			1/49 (2%)	1/50 (2%)			
Overall Incidence	Total	15/99 (15.15%)	Mean 15.22%	SD 10.22%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%		
*Adrenal Medulla: Pheochromocytoma Comple	ех									
	<b>.</b>	0/49 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/49 (0%)	0/50 (0%)	05.00/		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (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

Page: 246

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female  0/49 (0%) 0/50 (0%)  Total 0/99 (0%) Mean 0% SD 0%  1/49 (2%) 1/50 (2%)  Total 2/99 (2.02%) Mean 2.02% SD 0.03%				
*Adrenal Medulla: Pheochromocytoma M	alignant									
		0/49 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	•								
O	T-1-1	11/49 (22%)	5/50 (10%)	00.000	T-1-1	( ,	` ,	00.000/		
Overall Incidence	Total	16/99 (16.16%)	Mean 16.22%	SD 8.8%		` '		SD 0.03%		
#Blood Vessel: Leiomyosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Bone: Chordoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Bone: Osteoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Bone: Osteosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (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: 247

			Male				Female	
#Bone: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Brain: Glioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign		0/50 (00/)	0/50 (00/)			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,			10tai	0/100 (0%)	Weatt 076	
*Brain: Glioma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glioma								
	•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Osteosarcoma		0/50 (00/)	0/50 (000)			0/50 (00/)	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)			Total	` '		

<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: 248 Report Date: 06/05/2013

			Male				Female	Female		
*Clitoral/Preputial Gland: Adenoma										
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	6/50 (12%) 9/100 (9%)	3/50 (6%) Mean 9%	SD 4.24%		
Clitoral/Preputial Gland: Carcinoma										
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%		
Clitoral/Preputial Gland: Carcinoma or Adenoma		4/50 (00/)	0/50 (00)			0/50 (400/)	4/50 (00)			
Overall Incidence	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%	Total	9/50 (18%) 13/100 (13%)	4/50 (8%) Mean 13%	SD 7.07%		
Clitoral/Preputial Gland: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
Ear: Neural Crest Tumor										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
∉Eye: Melanoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

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

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

Contract/Lab: All Laboratories

**Species**: 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: 249

			Male				Female	
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Harderian Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
*Heart: Schwannoma Benign							•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (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** 

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 250

			Male				Female	
#Intestine Large: Colon/Rect Adenoma	um:							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rect Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma	:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma		•••••						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (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** 

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 251

			Male	Female				
#Intestine Small: Jejunum: Leiomyoma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	05.00/	<b>-</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	cified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspec Carcinoma	cified:	0/50 (0%)	0/50 (00/)			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspec								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Page: 252

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:									
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unsp Schwannoma Malignant	ecified:									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
Islets, Pancreatic:										
		5/49 (10%)	3/50 (6%)			3/49 (6%)	2/50 (4%)			
Overall Incidence	Total	8/99 (8.08%)	Mean 8.1%	SD 2.97%	Total	5/99 (5.05%)	Mean 5.06%	SD 1.5%		
Islets, Pancreatic: Carcinoma										
Overall Incidence	Total	3/49 (6%) 3/99 (3.03%)	0/50 (0%) Mean 3.06%	SD 4.33%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%		
fIslets, Pancreatic: Carcinoma or Adenoma		0/40 /469/								
O	Tatal	8/49 (16%)	3/50 (6%)	SD 7.3%	Tatal	3/49 (6%)	2/50 (4%)	CD 4.50/		
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	JU 1.3%	Total	5/99 (5.05%)	Mean 5.06%	SD 1.5%		
Kidney: Pelvis and Transi Papilloma	tional Epitheli									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: 253

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Kidney: Renal Tubule: Mesenchymal Tumor Malig	nant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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: 254

			Male				Female	
*Liver: Hepatocellular Adenoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
Liver: Hepatocellular Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatobla	u <b>stoma</b> 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma			1/50 (2%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Liver: Hepatocellular Carcinoma		lar Adenoma, or Hepatobl				0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Liver: Ito Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)	00.00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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

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

Contract/Lab: All Laboratories

Species: 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: 255

			Male				Female				
*Lung: Alveolar/Bronchiolar Adenoma											
		2/50 (4%)	1/50 (2%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
*Lung: Alveolar/Bronchiolar C											
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Lung: Alveolar/Bronchiolar C Overall Incidence	Carcinoma or Alve	eolar/Bronchiolar Adenon 2/50 (4%) 6/100 (6%)	na 4/50 (8%) Mean 6%	SD 2.83%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%			
Fibrosarcoma	Tatal	0/50 (0%)	0/50 (0%)	OD 00/	Takal	0/50 (0%)	0/50 (0%)	CD 00/			
	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
_	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
Fibrosarcoma  Overall Incidence  #Mammary Gland: Adenolipoma	Total Total		` '	SD 0% SD 0%	Total Total	` '	` ,	SD 0% SD 0%			
Fibrosarcoma  Overall Incidence  #Mammary Gland:		0/100 (0%)	Mean 0%			0/100 (0%) 0/50 (0%)	Mean 0% / O/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

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 256

			Male			Female				
#Mammary Gland: Carcinoma										
		0/50 (0%)	1/50 (2%)			2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
Mammary Gland: Carcinoma or Adenoma										
		0/50 (0%)	1/50 (2%)			3/50 (6%)	3/50 (6%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 0%		
#Mammary Gland: Fibroadenoma										
		2/50 (4%)	0/50 (0%)			19/50 (38%)	24/50 (48%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	43/100 (43%)	Mean 43%	SD 7.07%		
Mammary Gland: Fibroma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
Mammary Gland: Fibroma, Fibroadenoma or Ad	denoma									
		2/50 (4%)	0/50 (0%)			19/50 (38%)	25/50 (50%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	44/100 (44%)	Mean 44%	SD 8.49%		
#Mammary Gland: Fibroma, Fibroadenoma, Card	cinoma, or	· Adenoma								
		2/50 (4%)	1/50 (2%)			21/50 (42%)	26/50 (52%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	47/100 (47%)	Mean 47%	SD 7.07%		

<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: 257

Report Date: 06/05/2013
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			Male				Female	
#Mesentery: Fibrous Histiocytoma								
Occupation of James	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/	Taral	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Schwannoma Malignan	t							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Nose: Adenoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	a, Tongue, Phary	ynx, Tooth, Gingiva): 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary	ynx, Tooth, Gingiva):						
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary		1/50 (2%)			0/50 (0%)	0/50 (0%)	
		1,00 (= 70)	1,00 (= /0)			0,00 (0,0)	3, 33 (3,3)	

<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: 258

			Male				Female		
#Oral Mucosa: Squamous Cell Carcinon	na	(Fa)	(05.1)			(00)	(0)		
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Papillom					••••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Ovary: Cystadenoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Ovary: Fibrosarcoma						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor Be	enign						•••••	•••••	
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	
*Ovary: Granulosa Cell Tumor Ma	alignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (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** 

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 259

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Maligna	nt, NOS				4/50 (00()	4/50 (00()	
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumo						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignan	t					0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Mali						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	na							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (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** Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Vehicle: ETHANOL Length of Study: CHRONIC

Page: 260

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%
*Pituitary Gland: Pars Dist Adenoma								
Overall Incidence	Total	33/50 (66%) 66/100 (66%)	33/50 (66%) Mean 66%	SD 0%	Total	31/50 (62%) 56/100 (56%)	25/50 (50%) Mean 56%	SD 8.49%
*Pituitary Gland: Pars Dist						•••••		
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
*Pituitary Gland: Pars Dist Carcinoma or Adenoma	alis or Unspec							
Overall Incidence	Total	35/50 (70%) 68/100 (68%)	33/50 (66%) Mean 68%	SD 2.83%	Total	33/50 (66%) 58/100 (58%)	25/50 (50%) Mean 58%	SD 11.31%

<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: 261 Report Date: 06/05/2013

			Male		Female			
*Pituitary Gland: Pars Dist Ganglioneuroma	alis or Unspeci	fied Site:						
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Inte Adenoma	rmedia:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intel Carcinoma or Adenoma		2/22 (221)	(22)			2/-2 (221)	(704)	
	<b>.</b>	0/50 (0%)	1/50 (2%)	00 4 440/	<b>-</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Ner Craniopharyngioma	vosa:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (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

Page: 262

			Male				Female	
*Salivary Glands: Carcinoma								
Occupation of decree	Total	0/50 (0%)	1/50 (2%)	00 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Occupation of demand	Taral	0/50 (0%)	1/50 (2%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	1/50 (2%)	00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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

Page: 263

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Skeletal Muscle: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Overall Incidence	Basosquamous Total	Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)		5D 0%	ı otal	0/100 (0%)		3D 0%
#Skin: Basal Cell Adenoma. Ba	asosquamous T	umor Benign, or Trichoep	ithelioma					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:								
Basal Cell Carcinoma o	r Basosquamou	Is Tumor (malignant or NC				0/50 (00/)	4/50 (20/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Overall incluence	IUlai	1/100 (176)	IVICALI 170	SD 1.4170	TUlai	1/100 (170)	IVIEALI 170	3D 1.41%

<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

Page: 264

Report Date: 06/05/2013

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 1/50 (2%)0/50 0/50 (0%)1/50 (2%)Overall Incidence Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (0%) 7/50 (14%)3/50 (6%)0/50 1/50 (2%)Mean 1% **Overall Incidence** Total 10/100 (10%) Mean 10% SD 5.66% Total 1/100 (1%) SD 1.41% #Skin: **Fibroma** 5/50 (10%)1/50 (2%)3/50 (6%)1/50 (2%)**Overall Incidence** Total 6/100 (6%) Mean 6% SD 5.66% Total 4/100 (4%) Mean 4% SD 2.83% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 7/50 (14%) 1/50 3/50 (6%)1/50 (2%)**Overall Incidence** Total 8/100 (8%) Mean 8% SD 8.49% Total 4/100 (4%) Mean 4% SD 2.83% #Skin: **Fibrosarcoma** 2/50 (4%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/100 (0%) Mean 0% SD 0% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma

SD 2.83%

0/50

0/100 (0%)

Total

(0%)

0/50

(0%)Mean 0%

SD 0%

Total

(4%)

2/100 (2%)

0/50

Mean 2%

(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**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 265

			Male			Female			
#Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Keratoacanthoma									
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Lipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Neural Crest Tumor									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (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: 06/05/2013

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

		Male				Female									
#Skin: Neurofibroma or Schwan	#Skin: Neurofibroma or Schwannoma benign  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%)  0/50 (0%)  0/50 (0%)  0/50 (0%)														
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%							
#Skin: Neurofibrosarcoma or Sc	hwannoma (m	- ,	- /												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%							
#Skin: Neurofibrosarcoma, Neur	ofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)			0/50 (0%)	1/50 (2%)								
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%							
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)								
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%							
#Skin: Schwannoma Benign															
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%							
#Skin: Schwannoma Malignant		0/50 (00/)	0/50 /00/			0/50 (09/)	1/50 (20/)								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%							

<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: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female						
#Skin: Squamous Cell Carcinoma  1/50 (2%) 0/50 (0%)  0/50 (0%) 0/50 (0%)													
Overall Incidence	Total	1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell (	Carcinoma, Basosquamoı	us Tumor (malignant	or NOS),									
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%					
#Skin: Squamous Cell Papilloma		4/50 (20/)	4/50 (20/)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Skin: Squamous Cell Papilloma	or Papilloma		4/50 (20/)			0/50 (0%)	0/50 (00/)						
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Skin: Squamous Cell Papilloma,						0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Skin: Squamous Cell Papilloma,			3/50 (6%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 2.83%	Total	0/100 (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

Page: 268

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
#Skin: Trichoepithelioma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Adenoma		0/50 (00/)	0/50 (00)			0(50 (004)	2/52 (224)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Stomach, Glandular: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

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

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

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 269

Report Date: 06/05/2013

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

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		34/50 (68%)	37/50 (74%)					
Overall Incidence	Total	71/100 (71%)	Mean 71%	SD 4.24%				
*Testes: Hemangioma								
		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Thymus: Thymoma Benign		0/50 (0%)	0/47 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Thymus: Thymoma Malignant								
		0/50 (0%)	0/47 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS								
Overall Incidence	Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/97 (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: 270

			Male				Female						
*Thymus: Thymoma: Benign, Malignant, NOS													
		0/50 (0%)	0/47 (0%)			1/50 (2%)	1/50 (2%)						
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%					
*Thyroid Gland: C-Cell: Adenoma													
		6/46 (13%)	9/50 (18%)			7/50 (14%)	7/50 (14%)						
Overall Incidence	Total	15/96 (15.62%)	Mean 15.52%	SD 3.5%	Total	14/100 (14%)	Mean 14%	SD 0%					
*Thyroid Gland: C-Cell: Carcinoma													
		0/46 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)						
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
*Thyroid Gland: C-Cell: Carcinoma or Adenoma													
Overall Incidence	Total	6/46 (13%) 15/96 (15.62%)	9/50 (18%) Mean 15.52%	SD 3.5%	Total	8/50 (16%) 15/100 (15%)	7/50 (14%) Mean 15%	SD 1.41%					
	10tai	15/96 (15.62%)	10.52%	ას ა.ა%	ı Olal	15/100 (15%)	10%	3D 1.41%					
*Thyroid Gland: Follicular Ce Adenoma	ell:												
		0/46 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)						
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%					
*Thyroid Gland: Follicular Ce Carcinoma	ell:												
		2/46 (4%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	2/96 (2.08%)	Mean 2.17%	SD 3.07%	Total	0/100 (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** 

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 271

			Male				Female						
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma													
		2/46 (4%)	0/50 (0%)			1/50 (2%)	1/50 (2%)						
Overall Incidence	Total	2/96 (2.08%)	Mean 2.17%	SD 3.07%	Total	2/100 (2%)	Mean 2%	SD 0%					
#Tongue: Squamous Cell Carcinoma													
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Tongue: Squamous Cell Carcinoma o	or Papillom	a Squamous 0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Tooth: Adamantinoma Malignant		2(72)	2/52 (221)			2(72)	2/22 (22)						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
*Urinary Bladder: Carcinoma													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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** 

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

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Report Date: 06/05/2013

Page: 272

			Male				Female	
Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/30 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (00)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Urinary Bladder: Papilloma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma						2/22 (221)	(00)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Uterus: Leiomyosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (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** 

Page: 273

Report Date: 06/05/2013

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

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male **Female #Uterus: Polyp Stromal** 10/50 (20%)7/50 (14%) **Overall Incidence** Total 17/100 (17%) Mean 17% SD 4.24% **#Uterus:** Sarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% ..... #Uterus: Sarcoma Stromal or Polyp Stromal 10/50 (20%)7/50 (14%) **Overall Incidence** Total 17/100 (17%) Mean 17% SD 4.24% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (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: 274

			Male			Female			
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Schwannoma Malignant									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma			4/50 (00/)			0/50 (0%)	0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma									
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

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

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