

Version: Jun2013
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: 242
Report Date: 06/05/2013

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

Version: Jun2013
 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: 243
 Report Date: 06/05/2013

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

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

Version: Jun2013
 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: 244
 Report Date: 06/05/2013

		Male				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, Mononuclear, or Undifferentiated									
		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%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		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:									
Mesothelioma: Benign, Malignant, NOS									
		4/50 (8%)	2/50 (4%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Malignant									
		4/50 (8%)	2/50 (4%)		0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
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%	
.....									

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 245
 Report Date: 06/05/2013

		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									
		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%
.....									
*Adrenal Cortex:									
Adenoma									
		0/50	(0%)	0/50	(0%)	4/50	(8%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	5/100	(5%)	Mean 5%
									SD 4.24%
.....									
*Adrenal Cortex:									
Carcinoma									
		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%
.....									
*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 Complex									
		0/49	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
Overall Incidence	Total	0/99	(0%)	Mean 0%	SD 0%	Total	0/99	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 246
 Report Date: 06/05/2013

		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		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: Benign, Complex, Malignant, NOS									
		11/49 (22%)	5/50 (10%)		1/49 (2%)	1/50 (2%)			
Overall Incidence	Total	16/99 (16.16%)	Mean 16.22%	SD 8.8%	Total	2/99 (2.02%)	Mean 2.02%	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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 247
 Report Date: 06/05/2013

		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	(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 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%	
.....											
*Brain:											
Oligodendroglioma, Glioma, or Astrocytoma											
		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	(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%	

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

Version: Jun2013
 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					
*Clitoral/Preputial Gland:											
Adenoma											
		1/50	(2%)	0/50	(0%)			6/50	(12%)	3/50	(6%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	Total	9/100	(9%)	Mean 9%	SD 4.24%	
.....											
*Clitoral/Preputial Gland:											
Carcinoma											
		3/50	(6%)	0/50	(0%)			3/50	(6%)	1/50	(2%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 4.24%	Total	4/100	(4%)	Mean 4%	SD 2.83%	
.....											
*Clitoral/Preputial Gland:											
Carcinoma or Adenoma											
		4/50	(8%)	0/50	(0%)			9/50	(18%)	4/50	(8%)
Overall Incidence	Total	4/100	(4%)	Mean 4%	SD 5.66%	Total	13/100	(13%)	Mean 13%	SD 7.07%	
.....											
*Clitoral/Preputial Gland:											
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%	
.....											
#Ear:											
Neural Crest Tumor											
		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%	
.....											
#Eye:											
Melanoma Benign											
		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%	

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

Version: Jun2013
 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
 Report Date: 06/05/2013

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

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

Version: Jun2013
 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: 250
 Report Date: 06/05/2013

		Male				Female					
#Intestine Large: Colon/Rectum:											
Adenoma											
		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%	
.....											
#Intestine Large: Colon/Rectum:											
Carcinoma or Adenoma											
		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%	
.....											
#Intestine Small: Duodenum:											
Leiomyoma											
		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: Duodenum:											
Schwannoma 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%	
.....											
#Intestine Small: Ileum:											
Adenoma											
		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: Jejunum:											
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%	

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

Version: Jun2013
 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: 251
 Report Date: 06/05/2013

		Male				Female			
#Intestine Small: Jejunum:									
Leiomyoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	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%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Intestine Small: Site Unspecified:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
#Intestine Small: Site Unspecified:									
Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Intestine Small: Site Unspecified:									
Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
#Intestine Small: Site Unspecified:									
Leiomyoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 252
 Report Date: 06/05/2013

		Male			Female		
#Intestine Small: Site Unspecified:							
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 Unspecified:							
Schwannoma 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%
*Islets, Pancreatic:							
Adenoma							
		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							
		3/49 (6%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	3/99 (3.03%)	Mean 3.06%	SD 4.33%	Total	0/99 (0%)	Mean 0% SD 0%
*Islets, Pancreatic:							
Carcinoma or Adenoma							
		8/49 (16%)	3/50 (6%)		3/49 (6%)	2/50 (4%)	
Overall Incidence	Total	11/99 (11.11%)	Mean 11.16%	SD 7.3%	Total	5/99 (5.05%)	Mean 5.06% SD 1.5%
*Kidney: Pelvis and Transitional Epithelium:							
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%

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

Version: Jun2013
 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: 253
 Report Date: 06/05/2013

		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%	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%	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%	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%	1/100	(1%)	Mean 1%	SD 1.41%
.....									
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	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%	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 254
 Report Date: 06/05/2013

		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 Hepatoblastoma									
		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 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, Hepatocellular Adenoma, or Hepatoblastoma									
		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:									
Ito Cell Tumor Benign									
		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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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
 Report Date: 06/05/2013

		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%
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		0/50	(0%)	3/50	(6%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/100	(3%)	Mean 3%	SD 4.24%	Total	0/100	(0%)	Mean 0%
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		2/50	(4%)	4/50	(8%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	6/100	(6%)	Mean 6%	SD 2.83%	Total	1/100	(1%)	Mean 1%
.....									
*Lung:									
Fibrosarcoma									
		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%
.....									
#Mammary Gland:									
Adenolipoma									
		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%
.....									
#Mammary Gland:									
Adenoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	Total	3/100	(3%)	Mean 3%

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

Version: Jun2013
 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: 256
 Report Date: 06/05/2013

		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	(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%	
.....											
#Mammary Gland:											
Fibroma, Fibroadenoma or Adenoma											
		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, Carcinoma, 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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 257
 Report Date: 06/05/2013

		Male				Female					
#Mesentery:											
Fibrous Histiocytoma											
		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%	
.....											
#Mesentery:											
Schwannoma Malignant											
		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	0/98	(0%)	Mean 0%	SD 0%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Papilloma Squamous or 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%	
.....											
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma											
		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 Mucosa, Tongue, Pharynx, Tooth, Gingiva):											
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma											
		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%	

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

Version: Jun2013
 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: 258
 Report Date: 06/05/2013

	Male					Female				
#Oral Mucosa:										
Squamous Cell Carcinoma										
		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%
.....										
#Oral Mucosa:										
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%
.....										
*Ovary:										
Cystadenoma										
							0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Ovary:										
Fibrosarcoma										
							0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/100	(0%)	Mean 0%	SD 0%
.....										
*Ovary:										
Granulosa Cell Tumor Benign										
							1/50	(2%)	1/50	(2%)
Overall Incidence						Total	2/100	(2%)	Mean 2%	SD 0%
.....										
*Ovary:										
Granulosa Cell Tumor Malignant										
							0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/100	(0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 259
 Report Date: 06/05/2013

Male					Female								
*Ovary:													
Granulosa Cell Tumor: Benign, Malignant, NOS													
					1/50	(2%)	1/50	(2%)					
Overall Incidence					Total	2/100	(2%)	Mean	2%	SD 0%			
.....													
*Ovary:													
Granulosa-Theca Tumor Malignant													
					0/50	(0%)	0/50	(0%)					
Overall Incidence					Total	0/100	(0%)	Mean	0%	SD 0%			
.....													
*Ovary:													
Schwannoma Malignant													
					0/50	(0%)	0/50	(0%)					
Overall Incidence					Total	0/100	(0%)	Mean	0%	SD 0%			
.....													
*Ovary:													
Sertoli Cell Tumor Malignant													
					0/50	(0%)	0/50	(0%)					
Overall Incidence					Total	0/100	(0%)	Mean	0%	SD 0%			
.....													
*Ovary:													
Tubulostromal Adenoma													
					0/50	(0%)	0/50	(0%)					
Overall Incidence					Total	0/100	(0%)	Mean	0%	SD 0%			
.....													
*Pancreas:													
Adenoma													
		0/49	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)		
Overall Incidence		Total	0/99	(0%)	Mean	0%	SD 0%	Total	0/99	(0%)	Mean	0%	SD 0%
.....													

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 260
 Report Date: 06/05/2013

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

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 261
 Report Date: 06/05/2013

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Ganglioneuroma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Pituitary Gland: Pars Intermedia:									
Carcinoma or Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	0/100	(0%)	Mean 0%	SD 0%
.....									
*Pituitary Gland: Pars Nervosa:									
Craniopharyngioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	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%				

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 262
 Report Date: 06/05/2013

		Male				Female					
*Salivary Glands:											
 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%	
.....											
*Salivary Glands:											
 Carcinoma or Adenoma											
		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%	
.....											
*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%)			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%	
.....											
#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%	
.....											

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 263
 Report Date: 06/05/2013

		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 Basosquamous Tumor Benign									
		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, Basosquamous Tumor Benign, or Trichoepithelioma									
		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 or Basosquamous Tumor (malignant or NOS)									
		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%

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

Version: Jun2013
 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: 264
 Report Date: 06/05/2013

		Male				Female			
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		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 or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		7/50 (14%)	3/50 (6%)			0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 5.66%	Total	1/100 (1%)	Mean 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 (2%)			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%)			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									
		2/50 (4%)	0/50 (0%)			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%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 265
 Report Date: 06/05/2013

		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									
		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:									
Keratoacanthoma									
		4/50	(8%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	6/100	(6%)	Mean 6%	SD 2.83%	Total	0/100	(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									
		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:									
Neural Crest Tumor									
		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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 266
 Report Date: 06/05/2013

		Male			Female		
#Skin:							
Neurofibroma or Schwannoma benign							
		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 Schwannoma (malignant or NOS)							
		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%
.....							
#Skin:							
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)							
		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%
.....							
#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							
		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 Malignant							
		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%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 267
 Report Date: 06/05/2013

		Male				Female					
#Skin:											
Squamous Cell Carcinoma											
		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%	
.....											
#Skin:											
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma											
		2/50	(4%)	0/50	(0%)			0/50	(0%)	1/50	(2%)
Overall Incidence	Total	2/100	(2%)	Mean 2%	SD 2.83%	Total	1/100	(1%)	Mean 1%	SD 1.41%	
.....											
#Skin:											
Squamous Cell Papilloma											
		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%	
.....											
#Skin:											
Squamous Cell Papilloma or Papilloma											
		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%	
.....											
#Skin:											
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma											
		6/50	(12%)	3/50	(6%)			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, Papilloma, or Keratoacanthoma											
		5/50	(10%)	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%	

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

Version: Jun2013
 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: 268
 Report Date: 06/05/2013

		Male				Female			
#Skin:									
Trichoepithelioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Skin: Sebaceous Gland:									
Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/100	(0%)	Mean 0%	SD 0%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Skin: Sebaceous Gland:									
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%	0/100	(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%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Stomach, Glandular:									
Carcinoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	0/100	(0%)	Mean 0%	SD 0%
.....									
#Stomach, Glandular:									
Carcinoma or Adenoma									
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/100	(1%)	Mean 1%	SD 1.41%	0/100	(0%)	Mean 0%	SD 0%

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

Version: Jun2013
 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: 269
 Report Date: 06/05/2013

		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									
		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%	

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

Version: Jun2013
 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: 270
 Report Date: 06/05/2013

	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								
		6/46 (13%)	9/50 (18%)		8/50 (16%)	7/50 (14%)		
Overall Incidence	Total	15/96 (15.62%)	Mean 15.52%	SD 3.5%	Total	15/100 (15%)	Mean 15%	SD 1.41%
.....								
*Thyroid Gland: Follicular Cell:								
Adenoma								
		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 Cell:								
Carcinoma								
		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%
.....								

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 271
 Report Date: 06/05/2013

		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 or Papilloma 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							
		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%

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

Version: Jun2013
 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: 272
 Report Date: 06/05/2013

		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	0/100	(0%)	Mean 0%	SD 0%	
.....											
*Urinary Bladder:											
 Hemangiosarcoma											
		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:											
 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											
								0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/100	(0%)	Mean 0%	SD 0%	
.....											
#Uterus:											
 Leiomyosarcoma											
								0/50	(0%)	0/50	(0%)
Overall Incidence						Total	0/100	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 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: 273
 Report Date: 06/05/2013

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

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

Version: Jun2013
 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: 274
 Report Date: 06/05/2013

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

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