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

				Stu	dy 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 Battelle Columbus Laboratory	059500305 059903203	04/05/04 09/15/04	729 727	50(1) 50(1)	27(683) 23(651)	508.5 510.1	Methyl trans-styryl ketone Pyrogallol
					Female		
Southern Research Institute Battelle Columbus Laboratory	059500305 059903203	04/05/04 09/16/04	732 728	50(1) 50(1)	30(685) 29(670)	356.2 351.0	Methyl trans-styryl ketone Pyrogallol

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			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		22/50 (660/)	22/50 (449/)			22/50 (449/)	12/50 (249/)	
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 Tumc Overall Incidence	ors 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%
		, ,		SD 1.41%		· · ·		SD 5.00%
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 Hema		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%

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			Male			Female				
#All Organs: Histiocytic 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%		
#All Organs: Leukemia: Lymphocytic, Mo		ononuclear, or Undifferent	tiated							
Overall Incidence	Total	26/50 (52%) 37/100 (37%)	11/50 (22%) Mean 37%	SD 21.21%	Total	18/50 (36%) 26/100 (26%)	8/50 (16%) Mean 26%	SD 14.14%		
#All Organs: Malignant Lymphoma: Histi Overall Incidence		nphocytic, Mixed, NOS, or 0/50 (0%) 0/100 (0%)		I Type SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
All Organs: Mesothelioma: Benign, Mali			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%		
Overall Incidence		· · ·				()				
Overall Incidence #All Organs: Mesothelioma: Malignant		6/100 (6%)								
Overall Incidence #All Organs:		6/100 (6%) 4/50 (8%)	2/50 (4%)			0/50 (0%)	0/50 (0%)			

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			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								
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%
Adrenal Cortex: Adenoma		- / /				(
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	4/50 (8%) 5/100 (5%)	1/50 (2%) 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		44/40 (000%)	4/50 (02/)			4/40 (00/)	4/50 (00/)	
Overall Incidence	Total	11/49 (22%) 15/99 (15.15%)	4/50 (8%) Mean 15.22%	SD 10.22%	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%
Adrenal Medulla: Pheochromocytoma Comple		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%

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			Male			Female				
*Adrenal Medulla: Pheochromocytoma Malign	ant	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: Benig		x, 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	T .(.)	0/50 (0%)	0/50 (0%)	00.0%	Total	0/50 (0%)	0/50 (0%)	05.0%		
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%		

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			Male	Female				
#Bone: Osteosarcoma or Osteoma 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%
*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 Overall Incidence		0/50 (0%)	0/50 (0%)		Tatal	0/50 (0%)	0/50 (0%)	
	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		rtoma 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%

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			Male	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								
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						- / / / / `		
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%

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxicol Tumor Incider	Page: 249 Report Da	t e: 06/05/2013					
			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						2/50 (404)				
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%		

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxico Tumor Incider	Page: 250 Report Da	te: 06/05/2013					
			Male			Female				
#Intestine Large: Colon/Rectu Adenoma	m:									
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/Rectu 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%		

ersion: Jun2013 ontract/Lab: All Laboratories becies: RATS rain: F 344/N ength of Study: CHRONIC			Toxicol Tumor Inciden	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%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma			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 Unspeci Adenoma	fied:									
		0/50 (0%)	0/50 (0%)	05		0/50 (0%)	1/50 (2%)	05 ((10)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
#Intestine Small: Site Unspeci Carcinoma	fied:									
o	-	0/50 (0%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	OD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspeci Carcinoma or Adenoma	fied:									
		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 Unspeci Leiomyoma	fied:									
O	T . ()	0/50 (0%)	0/50 (0%)	00.001	T / 1	0/50 (0%)	0/50 (0%)	CD 00/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

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			Male			Female				
#Intestine Small: Site Unspec Leiomyosarcoma	ified:									
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%		
fIntestine Small: Site Unspec 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%		
Islets, Pancreatic: Adenoma						-/ />				
Overall Incidence	Total	5/49 (10%) 8/99 (8.08%)	3/50 (6%) Mean 8.1%	SD 2.97%	Total	3/49 (6%) 5/99 (5.05%)	2/50 (4%) 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%		
Islets, Pancreatic: Carcinoma or Adenoma		8/49 (16%)				3/49 (6%)	2/50 (49/)			
Overall Incidence	Total	11/99 (11.11%) ´	3/50 (6%) Mean 11.16%	SD 7.3%	Total	5/99 (5.05%)	2/50 (4%) Mean 5.06%	SD 1.5%		
Kidney: Pelvis and Transition Papilloma		um:								
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%		

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			Male			Female			
[•] Kidney: Renal Tubule: 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%	
Kidney: Renal Tubule: 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%	
Kidney: Renal Tubule: 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%	
Kidney: Renal Tubule: Lipoma						0/50 (00/)	4/50 (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%	
Kidney: Renal Tubule: Mesenchymal Tumor Malign									
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%	
Kidney: Renal Tubule: 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%	

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			Male				Female		
*Liver: Hepatocellular Adenoma Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	
	10tai	3/100 (3%)		50 1.41%	TOLAI	2/100 (2%)		50 2.03%	
*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 o			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 o		llular 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, H		lar Adenoma, or Hepatobl 2/50 (4%)				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%	

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Manageme Ince for Selected Contro Route: SKIN Vehicle: ETHANOL	ol Animal Groups		te: 06/05/2013	
			Male				Female	
*Lung: Alveolar/Bronchiolar Aden	oma	0/50 (49/)	4/50 (00/)			4/50 (00/)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Lung: Alveolar/Bronchiolar Carci								
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 Carci Overall Incidence				SD 2.83%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Dverall Incidence Mammary Gland: Adenolipoma	Total			SD 0%	Total		Mean 0%	SD 0%
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: 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%)	2/30 (4%) Mean 3%	SD 1.41%

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			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									
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	19/50 (38%) 44/100 (44%)	25/50 (50%) Mean 44%	SD 8.49%	
#Mammary Gland: Fibroma, Fibroadenoma		Adenoma							
		2/50 (4%)	1/50 (2%)			21/50 (42%)	26/50 (52%)		

			nce for Selected Contro Route: SKIN	ol Animal Groups		e: 06/05/2013	
		Male				Female	
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
••••••							
•	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	/nx, Tooth, Gingiva):						
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%
ngue, Phary	vnx, Tooth, Gingiva): iquamous, or Papilloma					0/50 (0%)	
Total	2/100 (2%)	Mean 2%	SD 0%	Total	()	Mean 0%	SD 0%
	Total Total ngue, Phary jilloma Total Total Total Total Papilloma S	1/50 (2%) Total 1/100 (1%) 0/50 (0%) Total 0/100 (0%) ngue, Pharynx, Tooth, Gingiva): 0/50 (0%) Total 0/100 (0%) ngue, Pharynx, Tooth, Gingiva): 1/50 (2%) Total 2/100 (2%) ngue, Pharynx, Tooth, Gingiva): 1/50 (2%) Total 2/100 (2%) Note, Pharynx, Tooth, Gingiva): Papilloma Squamous, or Papilloma 1/50 (2%)	Male Male 0/50 (0%) 1/50 (2%) Total 1/100 (1%) 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% 1/50 Total 1/100 (1%) Mean 1% 0/50 (0%) Total 1/100 (1%) Mean 1% 0/50 (0%) Mean 1% 0/50 (0%) Mean 0% Mean 0% ngue, Pharynx, Tooth, Gingiva): 0/50 (0%) Multiple 1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% mgue, Pharynx, Tooth, Gingiva): Mean 2% mgue, Pharynx, Tooth, Gingiva): 1/50 (2%) Total 2/100 (2%) 1/50 (2%)	Tumor Incidence for Selected Control Route: SKIN Vehicle: ETHANOL Male Male 1/100 (1%) 1/50 (2%) Total 1/100 (1%) 1/50 (2%) 0/50 (0%) Total 1/100 (1%) 1/50 (2%) 0/50 (0%) Total 1/100 (1%) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) 0/50 (0%) 0/50 (0%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) Mean 1% SD 0% mgue, Pharynx, Tooth, Gingiva): 0/50 (0%) 1/50 (2%) 1/50 (2%) Total 0/100 (0%) Mean 0% SD 0% mgue, Pharynx, Tooth, Gingiva): 1/50 (2%) Total 2/100 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% SD 0% mgue, Pharynx, Tooth, Gingiva): Papilloma 1/50 (2%) Papilloma Squamous, or Papilloma 1/50 (2%) 1/50 (2%)	Vehicle: ETHANOL Male 0/50 (0%) 1/50 (2%) Total 1/100 1% SD 1.41% Total 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 0/50 (0%) Mean 1% SD 1.41% Total 1/100 0/50 (0%) Mean 1% SD 0.41% Total 0/50 (0%) Mean 0% SD 0% Total Illoma 0/50 (0%) Mean % SD 0% Total Ingue, Pharynx, Tooth, Gingiva): Mean 2% SD 0% Total 1/50 (2%) 1/50 (2%) Notal Total To	Tumor Incidence for Selected Control Animal Groups Route: SKIN Vehicle: ETHANOL Male Male 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 0/48 (0%) Total 1/100 (1%) Mean 0% SD 0% Total 0/48 (0%) Male 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) mgue, Pharynx, Tooth, Gingiva): man 0% SD 0% Total 0/100 (0%) ngue, Pharynx, Tooth, Gingiva): 1/50 (2%) 1/50 (2%) SD 0% Total 0/100 (0%) mgue, Pharynx, Tooth, Gingiva): 1/50 (2%) Mean 2% SD 0% Total 0/100 (0%) Total 1/50 (2%) 1/50 (2%) SD 0%	Tumor Incidence for Selected Control Animal Groups Route: SKIN Vehicle: ETHANOL Report Dat Source: SKIN Vehicle: ETHANOL Male Female 0/50 (0%) 1/50 (2%) Total 1/100 1% SD 1.41% Total 0/50 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) Mean 0% Mean 0% Total 1/50 (2%) 0/50 (0%) Mean 0% Mean 0% Total 1/50 (2%) 0/50 (0%) Mean 2% Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/48 (0%) M/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/48 (0%) Mean 0% ngue, Pharynx, Tooth, Gingiva): Image: Pharynx, Tooth, Gingiva): Mean 0% SD 0% Total 0/100 0%) Mean 0% ngue, Pharynx, Tooth, Gingiva): Mean 2% SD 0% Total 0/100 0%) Mean 0%

Version: Jun2013 Contract/Lab: All Laboratori Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Management nce for Selected Contro Route: SKIN Vehicle: ETHANOL	ol Animal Groups		Page: 258 Report Date: 06/05/2013				
			Male				Female (0%) 0/50 (0%) %) Mean 0% SD 0% (2%) 1/50 (2%)				
#Oral Mucosa: Squamous Cell Carcinon	na	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%)		SD 0%			
#Oral Mucosa: Squamous Cell Papillom	a		- / /								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)		SD 0%			
*Ovary: Cystadenoma Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%			
Ovary: Fibrosarcoma											
Overall Incidence					Total	0/100 (0%)	()	SD 0%			
Ovary: Granulosa Cell Tumor Be	enign										
Overall Incidence					Total	2/100 (2%)	()	SD 0%			
*Ovary: Granulosa Cell Tumor Ma											
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

Version: Jun2013 Contract/Lab: All Laborato	ries			ogy Data Manageme		Page: 259 Report Date: 06/05/2013				
Species: RATS				Route: SKIN						
Strain: F 344/N	_			Vehicle: ETHANOL	-					
Length of Study: CHRONI	С									
			Male				Female			
'Ovary: Granulosa Cell Tumor: I	Benign. Maligna	nt. NOS								
		,				1/50 (2%)	1/50 (2%)			
Overall Incidence					Total	2/100 (2%)	Mean 2%	SD 0%		
'Ovary: Granulosa-Theca Tumo										
						0/50 (0%)	0/50 (0%)			
Overall Incidence					Total	0/100 (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%		
^t Ovary: Sertoli Cell Tumor Malig	gnant									
.					T ()	0/50 (0%)	0/50 (0%)	00.00/		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%		
[*] Ovary: Tubulostromal Adenom	a									
						0/50 (0%)	0/50 (0%)	65		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenoma										
	-	0/49 (0%)	0/50 (0%)	00.00/	T ()	0/49 (0%)	0/50 (0%)	00.00/		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%		

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Manageme nce for Selected Contr Route: SKIN Vehicle: ETHANOI	ol Animal Groups			
			Male		Premale Female 0/49 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% Total 0/99 (0%) 0/50 (0%) Total 0/99 (0%) Mean 0% SD 0% Total 1/50 (2%) 0/49 (0%) Total 1/99 (1.01%) Mean 1% SD 1.41% Total 31/50 (62%) 25/50 (50%) Total 56/100 (56%) Mean 56% SD 8.49% 2/50 (4%) 0/50 (0%) 0%)			
*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%			()	SD 0%
*Pancreas: Mixed Tumor Benign		0/49 (0%)	0/50 (0%)				0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	()	()	SD 0%
*Parathyroid Gland: Adenoma		0/49 (0%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	()	()	SD 1.41%
*Pituitary Gland: Pars Distalis Adenoma			33/50 (66%)					
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 0%		56/100 (56%)	Mean 56%	SD 8.49%
*Pituitary Gland: Pars Distalis Carcinoma								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%		2/100 (2%)	Mean 2%	SD 2.83%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma			33/50 (66%)			33/50 (66%)	25/50 (50%)	
Overall Incidence	Total	68/100 (68%)	Mean 68%	SD 2.83%	Total	58/100 (58%)	23/30 (30%) Mean 58%	SD 11.31%

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Manageme nce for Selected Contro Route: SKIN Vehicle: ETHANOL	ol Animal Groups) Mean 0% SD 0% 0%) 0/50 (0%)				
			Male				Female				
Pituitary Gland: Pars Distalis Ganglioneuroma	s or Unspeci	fied Site:									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	Mean 0%				
Pituitary Gland: Pars Intermo 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%)	()	SD 0%			
Pituitary Gland: Pars Intermo Carcinoma or Adenoma						0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	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%			
Pituitary Gland: Pars Nervos Craniopharyngioma						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%			
Prostate: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%							
Prostate: Carcinoma or Adenoma		0/50 (0%)									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%							

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxico Tumor Incider	e: 06/05/2013				
			Male				Female	
*Salivary Glands: Carcinoma		0/50 (0%)	4/50 (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%
*Salivary Glands: 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%
Salivary Glands: Sarcoma			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%
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%

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		rol Animal Groups Report Date: 06/05/201: IL Female 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 09 0/50 (0%) 0/50 (0%) SD 09 Total 0/100 (0%) Mean 0% SD 09 0/50 (0%) 0/50 (0%) Mean 0% SD 09 0/50 (0%) 0/50 (0%) SD 09 09						
#Skeletal Muscle: Lipoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	()	()	SD 0%			
		. ,				0,100 (0,0)					
#Skin: Basal Cell Adenoma		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 Bas Overall Incidence	osquamous Total	Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	()	()	SD 0%			
#Skin:											
Basal Cell Adenoma, Basos	quamous T					0/50 (00/)	0/50 (00()				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Carcinoma											
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		1/100 (1%)	Mean 1%	SD 1.41%			
#Skin: Basal Cell Carcinoma or Ba											
		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%			

			Male				Page: 264 Report Date: 06/05/20 ⁻				
Basal Cell Carcinoma, Basa							Female				
		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 Adenoma, Papilloma, Sq Pa	a, Carcinom pilloma, Ke	ratoacanthoma, Trichoepi	ithelioma	na,		0/50 (001)					
	T	7/50 (14%)	3/50 (6%)		T ()	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, Sar	rcoma, Myxo	oma, Myxosarcoma, or Fil 7/50 (14%)	brous Histiocytoma 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, My											
······································		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%			

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Manageme nce for Selected Contr Route: SKIN Vehicle: ETHANOI	ol Animal Groups	Page: 265 Dups Report Date: 06/05/20				
			Male				Fe	male		
#Skin: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	Route: SKIN Vehicle: ETHANOL Male 0/50 (0%) Mean 0% 0/50 (0%) SD 0% 0/50 (0%) Total 0/50 (0%) 0/100 (0%) 0/5 Mean 0% 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% 2/50 (4%) Mean 6% SD 2.83% Total 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/5	0/50 Mean	(0%) 0%	SD 0%			
#Skin: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	()	SD 0%	Total	()	0/50 Mean	(0%) 0%	SD 0%	
¥Skin: Keratoacanthoma Overall Incidence	Total	4/50 (8%) 6/100 (6%)	Mean 6%	SD 2.83%	Total	. ,	0/50 Mean	(0%) 0%	SD 0%	
Skin: Lipoma Dverall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%)	SD 0%	Total	()	0/50 Mean	(0%) 0%	SD 0%	
łSkin: Liposarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)		(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%	

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Manageme ce for Selected Conti Route: SKIN Vehicle: ETHANO		Page: 266 Report Da	te: 06/05/2013	
			Male				Female	
#Skin: Neurofibroma or Schwanno	ma 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: Neurofibrosarcoma or Schv			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, Neurof 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: Sarcoma Dverall 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 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%

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Manageme nce for Selected Contro Route: SKIN Vehicle: ETHANOL		Page: 267 Report Date: 06/05/2013		
			Male				Female	
#Skin:								
Squamous Cell Carcinoma								
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%
#Skin:								
Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	arcinoma, Basosquamou	us Tumor (malignan	t 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								
	i upinoinu	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, P	apilloma, So	-		a				
		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:	apilloma, or	Keratoacanthoma						
	apilloma, or	Keratoacanthoma 5/50 (10%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Manageme nce for Selected Contr Route: SKIN Vehicle: ETHANOI	Page: 268 Report Dat	e: 06/05/2013		
			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								
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		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%
tSpinal Cord: Glioma Malignant						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%
∕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						0/50 (00/.)	0/50 /00/)	
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%

			nce for Selected Contro Route: SKIN	Page: 269 Report Date: 06/05/2013			
		Male				Female	
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%
	34/50 (68%)	37/50 (74%)					
Total	71/100 (71%)	Mean 71%	SD 4.24%				
Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
Total	0/50 (0%)	0/47 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
	0/50 (0%)				0/50 (0%)	0/50 (0%)	
Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/47 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	Total Total Total	Total 0/100 (0%) 34/50 (68%) Total 71/100 (71%) 0/50 (0%) Total 1/100 (1%) 0/50 (0%) Total 0/97 (0%) Total 0/97 (0%) 0/50 (0%) 0/97 (0%)	Male Male 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% 34/50 (68%) Total 34/50 (68%) Total 71/100 (71%) Mean 71% Total 0/50 (0%) 1/100 (1%) Mean 71% Total 1/100 (1%) Mean 1% 0/97 (0%) Mean 0% 0/47 (0%) 0/50 (0%) 0/47 (0%) 0/50 (0%) 0/47 (0%) 0/50 (0%) 0/47 (0%)	Tumor Incidence for Selected Contra Route: SKIN Vehicle: ETHANOL Male 0/50 0%) 0/50 0%) Total 0/100 0%) Mean 0% SD 0% Total 0/100 0%) Mean 0% SD 0% Total 34/50 (68%) 37/50 (74%) SD 4.24% Total 71/100 71%) Mean 71% SD 4.24% Total 0/50 (0%) 1/50 (2%) SD 1.41% O/50 0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% 0/50 (0%) 0/47 (0%) Mean 0% SD 0% 0/50 (0%) 0/47 (0%) Mean 0% D 0% 0/50 (0%) 0/47 (0%) Mean 0% <	Vehicle: ETHANOL Male Total 0/50 (0%) 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total Total 0/100 (0%) Mean 0% SD 0% Total Total 0/100 (0%) Mean 0% SD 0% Total Total 0/100 (1%) Mean 71% SD 4.24% Total 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total Total 0/97 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% Total	Tumor Incidence for Selected Control Animal Groups Route: SKIN Vehicle: ETHANOL Male 0/50 00% 0 0 <t< td=""><td>Tumor Incidence for Selected Control Animal Groups Route: SKIN Vehicle: ETHANOL Report Dat Route: SKIN Vehicle: ETHANOL Male Female 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Total 34/50 (68%) 37/50 (74%) Mean 71% SD 4.24% Mean 0% Mean 0% Total 0/50 (0%) 1/50 (2%) Mean 1% SD 1.41% Mean 1% SD 1.41% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 2/100 (2%) 1/50 (2%) Mean 2% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/00 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/00 (0%) 0/50 (0%) Mean 0%</td></t<>	Tumor Incidence for Selected Control Animal Groups Route: SKIN Vehicle: ETHANOL Report Dat Route: SKIN Vehicle: ETHANOL Male Female 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Total 34/50 (68%) 37/50 (74%) Mean 71% SD 4.24% Mean 0% Mean 0% Total 0/50 (0%) 1/50 (2%) Mean 1% SD 1.41% Mean 1% SD 1.41% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 2/100 (2%) 1/50 (2%) Mean 2% Total 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/00 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/47 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/00 (0%) 0/50 (0%) Mean 0%

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Manageme nce for Selected Contr Route: SKIN Vehicle: ETHANOI	ol Animal Groups	Page: 270 Report Da	te: 06/05/2013	
			Male			Female		
*Thymus: Thymoma: Benign, Malignar		0/50 (0%)	0/47 (0%)	05.0%	T	1/50 (2%)	1/50 (2%)	25 <i>ani</i>
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%)	0/50 (199/)			7/50 (149/)	7/50 (149/)	
Overall Incidence	Total	15/96 (15.62%)	9/50 (18%) Mean 15.52%	SD 3.5%	Total	7/50 (14%) 14/100 (14%)	7/50 (14%) Mean 14%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) 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								
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma		()						
	Tatal	2/46 (4%)	0/50 (0%)		Tatal	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%

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				logy Data Manageme nce for Selected Contro Route: SKIN Vehicle: ETHANOL	Page: 271 Report Date: 06/05/2013				
			Male		Female				
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:								
Overall Incidence	Total	2/46 (4%) 2/96 (2.08%)	0/50 (0%) Mean 2.17%	SD 3.07%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	
∉Tongue: Squamous Cell 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%	
≭Tongue: Squamous Cell Carcinoma c	or Papillom		4/50 (20/)			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%	
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%	
FTooth: Adamantinoma 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%	
Urinary Bladder: 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%	

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxico Tumor Incider	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%
^t Urinary Bladder: 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%
Urinary Bladder: Papilloma			4/50 (00/)			0/50 (00/)	0/50 (00/)	
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%
Uterus: Adenoma						0/50 (00/)	0/50 /00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
ŧUterus: Carcinoma								
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%

Version: Jun2013	Toxicology Data Management System						
Contract/Lab: All Laboratories	Tumor Incidence for Selected Control Animal Groups Route: SKIN	Report Da	te: 06/05/2013				
Species: RATS							
Strain: F 344/N	Vehicle: ETHANOL						
Length of Study: CHRONIC							
	Male		Female				
#Uterus:							
Polyp Stromal							
	-	10/50 (20%)	7/50 (14%)	00 40494			
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%)	65 (6 (6)			
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 4.24%			
#Uterus:							
Schwannoma Malignant			o /= o (o o /)				
	-	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%			

Version: Jun2013 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Manageme ce for Selected Contr Route: SKIN Vehicle: ETHANO	Page: 274 Report Dat	Page: 274 Report Date: 06/05/2013		
			Male				Female	
¥Vagina: Sarcoma Dverall 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 werall 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		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