Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

	Study Summary											
Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical					
					Male							
Battelle Columbus Laboratory	058812305	03/21/01	727	50(3)	26(673)	509.7	Formamide					
Battelle Columbus Laboratory	052000505	01/21/04	727	50(3)	30(679)	498.5	Ginseng					
Battelle Columbus Laboratory	059501107	03/06/02	727	50(3)	22(673)	510.3	5-(Hydroxymethyl)-2-furfural					
					Female							
Battelle Columbus Laboratory	058812305	03/20/01	730	50(5)	38(703)	358.3	Formamide					
Battelle Columbus Laboratory	052000505	01/22/04	728	50(5)	36(700)	355.0	Ginseng					
Battelle Columbus Laboratory	059501107	03/07/02	728	50(5)	31(679)	332.2	5-(Hydroxymethyl)-2-furfural					

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Page: 97 Report Date: 03/20/2010					
			Male	Female				
#All Organs: Benign Tumors	T	45/50 (90%)	49/50 (98%)	50/50 (100%)	-	43/50 (86%)	42/50 (84%)	46/50 (92%)
Overall Incidence	Total	144/150 (96%)	Mean 96%	SD 5.29%	Total	131/150 (87.33%)	Mean 87.33%	SD 4.16%
#All Organs: Malignant Tumors		25/50 (50%)	26/50 (52%)	35/50 (70%)		15/50 (30%)	10/50 (20%)	16/50 (32%)
Overall Incidence	Total	86/150 (57.33%)	Mean 57.33%	SD 11.02%	Total	41/150 (27.33%)	Mean 27.33%	SD 6.43%
#All Organs: Malignant and Benign Tum		48/50 (96%)	49/50 (98%)	50/50 (100%)		49/50 (98%)	45/50 (90%)	48/50 (96%)
Overall Incidence	Total	147/150 (98%)	Mean 98%	SD 2%	Total	142/150 (94.67%)	Mean 94.67%	SD 4.16%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Hemangiosarcoma or Hema	angioma							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male		Female				
#All Organs: Histiocytic Sarcoma		4/50 (0%)		0/50 (0%)		0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#All Organs: Leukemia: Erythrocytic		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Leukemia: Lymphocytic, M Overall Incidence	Total	15/50 (30%) 61/150 (40.67%)	18/50 (36%) Mean 40.67%	28/50 (56%) SD 13.61%	Total	10/50 (20%) 25/150 (16.67%)	6/50 (12%) Mean 16.67%	9/50 (18%) SD 4.16%	
#All Organs: Malignant Lymphoma: Hist									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#All Organs:									
Mesothelioma: Benign									
Mesothelioma: Benign	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	
	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Mesothelioma: Benign		0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Mesothelioma: Benign Overall Incidence #All Organs:		0/150 (0%)	()	()	Total Total		()	()	

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 (4%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#All Organs: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%
≮All Organs: Osteosarcoma		0/50 (0%)	4/50 (00/)	0/50 (08/)		0/50 (00%)	0/50 (00/.)	4/50 /00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
All Organs: Osteosarcoma or Osteoma								4/50 (20())
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Adrenal Cortex: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Adrenal Cortex: Carcinoma			0/50 (001)	0/50 (00%)		0/50 (00/)	0/50 (00/.)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
*Adrenal Medulla: Ganglioneuroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Be	nign	9/50 (18%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	9/30 (18%) 18/150 (12%)	Mean 12%	SD 5.29%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Adrenal Medulla: Pheochromocytoma Co	mplex	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Ma	lignant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma: Be	enign, Complex	, Malignant, NOS 9/50 (18%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Management ice for Selected Control A Route: GAVAGE Vehicle: WATER		Page: 101 Report Date: 03/20/2010			
			Male		Female				
#Bone: Chondrosarcoma		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (0)()	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Chondrosarcoma or Chondi									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Chordoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%		
#Bone: Osteoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Bone: Osteosarcoma		·····							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	

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Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male			Female					
*Brain: Oligodendroglioma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
*Brain: Oligodendroglioma Mali		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Brain: Oligodendroglioma, Glic	oma, or Astrocy										
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Brain: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
Brain: Schwannoma Malignant											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Clitoral/Preputial Gland: Adenoma											
Overall Incidence	Total	1/50 (2%) 6/150 (4%)	0/50 (0%) Mean 4%	5/50 (10%) SD 5.29%	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%			

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxicol Tumor Incider	Page: 104 Report Date: 03/20/2010				
			Male	Female				
*Clitoral/Preputial Gland: Carcinoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Clitoral/Preputial Gland: Carcinoma or Adenoma				0/50 (40%)			0/50 (40/)	2/52 /02/)
Overall Incidence	Total	2/50 (4%) 8/150 (5.33%)	0/50 (0%) Mean 5.33%	6/50 (12%) SD 6.11%	Total	2/50 (4%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	3/50 (6%) SD 1.15%
*Clitoral/Preputial Gland: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male					Female	
#Esophagus: Lipoma		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	、	Total	0/150 (0%)	Mean 0%	SD 0%
∉Eye: Melanoma Malignant		0/50 (0%)	0/50 (0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	(0 %)	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%/)	0/50	(00/)		0/50 (09/)	0/50 (00/.)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Harderian Gland: Carcinoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 SD 1.15%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Harderian Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 SD 1.15%	(0%) ,	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Schwannoma Benign									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
*Heart: Schwannoma Malignan	t						- /	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
		()				(/		
Intestine Large: Colon/R Adenoma	ectum:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Intestine Large: Colon/R Carcinoma	ectum:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Intestine Large: Colon/R Carcinoma or Adenoma	ectum:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
fIntestine Large: Colon/R Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duoden Carcinoma	um:							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
#Intestine Small: Duodenum Leiomyoma	:	0/50 (0%)	0/50 (0%)	0/50 (0)%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Ileum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	9%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	SD 1.15%	9%) Total		0/50 (0%) Mean 0%	0/50 (0%) SD 0%
fIntestine Small: Jejunum: Granular Cell Tumor Malig								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	9%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
fIntestine Small: Jejunum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%)%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%)%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
#Intestine Small: Site Uns Adenoma	specified:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma or Adenoma	•	0/50 (00/)	4/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%()
Overall Incidence	Total	0/50 (0%)	1/50 (2%) Mean 0.67%	0/50 (0%)	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		1/150 (0.67%)		SD 1.15%	Total	()		50 0%
Intestine Small: Site Uns Granular Cell Tumor Ma	•							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Leiomyoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Site Uns Leiomyosarcoma	specified:	0/50 (00/)	0/50 (00%)	0/50 (0%)		0/50 (00/)	0/50 (00/.)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Page: 109 Report Date: 03/20/2010

			Male				Female	
Islets, Pancreatic: Adenoma		2/50 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Islets, Pancreatic: Carcinoma		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma		3/50 (6%)	0/50 (0%)	4/E0 (99/)		1/50 (2%)	1/50 (29/)	0/50 (0%)
Overall Incidence	Total	7/150 (4.67%)	0/50 (0%) Mean 4.67%	4/50 (8%) SD 4.16%	Total	2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
Kidney: Pelvis and Transit Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Pelvis and Transit Carcinoma or Adenoma		um:						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Pelvis and Transit Papilloma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Page: 110 Report Date: 03/20/2010

			Male				Female	
'Kidney: Renal Tubule: Adenoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma		4/50 (00%)	0/50 (40/)	0/50 (00()		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	2/50 (4%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benign	 I	0/50 (00%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Malig	jnant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Liver: Cholangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
'Liver: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocellular Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

Page: 112 Report Date: 03/20/2010

			Male		Female						
*Liver: Hepatocellular Carcinoma 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcinon		astoma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
'Liver: Hepatocellular Carcinon	na or Hepatoce	Ilular Adenoma						- ()			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%			
*Liver: Hepatocellular Carcinon	na, Hepatocellı	Ilar Adenoma, or Hepatob 0/50 (0%)	lastoma 1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%			
'Liver: Ito Cell Tumor Benign											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
*Lung: Alveolar/Bronchiolar Ad	enoma	0/50 (00/)	0/50 (00%)	0/50 (0%)		4/50 (20/)	4/50 (20/.)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%			

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Page: 113 Report Date: 03/20/2010

			Male				Female					
*Lung: Alveolar/Bronchiolar Carcinoma 1/50 (2%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				
*Lung:		veolar/Bronchiolar Adeno	ma									
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%				
′Lung: Fibrosarcoma		0/50 (00%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (00/.)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Lung: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Lung: Squamous Cell Carcino	ma											
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Łymph Node: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Page: 114 Report Date: 03/20/2010

			Male				Female	
#Mammary Gland: Adenolipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	2/50 (4%) SD 2.31%
Mammary Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Mammary Gland: Carcinoma or Adenoma			- / / /			- ()	- ()	- (
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 6/150 (4%)	2/50 (4%) Mean 4%	2/50 (4%) SD 0%
Mammary Gland: Fibroadenoma								
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	1/50 (2%) SD 1.15%	Total	33/50 (66%) 94/150 (62.67%)	32/50 (64%) Mean 62.67%	29/50 (58%) SD 4.16%
#Mammary Gland: Fibroma						······		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Management ace for Selected Control A Route: GAVAGE Vehicle: WATER	Page: 115 Report Date: 03/20/2010				
			Male			Female 33/50 (66%) 96/150 (64%) 33/50 (66%) Mean 64% 30/50 (60%) SD 3.46% Total 35/50 (70%) 98/150 (65.33%) 33/50 (66%) Mean 65.33% 30/50 (60%) SD 5.03% 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) SD 0%			
#Mammary Gland: Fibroma, Fibroadenoma or A	Adenoma	4/50 (8%)	2/50 (4%)	1/50 (2%)		33/50 (66%)	33/50 (66%)	30/50 (60%)	
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	96/150 (64%)	Mean 64%	SD 3.46%	
#Mammary Gland: Fibroma, Fibroadenoma, Ca	ircinoma, oi	r Adenoma 4/50 (8%)	2/50 (4%)	1/50 (2%)		35/50 (70%)	33/50 (66%)	30/50 (60%)	
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total		· · ·	()	
#Mesentery: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	()	()		
		0/100 (070)				0/100 (0/0)			
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Mesentery: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Mesentery: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
*Nose: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcin	oma	0/50 /00()		0/50 (0%)			0/50 (00/.)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phar			0/50 (0%)		0/50 /00/)	0/50 (00/.)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phar	ynx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 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: GAVAGE Vehicle: WATER						Page: 117 Report Date: 03/20/2010		
			Male		Female					
#Oral Mucosa: Squamous Cell Carcinoma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		
		0/100 (078)		30 0%		1/130 (0.07 /8)				
#Oral Mucosa: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
						0/100 (0/0)				
*Ovary: Cystadenoma						0/50 (0%)	0/50 (00/)	0/40 (0%)		
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Ovary: Granulosa Cell Tumor Beni	gn									
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Ovary: Granulosa Cell Tumor Malig	gnant									
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*Ovary: Granulosa Cell Tumor: Ben	ign, Maligna	ant, NOS								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%		
*: Denominator is number of animals #: Denominator is number of animals		examined microscopically				5/145 (070)				

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC	5		Toxicol Tumor Incider	te: 03/20/2010				
			Male		Female			
*Ovary: Granulosa-Theca Tumor B	enian							
Overall Incidence	-				Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Granulosa-Theca Tumor M								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Carcinoma or Adenoma		0/50 (00%)		4/50 (00/)			0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
*Pancreas: Mixed Tumor Benign		0/50 /02//	0/50 (00%)	0/50 (0%)		0/50 (0%)	0/50 /00//)	0/50 (0)()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Mixed Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/48 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/46 (0%) 0/142 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Pituitary Gland: Pars Dista Adenoma		cified Site:						
Overall Incidence	Total	11/50 (22%) 46/150 (30.67%)	20/50 (40%) Mean 30.67%	15/50 (30%) SD 9.02%	Total	22/50 (44%) 62/150 (41.33%)	16/50 (32%) Mean 41.33%	24/50 (48%) SD 8.33%
Pituitary Gland: Pars Dista Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
Pituitary Gland: Pars Dista Carcinoma or Adenoma		cified Site:						
Overall Incidence	Total	11/50 (22%) 46/150 (30.67%)	20/50 (40%) Mean 30.67%	15/50 (30%) SD 9.02%	Total	24/50 (48%) 65/150 (43.33%)	16/50 (32%) Mean 43.33%	25/50 (50%) SD 9.87%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxicol Tumor Incider		Page: 120 Report Date: 03/20/2010			
			Male				Female	
*Pituitary Gland: Pars Distalis Ganglioneuroma	or Unspeci							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pituitary Gland: Pars Interme Adenoma	dia:	- / /		- ()			- / />	- / //
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nervos Craniopharyngioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (00/)		0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%				

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	, Total	0/150 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Salivary Glands: Sarcoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
alivary Glands: Schwannoma Malignant		2/52 (201)	0/50 (00/)	0/50 (00/		0/50 (00/)	0/50 (00/)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Seminal Vesicle: Adenoma								
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	,			
Skeletal Muscle: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or R	habdomyoma		0/50 (0)()	0/50 (0%)		0/50 (00/.)	0/50 (00/.)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma								
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
Skin: Basal Cell Adenoma or Ba		Tumor Benign						
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
#Skin: Basal Cell Adenoma, Baso		umor Benign, or Trichoep						
	•	1/50 (2%)	1/50 (2%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male			Female						
#Skin: Basal Cell Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
		()	()	· · ·		()	()	()				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Carcinoma oi	r Basosquamo	us Tumor (malignant or N	OS)									
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
#Skin: Basal Cell Carcinoma, E NOS), or Trichoepithelic		noma, Basosquamous Tur 1/50 (2%)	nor (benign, malignai 1/50 (2%)	nt or 1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%				
Basal or Sq. Cell Carcin Adenoma, Papilloma, So		na, Basosq. Tumor (M or I eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%)		na, 4/50 (8%) SD 8.33%	Total	4/50 (8%) 7/150 (4.67%)	3/50 (6%) Mean 4.67%	0/50 (0%) SD 4.16%				
	q Papilloma, K	eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%)	oithelioma 2/50 (4%) Mean 10.67%	4/50 (8%) SD 8.33%	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%				
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence #Skin: Fibroma	q Papilloma, K Total	eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%) 6/50 (12%)	oithelioma 2/50 (4%) Mean 10.67% 2/50 (4%)	4/50 (8%) SD 8.33% 5/50 (10%)		7/150 (4.67%)	Mean 4.67%	SD 4.16%				
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence #Skin: Fibroma Overall Incidence	q Papilloma, K a Total Total	eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%) 6/50 (12%) 13/150 (8.67%)	oithelioma 2/50 (4%) Mean 10.67% 2/50 (4%) Mean 8.67%	4/50 (8%) SD 8.33% 5/50 (10%) SD 4.16%	Total	7/150 (4.67%) 1/50 (2%) 2/150 (1.33%)	Mean 4.67% 0/50 (0%) Mean 1.33%	SD 4.16% 1/50 (2%) SD 1.15%				
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence #Skin: Fibroma Overall Incidence #Skin:	q Papilloma, K a Total Total	eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%) 6/50 (12%) 13/150 (8.67%) xoma, Myxosarcoma, or F	bithelioma 2/50 (4%) Mean 10.67% 2/50 (4%) Mean 8.67% ibrous Histiocytoma	4/50 (8%) SD 8.33% 5/50 (10%) SD 4.16%	Total	7/150 (4.67%) 1/50 (2%) 2/150 (1.33%)	Mean 4.67% 0/50 (0%) Mean 1.33%	SD 4.16% 1/50 (2%) SD 1.15%				
Basal or Sq. Cell Carcin Adenoma, Papilloma, So Overall Incidence #Skin: Fibroma Overall Incidence #Skin:	q Papilloma, K a Total Total	eratoacanthoma, Trichoeg 10/50 (20%) 16/150 (10.67%) 6/50 (12%) 13/150 (8.67%)	oithelioma 2/50 (4%) Mean 10.67% 2/50 (4%) Mean 8.67%	4/50 (8%) SD 8.33% 5/50 (10%) SD 4.16%	Total	7/150 (4.67%) 1/50 (2%) 2/150 (1.33%)	Mean 4.67% 0/50 (0%) Mean 1.33%	SD 4.16% 1/50 (2%) SD 1.15%				

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
#Skin: Fibrosarcoma		0/50 (09/)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%/)	0/50 (0%/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
≴Skin: Fibrosarcoma, Sarcoma		a, or Fibrous Histiocytom						
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Fibrous Histiocytoma		4/50 (20/)		0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Hemangioma		0/50 (00/)		0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
≮Skin: Keratoacanthoma		0/50 (400%)	0/50 (00/1)	0/50 (49/)		0/50 (40%)	0/50 (40/)	0/50 (00/)
Overall Incidence	Total	8/50 (16%) 10/150 (6.67%)	0/50 (0%) Mean 6.67%	2/50 (4%) SD 8.33%	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
#Skin: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)		0/50 (0%)			0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor, Ma	alignant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibroma or Schwa								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or \$	Schwannoma (n		0/50 (001)	4/50 (000)		0/50 (00/1)	0/50 (00/)	4/50 (00)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC				ogy Data Management ace for Selected Control A Route: GAVAGE Vehicle: WATER	•		Page: 126 Report Dat	e: 03/20/2010
			Male				Female	
#Skin: Neurofibrosarcoma, Neurofi	broma, or	Schwannoma (benign, ma 1/50 (2%)	lignant or NOS) 0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
¢Skin: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
≮Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Malignant		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Squamous Cell Carcinoma						0/50 (0%/)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
fSkin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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1/50 (2%) 1/150 (0.67%) oma 1/50 (2%) 1/150 (0.67%) a, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	0/50 (0%) Mean 0.67% 0/50 (0%) Mean 0.67% na or Keratoacanthom 1/50 (2%) Mean 8.67%	0/50 (0%) SD 1.15% 0/50 (0%) SD 1.15% na 3/50 (6%) SD 8.33%	Total Total Total	0/50 (0%) 1/150 (0.67%) 0/50 (0%) 1/150 (0.67%) 2/50 (4%) 5/150 (3.33%)	1/50 (2%) Mean 0.67% 1/50 (2%) Mean 0.67% 3/50 (6%) Mean 3.33%	0/50 (0%) SD 1.15% 0/50 (0%) SD 1.15% 0/50 (0%) SD 3.06%
1/150 (0.67%) oma 1/50 (2%) 1/150 (0.67%) a, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	Mean 0.67% 0/50 (0%) Mean 0.67% na or Keratoacanthom 1/50 (2%)	SD 1.15% 0/50 (0%) SD 1.15% na 3/50 (6%)	Total	1/150 (0.67%) 0/50 (0%) 1/150 (0.67%) 2/50 (4%)	Mean 0.67% 1/50 (2%) Mean 0.67% 3/50 (6%)	SD 1.15% 0/50 (0%) SD 1.15% 0/50 (0%)
oma 1/50 (2%) 1/150 (0.67%) a, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	0/50 (0%) Mean 0.67% na or Keratoacanthom 1/50 (2%)	0/50 (0%) SD 1.15% na 3/50 (6%)	Total	0/50 (0%) 1/150 (0.67%) 2/50 (4%)	1/50 (2%) Mean 0.67% 3/50 (6%)	0/50 (0%) SD 1.15% 0/50 (0%)
1/50 (2%) 1/150 (0.67%) a, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	Mean 0.67% na or Keratoacanthom 1/50 (2%)	SD 1.15% na 3/50 (6%)		1/150 (0.67%) ´ 2/50 (4%)	Mean 0.67% 3/50 (6%)	SD 1.15% 0/50 (0%)
1/150 (0.67%) na, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	Mean 0.67% na or Keratoacanthom 1/50 (2%)	SD 1.15% na 3/50 (6%)		1/150 (0.67%) ´ 2/50 (4%)	Mean 0.67% 3/50 (6%)	SD 1.15% 0/50 (0%)
a, Squamous Cell Carcinom 9/50 (18%) 13/150 (8.67%)	na or Keratoacanthom 1/50 (2%)	na 3/50 (6%)		2/50 (4%)	3/50 (6%)	0/50 (0%)
9/50 (18%) 13/150 (8.67%)	1/50 (2%)	3/50 (6%)	Total			()
a, or Keratoacanthoma 9/50 (18%)	0/50 (0%)	2/50 (4%)		2/50 (4%)	3/50 (6%)	0/50 (0%)
11/150 (7.33%)	Mean 7.33%	SD 9.45%	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%
0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	()	()	Total	()		0/50 (0%) SD 0%
-	11/150 (7.33%) 0/50 (0%)	11/150 (7.33%) Mean 7.33% 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	11/150 (7.33%) Mean 7.33% SD 9.45% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% 0/50 (0%) 0/50 (0%) 0/50 (0%)	11/150 (7.33%) Mean 7.33% SD 9.45% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total	11/150 (7.33%) Mean 7.33% SD 9.45% Total 5/150 (3.33%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/150 (0%) Mean 0% SD 0% Total 1/150 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	11/150 (7.33%) Mean 7.33% SD 9.45% Total 5/150 (3.33%) Mean 3.33% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign		0/50 (0%)		0/50 /00/	、	0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spinal Cord: Astrocytoma Malignant		0/50 /00/)	0/50 (00/)	0/50 /00/	、	0/50 (0%)	0/50 (00/.)	0/50 (00/.)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spinal Cord: Glioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Spleen: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%	5) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Fibrous Histiocytoma			- /		、			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
*Spleen: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma		0/50 (001)	0/50 (001)	0/50 (001)		0/50 (00/)	0/50 (00/.)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Squamous Cell Carcinon								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Stomach, Forestomach: Squamous Cell Carcinon	na or Papillom							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%	\ \	0/50 (0%)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%) Total	0/50 (0%)	Mean 0%	0/50 (0%) SD 0%
Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%/)	0/50 (0%)	\ \	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Glandular: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Glandular: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0% SD 0%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Testes: Adenoma								
Overall Incidence	Total	44/50 (88%) 137/150 (91.33%)	45/50 (90%) Mean 91.33%	48/50 (96% SD 4.16%	b)			

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N Length of Study: CHRONIC			Toxicol Tumor Inciden	ogy Data Mai ce for Selecte Route: G Vehicle: \	ed Control A	-	Page: 131 Report Date: 03/20/2010		
			Male	Female					
*Testes: Hemangioma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 SD 0%	(0%)				
	10tai	0/130 (078)							
*Thymus: Thymoma Benign				.	(00/)		e//e /	o//o	
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 SD 0%	(0%)	Total	0/48 (0%) 1/144 (0.69%)	0/48 (0%) Mean 0.69%	1/48 (2%) SD 1.2%
*Thymus: Thymoma Malignant		0/40 (004)	0/50 (00/)	0/40	(00()		0/40 (00/)	4/40 (00/)	0/40 (00/)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 SD 0%	(0%)	Total	0/48 (0%) 1/144 (0.69%)	1/48 (2%) Mean 0.69%	0/48 (0%) SD 1.2%
*Thymus: Thymoma NOS									
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 SD 0%	(0%)	Total	0/48 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
*Thymus: Thymoma: Benign, Malignar									
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 SD 0%	(0%)	Total	0/48 (0%) 2/144 (1.39%)	1/48 (2%) Mean 1.39%	1/48 (2%) SD 1.2%
*Thyroid Gland: C-Cell: Adenoma									
Overall Incidence	Total	6/50 (12%) 18/150 (12%)	11/50 (22%) Mean 12%	1/50 SD 10%		Total	5/50 (10%) 22/150 (14.67%)	6/50 (12%) Mean 14.67%	11/50 (22%) SD 6.43%

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

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Thyroid Gland: C-Cell: Carcinoma or Adenoma		6/50 (12%)	11/50 (22%)	1/50 (2%)		5/50 (10%)	6/50 (12%)	12/50 (24%)
Overall Incidence	Total	18/150 (12%)	Mean 12%	SD 10%	Total	23/150 (15.33%)	Mean 15.33%	SD 7.57%
Thyroid Gland: Follicular Cell: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Thyroid Gland: Follicular Cell: Carcinoma								
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	3/50 (6%) SD 2.31%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
≭Tissue NOS: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

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			Male				Female	
#Tissue NOS: Paraganglioma		0/50 (00/)	0/50 /00/3	0/50 /2	•	0/50 /00/1	0/50 (00/)	0/50 /00/.`
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	l%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	l%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
≭Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous 0/50 (0%)	0/50 (0%)	0/50 (0	%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	, Total	0/150 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)		%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
fTooth: Adamantinoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	l%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
fTooth: Odontoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	l%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

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			Male				Female	
Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Papilloma						- ()	- / / /	- ()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Adenoma								
overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Uterus: Carcinoma						0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

*: Denominator is number of animals with tissues examined microscopically

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER		Page: 135 Report Date: 03/20/2010				
Male		Female				
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Total	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
	Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER Male Total Total Total Total Total	Male 0/50 (0%) 0/50 (0%) 0/150 (0%) Total 0/50 (0%) 0/150 (0%) 0/150 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/150 (0%)	Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER Report Date Male Female 0/50 0%0 0/50 0%0 Total 0/150 0%0 Mean 0% 0/50 0(%) Mean 0% Mean 0% Total 0/150 0%0 Mean 0% Mano 7/50 (14%) Mean 0% Mean 15.33% Mean 15.33% Mean 15.33%			

Version: Mar2010 Contract/Lab: All Laboratories Species: RATS Strain: F 344/N			Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER					Page: 136 Report Date: 03/20/2010		
Length of Study: CHRONIC										
			Male				Female			
#Uterus: Sarcoma Stromal										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
#Uterus: Sarcoma Stromal or Polyp S										
Overall Incidence					Total	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%		
#Uterus: Schwannoma Malignant										
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%		
#Vagina: Polyp										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
≭Vagina: Sarcoma										
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
≭Zymbal's Gland: Adenoma		0/50 (00%)	0/50 (00)	0/50 /2	~^)	0/50 (00/)	0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0 SD 0%	%) Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

Version: Mar2010 Contract/Lab: All Laboratorie Species: RATS Strain: F 344/N Length of Study: CHRONIC	ì			ogy Data Management ce for Selected Control / Route: GAVAGE Vehicle: WATER	Page: 137 Report Date: 03/20/2010 Female			
			Male					
#Zymbal's Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%