

NTP Historical Controls Report

All Routes And Vehicles

Sprague-Dawley Rats

November 2008

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

The report combines all the data from all of the historical control studies into one section. To see this data broken up by route and vehicle you must run the "By Route And Vehicle" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male

M1
M2
M3
M4
M5

Female

F1
F2
F3
F4
F5

the data would be shown as:

Male			Female		
M1	M2	M3	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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	059602001	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (Binary mixture; PCB 126/PCB 153)
Battelle Columbus Laboratory	059600704	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (Dioxin mixture)
Battelle Columbus Laboratory	052030401	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	059602202	N/A	N/A	0 (0)	0(0)	N/A	Tef Evaluation (Pcb Mixture; Pcb 126/Pcb 118)
Battelle Columbus Laboratory	059600705	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (PECDF (Pentachlorodibenzofuran))
Battelle Columbus Laboratory	059600703	N/A	N/A	0 (0)	0(0)	N/A	TEF evaluation (TCDD)
Battelle Columbus Laboratory	058814806	01/29/03	727	50 (3)	28(665)	606.4	3,3',4,4'-Tetrachloroazobenzene
Battelle Columbus Laboratory	059600701	N/A	N/A	0 (0)	0(0)	N/A	Toxic equivalency factor evaluation ((PCB 126) 3,3',4,4',5-pentachlorobiphenyl)
Battelle Columbus Laboratory	059602101	N/A	N/A	0 (0)	0(0)	N/A	Toxic equivalency factor evaluation (PCB 153- 2,2'-4,4',5,5'-hexachlorobiphenyl)
Female							
Battelle Columbus Laboratory	059602001	09/16/98	729	53 (5)	22(629)	403.6	TEF evaluation (Binary mixture; PCB 126/PCB 153)
Battelle Columbus Laboratory	059600704	06/16/98	729	53 (5)	16(616)	381.2	TEF evaluation (Dioxin mixture)
Battelle Columbus Laboratory	052030401	03/26/04	733	52 (5)	21(616)	383.5	TEF evaluation (PCB 118)
Battelle Columbus Laboratory	059602202	10/14/99	726	53 (5)	27(656)	386.5	Tef Evaluation (Pcb Mixture; Pcb 126/Pcb 118)
Battelle Columbus Laboratory	059600705	04/07/99	728	53 (5)	25(655)	365.7	TEF evaluation (PECDF (Pentachlorodibenzofuran))
Battelle Columbus Laboratory	059600703	06/01/98	731	53 (5)	25(637)	382.6	TEF evaluation (TCDD)
Battelle Columbus Laboratory	058814806	01/30/03	727	50 (5)	25(652)	385.7	3,3',4,4'-Tetrachloroazobenzene
Battelle Columbus Laboratory	059600701	02/26/98	727	53 (5)	15(567)	397.1	Toxic equivalency factor evaluation ((PCB 126) 3,3',4,4',5-pentachlorobiphenyl)
Battelle Columbus Laboratory	059602101	08/24/98	731	53 (5)	24(641)	394.5	Toxic equivalency factor evaluation (PCB 153- 2,2'-4,4',5,5'-hexachlorobiphenyl)

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

		Male			Female		
#All Organs:							
Benign Tumors							
					49/53 (92%)	45/53 (85%)	43/52 (83%)
					53/53 (100%)	45/53 (85%)	45/53 (85%)
		40/50 (80%)			40/50 (80%)	45/53 (85%)	50/53 (94%)
Overall Incidence	Total	40/50 (80%)	Mean 80%	SD 0%	Total 415/473 (87.74%)	Mean 87.68%	SD 6.46%
.....							
#All Organs:							
Malignant Tumors							
					14/53 (26%)	18/53 (34%)	15/52 (29%)
					16/53 (30%)	12/53 (23%)	13/53 (25%)
		9/50 (18%)			13/50 (26%)	13/53 (25%)	12/53 (23%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total 126/473 (26.64%)	Mean 26.64%	SD 3.75%
.....							
#All Organs:							
Malignant and Benign Tumors							
					51/53 (96%)	51/53 (96%)	48/52 (92%)
					53/53 (100%)	48/53 (91%)	47/53 (89%)
		44/50 (88%)			44/50 (88%)	49/53 (92%)	52/53 (98%)
Overall Incidence	Total	44/50 (88%)	Mean 88%	SD 0%	Total 443/473 (93.66%)	Mean 93.62%	SD 4.23%
.....							
#All Organs:							
Hemangioma							
					1/53 (2%)	0/53 (0%)	0/52 (0%)
					0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)			0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#All Organs:									
Hemangiosarcoma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)		2/53 (4%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 1.37%	
.....									
#All Organs:									
Hemangiosarcoma or Hemangioma									
						1/53 (2%)		0/53 (0%)	1/52 (2%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)		2/53 (4%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	5/473 (1.06%)	Mean 1.05%	SD 1.37%	
.....									
#All Organs:									
Histiocytic Sarcoma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.44%	SD 0.87%	
.....									
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						1/53 (2%)		1/53 (2%)	0/53 (0%)
		1/50 (2%)				1/50 (2%)		0/53 (0%)	1/53 (2%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.85%	SD 1.01%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

					Male						Female				
#All Organs:															
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type															
					0/53	(0%)						2/53	(4%)	2/52	(4%)
					0/53	(0%)						0/53	(0%)	0/53	(0%)
					0/50	(0%)						0/53	(0%)	2/53	(4%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	6/473	(1.27%)	Mean 1.27%	SD 1.9%					
.....															
#All Organs:															
Osteosarcoma															
					0/53	(0%)						0/53	(0%)	0/52	(0%)
					0/53	(0%)						0/53	(0%)	0/53	(0%)
					0/50	(0%)						1/53	(2%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
#All Organs:															
Osteosarcoma or Osteoma															
					0/53	(0%)						0/53	(0%)	0/52	(0%)
					0/53	(0%)						0/53	(0%)	0/53	(0%)
					0/50	(0%)						1/53	(2%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
*Adrenal Cortex:															
Adenoma															
					0/53	(0%)						0/52	(0%)	2/52	(4%)
					0/53	(0%)						1/53	(2%)	1/53	(2%)
					1/50	(2%)						0/52	(0%)	0/53	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	5/471	(1.06%)	Mean 1.07%	SD 1.4%					

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

		Male				Female			
*Adrenal Cortex:									
 Carcinoma									
						0/53 (0%)		0/52 (0%)	1/52 (2%)
						1/53 (2%)		1/53 (2%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.63%	SD 0.95%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Benign									
						3/52 (6%)		5/52 (10%)	3/52 (6%)
						3/53 (6%)		4/53 (8%)	3/53 (6%)
		5/50 (10%)				3/50 (6%)		8/52 (15%)	2/53 (4%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	34/470 (7.23%)	Mean 7.24%	SD 3.44%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Complex									
						0/52 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		1/53 (2%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/470 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
*Adrenal Medulla:									
 Pheochromocytoma Malignant									
						0/52 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	1/53 (2%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/470 (0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
						3/52 (6%)		5/52 (10%)	3/52 (6%)
						3/53 (6%)		5/53 (9%)	3/53 (6%)
						3/50 (6%)		8/52 (15%)	3/53 (6%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	36/470 (7.66%)	Mean 7.66%	SD 3.33%	
.....									
*Bone Marrow:									
Lipoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						0/50 (0%)		0/53 (0%)	1/53 (2%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Bone:									
Osteosarcoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Male					Female					
*Brain:										
Astrocytoma Benign										
					0/53	(0%)	0/53	(0%)	0/52	(0%)
					0/53	(0%)	0/53	(0%)	0/53	(0%)
		1/50	(2%)		0/50	(0%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	0/473	(0%)	Mean 0%	SD 0%
.....										
*Brain:										
Astrocytoma Malignant										
					0/53	(0%)	0/53	(0%)	0/52	(0%)
					0/53	(0%)	0/53	(0%)	0/53	(0%)
		0/50	(0%)		0/50	(0%)	2/53	(4%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.42%	SD 1.26%
.....										
*Brain:										
Medulloblastoma Mal										
					0/53	(0%)	0/53	(0%)	0/52	(0%)
					1/53	(2%)	0/53	(0%)	0/53	(0%)
		0/50	(0%)		0/50	(0%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%
.....										
*Brain:										
Oligodendroglioma Malignant										
					0/53	(0%)	0/53	(0%)	0/52	(0%)
					0/53	(0%)	0/53	(0%)	0/53	(0%)
		0/50	(0%)		0/50	(0%)	1/53	(2%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

		Male				Female			
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		1/50 (2%)				0/50 (0%)		3/53 (6%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/473 (0.63%)	Mean 0.63%	SD 1.89%	
.....									
*Clitoral/Preputial Gland:									
Adenoma									
						1/53 (2%)		0/51 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		0/50 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/465 (0.22%)	Mean 0.21%	SD 0.63%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
						1/53 (2%)		0/51 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		0/50 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/465 (0.22%)	Mean 0.21%	SD 0.63%	
.....									
#Ear:									
Neural Crest Tumor									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Eye:									
Schwannoma Malignant									
						0/53 (0%)	0/53 (0%)	0/52 (0%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Hemangiosarcoma									
						0/53 (0%)	0/53 (0%)	0/52 (0%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		0/50 (0%)				0/50 (0%)	0/52 (0%)	1/52 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/471 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
*Heart:									
Schwannoma Malignant									
						0/53 (0%)	2/53 (4%)	0/52 (0%)	
						0/53 (0%)	1/53 (2%)	0/53 (0%)	
		0/50 (0%)				0/50 (0%)	0/52 (0%)	0/52 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.63%	SD 1.33%	
.....									
#Intestine Large: Cecum:									
Leiomyoma									
						0/53 (0%)	0/53 (0%)	0/52 (0%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		0/50 (0%)				0/50 (0%)	0/53 (0%)	1/53 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 12

Report Date: 11/13/2008

					Male						Female			
#Intestine Large: Colon/Rectum: Carcinoma														
						0/53	(0%)			1/53	(2%)	0/52	(0%)	
						0/53	(0%)			0/53	(0%)	0/53	(0%)	
						0/50	(0%)			0/53	(0%)	0/53	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean	0%	SD	0%	Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%
.....														
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma														
						0/53	(0%)			1/53	(2%)	0/52	(0%)	
						0/53	(0%)			0/53	(0%)	0/53	(0%)	
						0/50	(0%)			0/53	(0%)	0/53	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean	0%	SD	0%	Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%
.....														
#Intestine Small: Duodenum: Carcinoma														
						0/53	(0%)			0/53	(0%)	0/52	(0%)	
						0/53	(0%)			0/53	(0%)	0/53	(0%)	
						1/50	(2%)			0/53	(0%)	0/53	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean	0%	SD	0%	Total	1/473	(0.21%)	Mean	0.22%	SD	0.67%
.....														
#Intestine Small: Jejunum: Leiomyosarcoma														
						1/53	(2%)			1/53	(2%)	0/52	(0%)	
						0/53	(0%)			0/53	(0%)	0/53	(0%)	
						0/50	(0%)			0/53	(0%)	0/53	(0%)	
Overall Incidence	Total	0/50	(0%)	Mean	0%	SD	0%	Total	2/473	(0.42%)	Mean	0.42%	SD	0.83%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

Page: 13

Report Date: 11/13/2008

		Male				Female			
#Intestine Small: Site Unspecified: Carcinoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
#Intestine Small: Site Unspecified: Carcinoma or Adenoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
#Intestine Small: Site Unspecified: Leiomyosarcoma									
						1/53 (2%)		1/53 (2%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
*Islets, Pancreatic: Adenoma									
						1/53 (2%)		1/52 (2%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	1/51 (2%)
		2/50 (4%)				0/50 (0%)		0/52 (0%)	1/53 (2%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	5/469 (1.07%)	Mean 1.06%	SD 1.01%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Islets, Pancreatic: Carcinoma									
						0/53 (0%)		1/52 (2%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	1/51 (2%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/469 (0.64%)	Mean 0.64%	SD 0.96%	
.....									
*Islets, Pancreatic: Carcinoma or Adenoma									
						1/53 (2%)		2/52 (4%)	0/52 (0%)
						2/53 (4%)		0/53 (0%)	2/51 (4%)
		2/50 (4%)				0/50 (0%)		0/52 (0%)	1/53 (2%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	8/469 (1.71%)	Mean 1.7%	SD 1.78%	
.....									
*Kidney: Renal Tubule: Adenoma									
						1/53 (2%)		0/52 (0%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
*Kidney: Renal Tubule: Carcinoma									
						0/53 (0%)		1/52 (2%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/472 (0.21%)	Mean 0.21%	SD 0.64%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma									
						1/53 (2%)		1/52 (2%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/472 (0.64%)	Mean 0.63%	SD 0.95%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
						0/53 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/472 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
*Kidney: Renal Tubule: Lipoma									
						0/53 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		1/53 (2%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.43%	SD 0.86%	
.....									
*Kidney: Renal Tubule: Nephroblastoma									
						0/53 (0%)		1/52 (2%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.42%	SD 0.84%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Liver:									
Cholangiocarcinoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
*Liver:									
Cholangioma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
*Liver:									
Hemangioma									
						1/53 (2%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
						0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
*Liver:									
Hepatocellular Adenoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						2/53 (4%)		1/53 (2%)	0/53 (0%)
						2/50 (4%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female			
*Liver:								
Hepatocellular Carcinoma or Hepatocellular Adenoma								
					0/53 (0%)	0/53 (0%)	0/52 (0%)	
					2/53 (4%)	1/53 (2%)	0/53 (0%)	
					2/50 (4%)	1/53 (2%)	0/53 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%
.....								
*Liver:								
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma								
					0/53 (0%)	0/53 (0%)	0/52 (0%)	
					2/53 (4%)	1/53 (2%)	0/53 (0%)	
					2/50 (4%)	1/53 (2%)	0/53 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	6/473 (1.27%)	Mean 1.28%	SD 1.68%
.....								
*Lung:								
Alveolar/Bronchiolar Adenoma								
					0/53 (0%)	0/53 (0%)	0/51 (0%)	
					0/53 (0%)	0/53 (0%)	0/53 (0%)	
					0/50 (0%)	1/53 (2%)	1/52 (2%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/471 (0.42%)	Mean 0.42%	SD 0.84%
.....								
*Lung:								
Alveolar/Bronchiolar Carcinoma								
					0/53 (0%)	0/53 (0%)	0/51 (0%)	
					0/53 (0%)	0/53 (0%)	0/53 (0%)	
					0/50 (0%)	0/53 (0%)	0/52 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/471 (0%)	Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female		
*Lung:							
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma							
					0/53 (0%)	0/53 (0%)	0/51 (0%)
					0/53 (0%)	0/53 (0%)	0/53 (0%)
		2/50 (4%)			0/50 (0%)	1/53 (2%)	1/52 (2%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total 2/471 (0.42%)	Mean 0.42%	SD 0.84%
.....							
#Lymph Node, Mesenteric:							
Hemangiosarcoma							
					0/53 (0%)	0/53 (0%)	0/52 (0%)
					0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)			0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%
.....							
#Mammary Gland:							
Adenoma							
					2/53 (4%)	0/53 (0%)	0/52 (0%)
					2/53 (4%)	1/53 (2%)	2/53 (4%)
		0/50 (0%)			1/50 (2%)	2/53 (4%)	2/53 (4%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 12/473 (2.54%)	Mean 2.53%	SD 1.63%
.....							
#Mammary Gland:							
Carcinoma							
					8/53 (15%)	6/53 (11%)	2/52 (4%)
					5/53 (9%)	5/53 (9%)	4/53 (8%)
		0/50 (0%)			4/50 (8%)	6/53 (11%)	8/53 (15%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 48/473 (10.15%)	Mean 10.12%	SD 3.6%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Mammary Gland: Carcinoma or Adenoma									
						10/53 (19%)	6/53 (11%)	2/52 (4%)	
						6/53 (11%)	6/53 (11%)	6/53 (11%)	
						5/50 (10%)	7/53 (13%)	9/53 (17%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	57/473 (12.05%)	Mean 12.02%	SD 4.27%	
.....									
#Mammary Gland: Fibroadenoma									
						40/53 (75%)	34/53 (64%)	25/52 (48%)	
						42/53 (79%)	34/53 (64%)	33/53 (62%)	
						31/50 (62%)	39/53 (74%)	41/53 (77%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	319/473 (67.44%)	Mean 67.37%	SD 9.96%	
.....									
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma									
						40/53 (75%)	34/53 (64%)	25/52 (48%)	
						42/53 (79%)	35/53 (66%)	35/53 (66%)	
						31/50 (62%)	40/53 (75%)	41/53 (77%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	323/473 (68.29%)	Mean 68.21%	SD 9.88%	
.....									
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
						42/53 (79%)	37/53 (70%)	27/52 (52%)	
						42/53 (79%)	38/53 (72%)	35/53 (66%)	
						32/50 (64%)	42/53 (79%)	43/53 (81%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	338/473 (71.46%)	Mean 71.37%	SD 9.65%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Mesentery:									
Schwannoma Malignant									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
						0/53 (0%)		1/53 (2%)	0/52 (0%)
						1/53 (2%)		1/53 (2%)	1/53 (2%)
		1/50 (2%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
						0/53 (0%)		1/53 (2%)	0/52 (0%)
						1/53 (2%)		1/53 (2%)	1/53 (2%)
		1/50 (2%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%	
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
						0/53 (0%)		1/53 (2%)	0/52 (0%)
						1/53 (2%)		1/53 (2%)	1/53 (2%)
		1/50 (2%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

Page: 21

Report Date: 11/13/2008

	Male	Female
*Ovary:		
Cystadenoma		
	0/53 (0%)	0/52 (0%)
	0/53 (0%)	0/53 (0%)
	0/50 (0%)	0/52 (0%)
Overall Incidence	Total 1/469 (0.21%)	Mean 0.21% SD 0.63%
.....		
*Ovary:		
Granulosa Cell Tumor Malignant		
	1/53 (2%)	0/52 (0%)
	1/53 (2%)	0/53 (0%)
	1/50 (2%)	0/52 (0%)
Overall Incidence	Total 3/469 (0.64%)	Mean 0.64% SD 0.96%
.....		
*Ovary:		
Granulosa Cell Tumor: Benign, Malignant, NOS		
	1/53 (2%)	0/52 (0%)
	1/53 (2%)	0/53 (0%)
	1/50 (2%)	0/52 (0%)
Overall Incidence	Total 3/469 (0.64%)	Mean 0.64% SD 0.96%
.....		
*Ovary:		
Luteoma		
	0/53 (0%)	0/52 (0%)
	1/53 (2%)	1/53 (2%)
	0/50 (0%)	0/52 (0%)
Overall Incidence	Total 3/469 (0.64%)	Mean 0.63% SD 0.95%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Pancreas:									
Adenoma									
						0/53 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/51 (0%)
		9/50 (18%)				0/50 (0%)		1/51 (2%)	0/53 (0%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.65%	
.....									
*Pancreas:									
Carcinoma									
						0/53 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/51 (0%)
		0/50 (0%)				1/50 (2%)		0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
*Pancreas:									
Carcinoma or Adenoma									
						0/53 (0%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/51 (0%)
		9/50 (18%)				1/50 (2%)		1/51 (2%)	0/53 (0%)
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/468 (0.43%)	Mean 0.44%	SD 0.87%	
.....									
*Parathyroid Gland:									
Adenoma									
						0/45 (0%)		1/50 (2%)	0/47 (0%)
						0/50 (0%)		0/49 (0%)	0/46 (0%)
		1/43 (2%)				0/46 (0%)		0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/43 (2.33%)	Mean 2.33%	SD 0%	Total	1/429 (0.23%)	Mean 0.22%	SD 0.67%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Peripheral Nerve:									
Schwannoma Malignant									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
#Peripheral Nerve:									
Schwannoma: Benign, Malignant, NOS									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				1/50 (2%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
						22/53 (42%)		28/53 (53%)	17/52 (33%)
						30/53 (57%)		15/53 (28%)	25/53 (47%)
		13/50 (26%)				13/50 (26%)		15/51 (29%)	18/53 (34%)
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	183/471 (38.85%)	Mean 38.72%	SD 11.26%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
						1/53 (2%)		0/53 (0%)	2/52 (4%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.64%	SD 1.36%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female		
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma							
					23/53 (43%)	28/53 (53%)	19/52 (37%)
					30/53 (57%)	15/53 (28%)	25/53 (47%)
		13/50 (26%)			13/50 (26%)	15/51 (29%)	18/53 (34%)
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total 186/471 (39.49%)	Mean 39.36%	SD 11.14%
.....							
*Pituitary Gland: Pars Intermedia: Adenoma							
					0/53 (0%)	0/53 (0%)	0/52 (0%)
					1/53 (2%)	0/53 (0%)	2/53 (4%)
		0/50 (0%)			1/50 (2%)	1/51 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 5/471 (1.06%)	Mean 1.07%	SD 1.39%
.....							
*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma							
					0/53 (0%)	0/53 (0%)	0/52 (0%)
					1/53 (2%)	0/53 (0%)	2/53 (4%)
		0/50 (0%)			1/50 (2%)	1/51 (2%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 5/471 (1.06%)	Mean 1.07%	SD 1.39%
.....							
*Prostate: Adenoma							
		5/50 (10%)					
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008
 Contract/Lab: All Laboratories
 Species: Sprague-Dawley Rats
 Strain: SD
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

Page: 25
 Report Date: 11/13/2008

		Male				Female			
*Prostate:									
Carcinoma or Adenoma									
		5/50	(10%)						
Overall Incidence	Total	5/50	(10%)	Mean 10%	SD 0%				
.....									
*Salivary Glands:									
Schwannoma Malignant									
		1/50	(2%)			0/53	(0%)	0/53	(0%)
		1/50	(2%)			0/53	(0%)	0/51	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	0/50	(0%)	0/51	(0%)
						Total	0/466	(0%)	Mean 0%
									SD 0%
.....									
#Skeletal Muscle:									
Fibrous Histiocytoma									
		0/50	(0%)			1/53	(2%)	0/53	(0%)
		0/50	(0%)			0/53	(0%)	0/52	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	0/50	(0%)	0/53	(0%)
						Total	1/473	(0.21%)	Mean 0.21%
									SD 0.63%
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma									
		0/50	(0%)			0/53	(0%)	0/53	(0%)
		0/50	(0%)			0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	1/50	(2%)	0/53	(0%)
						Total	1/473	(0.21%)	Mean 0.22%
									SD 0.67%

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

		Male				Female					
#Skeletal Muscle:											
Rhabdomyosarcoma or Rhabdomyoma											
						0/53	(0%)	0/53	(0%)	0/52	(0%)
						0/53	(0%)	0/53	(0%)	0/53	(0%)
		0/50	(0%)			1/50	(2%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.22%	SD 0.67%	
.....											
#Skin:											
Basal Cell Adenoma											
						0/53	(0%)	0/53	(0%)	0/52	(0%)
						1/53	(2%)	0/53	(0%)	0/53	(0%)
		1/50	(2%)			0/50	(0%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%	
.....											
#Skin:											
Basal Cell Adenoma or Basosquamous Tumor Benign											
						0/53	(0%)	0/53	(0%)	0/52	(0%)
						1/53	(2%)	0/53	(0%)	0/53	(0%)
		1/50	(2%)			0/50	(0%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%	
.....											
#Skin:											
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
						0/53	(0%)	0/53	(0%)	0/52	(0%)
						1/53	(2%)	0/53	(0%)	0/53	(0%)
		1/50	(2%)			0/50	(0%)	0/53	(0%)	0/53	(0%)
Overall Incidence	Total	1/50	(2%)	Mean 2%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Skin:									
Basal Cell Carcinoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	1/53 (2%)
		1/50 (2%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						2/53 (4%)		0/53 (0%)	1/53 (2%)
		3/50 (6%)				0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	5/473 (1.06%)	Mean 1.05%	SD 1.37%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female		
#Skin:							
Fibroma							
					2/53 (4%)	1/53 (2%)	2/52 (4%)
					1/53 (2%)	0/53 (0%)	1/53 (2%)
		5/50 (10%)			0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 8/473 (1.69%)	Mean 1.69%	SD 1.49%
.....							
#Skin:							
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma							
					2/53 (4%)	2/53 (4%)	2/52 (4%)
					1/53 (2%)	0/53 (0%)	1/53 (2%)
		5/50 (10%)			0/50 (0%)	1/53 (2%)	0/53 (0%)
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total 9/473 (1.9%)	Mean 1.89%	SD 1.64%
.....							
#Skin:							
Fibrosarcoma							
					0/53 (0%)	1/53 (2%)	0/52 (0%)
					0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)			0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%
.....							
#Skin:							
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma							
					0/53 (0%)	1/53 (2%)	0/52 (0%)
					0/53 (0%)	0/53 (0%)	0/53 (0%)
		0/50 (0%)			0/50 (0%)	0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Skin:									
Hemangiosarcoma									
						0/53 (0%)	0/53 (0%)	1/52 (2%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
#Skin:									
Keratoacanthoma									
						0/53 (0%)	0/53 (0%)	1/52 (2%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		2/50 (4%)				0/50 (0%)	1/53 (2%)	0/53 (0%)	
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%	
.....									
#Skin:									
Neural Crest Tumor									
						0/53 (0%)	0/53 (0%)	0/52 (0%)	
						0/53 (0%)	0/53 (0%)	0/53 (0%)	
		1/50 (2%)				0/50 (0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
						0/53 (0%)	0/53 (0%)	1/52 (2%)	
						0/53 (0%)	0/53 (0%)	1/53 (2%)	
		0/50 (0%)				0/50 (0%)	0/53 (0%)	0/53 (0%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

					Male						Female				
#Skin:															
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)															
					0/53	(0%)						0/53	(0%)	1/52	(2%)
					0/53	(0%)						0/53	(0%)	1/53	(2%)
					0/50	(0%)						0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.42%	SD 0.84%					
.....															
#Skin:															
Schwannoma Malignant															
					0/53	(0%)						0/53	(0%)	1/52	(2%)
					0/53	(0%)						0/53	(0%)	1/53	(2%)
					0/50	(0%)						0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.42%	SD 0.84%					
.....															
#Skin:															
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma															
					0/53	(0%)						0/53	(0%)	0/52	(0%)
					0/53	(0%)						0/53	(0%)	1/53	(2%)
					0/50	(0%)						0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
#Skin:															
Squamous Cell Papilloma															
					0/53	(0%)						0/53	(0%)	0/52	(0%)
					1/53	(2%)						0/53	(0%)	0/53	(0%)
					0/50	(0%)						0/53	(0%)	0/53	(0%)
Overall Incidence	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
*: Denominator is number of animals with tissues examined microscopically															
#: Denominator is number of animals necropsied															

		Male				Female			
#Skin:									
Squamous Cell Papilloma or Papilloma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						1/53 (2%)		0/53 (0%)	0/53 (0%)
		2/50 (4%)				0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	3/473 (0.63%)	Mean 0.63%	SD 0.95%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						1/53 (2%)		0/53 (0%)	0/53 (0%)
		2/50 (4%)				0/50 (0%)		1/53 (2%)	0/53 (0%)
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	3/473 (0.63%)	Mean 0.63%	SD 0.95%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008
 Contract/Lab: All Laboratories
 Species: Sprague-Dawley Rats
 Strain: SD
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

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		Male				Female			
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						1/53 (2%)		0/53 (0%)	1/53 (2%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
*Testes:									
Adenoma									
		2/50 (4%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%					
.....									
*Thymus:									
Thymoma Benign									
						0/53 (0%)		0/52 (0%)	0/51 (0%)
						1/53 (2%)		0/53 (0%)	0/51 (0%)
		0/48 (0%)				0/50 (0%)		0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/461 (0.22%)	Mean 0.21%	SD 0.63%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
						0/53 (0%)		0/52 (0%)	0/51 (0%)
						1/53 (2%)		0/53 (0%)	0/51 (0%)
		0/48 (0%)				0/50 (0%)		0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/461 (0.22%)	Mean 0.21%	SD 0.63%	

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

		Male			Female		
*Thyroid Gland: C-Cell: Adenoma							
					10/53 (19%)	17/53 (32%)	9/51 (18%)
					9/53 (17%)	13/53 (25%)	20/52 (38%)
		13/50 (26%)			10/50 (20%)	15/52 (29%)	16/51 (31%)
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total 119/468 (25.43%)	Mean 25.42%	SD 7.63%
.....							
*Thyroid Gland: C-Cell: Carcinoma							
					4/53 (8%)	2/53 (4%)	2/51 (4%)
					4/53 (8%)	2/53 (4%)	1/52 (2%)
		1/50 (2%)			1/50 (2%)	0/52 (0%)	2/51 (4%)
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total 18/468 (3.85%)	Mean 3.82%	SD 2.48%
.....							
*Thyroid Gland: C-Cell: Carcinoma or Adenoma							
					13/53 (25%)	18/53 (34%)	11/51 (22%)
					13/53 (25%)	15/53 (28%)	21/52 (40%)
		13/50 (26%)			11/50 (22%)	15/52 (29%)	18/51 (35%)
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total 135/468 (28.85%)	Mean 28.82%	SD 6.5%
.....							
*Thyroid Gland: Follicular Cell: Adenoma							
					0/53 (0%)	0/53 (0%)	1/51 (2%)
					0/53 (0%)	0/53 (0%)	1/52 (2%)
		0/50 (0%)			0/50 (0%)	0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total 2/468 (0.43%)	Mean 0.43%	SD 0.86%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma									
						0/53 (0%)		0/53 (0%)	0/51 (0%)
						1/53 (2%)		0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
						0/53 (0%)		0/53 (0%)	1/51 (2%)
						1/53 (2%)		0/53 (0%)	1/52 (2%)
		0/50 (0%)				0/50 (0%)		0/52 (0%)	0/51 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/468 (0.64%)	Mean 0.64%	SD 0.96%	
.....									
#Tooth: Fibrosarcoma									
						0/53 (0%)		1/53 (2%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Tooth: Neurofibrosarcoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	1/53 (2%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008
 Contract/Lab: All Laboratories
 Species: Sprague-Dawley Rats
 Strain: SD
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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		Male				Female			
#Tooth:									
Odontoma									
						0/53 (0%)		0/53 (0%)	1/52 (2%)
						0/53 (0%)		0/53 (0%)	0/53 (0%)
		0/50 (0%)				0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
*Urinary Bladder:									
Carcinoma or Papilloma									
						1/53 (2%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)		0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
*Urinary Bladder:									
Papilloma									
						1/53 (2%)		0/52 (0%)	0/52 (0%)
						0/53 (0%)		0/53 (0%)	0/52 (0%)
		0/50 (0%)				0/50 (0%)		0/51 (0%)	0/53 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
#Uterus:									
Adenoma									
						0/53 (0%)		0/53 (0%)	0/52 (0%)
						0/53 (0%)		2/53 (4%)	0/53 (0%)
						0/50 (0%)		0/53 (0%)	0/53 (0%)
Overall Incidence	Total				Total	2/473 (0.42%)	Mean 0.42%	SD 1.26%	

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

Version: Nov2008
 Contract/Lab: All Laboratories
 Species: Sprague-Dawley Rats
 Strain: SD
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: ALL ROUTES
 Vehicle: ALL VEHICLES

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 Report Date: 11/13/2008

	Male	Female
#Uterus:		
Carcinoma		
	0/53 (0%)	1/53 (2%)
	1/53 (2%)	1/53 (2%)
	1/50 (2%)	0/53 (0%)
Overall Incidence	Total 6/473 (1.27%)	Mean 1.28% SD 1.36%
.....		
#Uterus:		
Fibroma		
	0/53 (0%)	0/53 (0%)
	0/53 (0%)	1/53 (2%)
	0/50 (0%)	0/53 (0%)
Overall Incidence	Total 1/473 (0.21%)	Mean 0.21% SD 0.63%
.....		
#Uterus:		
Leiomyoma		
	0/53 (0%)	0/53 (0%)
	0/53 (0%)	1/53 (2%)
	0/50 (0%)	0/53 (0%)
Overall Incidence	Total 1/473 (0.21%)	Mean 0.21% SD 0.63%
.....		
#Uterus:		
Leiomyosarcoma		
	0/53 (0%)	1/53 (2%)
	0/53 (0%)	0/53 (0%)
	0/50 (0%)	0/53 (0%)
Overall Incidence	Total 1/473 (0.21%)	Mean 0.21% SD 0.63%

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

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

	Male	Female
#Uterus:		
Polyp Stromal		
	8/53 (15%)	4/53 (8%)
	11/53 (21%)	9/53 (17%)
	8/50 (16%)	4/53 (8%)
Overall Incidence	Total 65/473 (13.74%)	Mean 13.74% SD 5.66%
.....		
#Uterus:		
Sarcoma Stromal or Polyp Stromal		
	8/53 (15%)	4/53 (8%)
	11/53 (21%)	9/53 (17%)
	8/50 (16%)	4/53 (8%)
Overall Incidence	Total 65/473 (13.74%)	Mean 13.74% SD 5.66%
.....		
#Uterus:		
Schwannoma Malignant		
	0/53 (0%)	1/53 (2%)
	1/53 (2%)	0/53 (0%)
	0/50 (0%)	0/53 (0%)
Overall Incidence	Total 4/473 (0.85%)	Mean 0.84% SD 1%
.....		
#Uterus:		
Squamous Cell Carcinoma		
	1/53 (2%)	0/53 (0%)
	0/53 (0%)	0/53 (0%)
	1/50 (2%)	0/53 (0%)
Overall Incidence	Total 2/473 (0.42%)	Mean 0.43% SD 0.86%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Nov2008
 Contract/Lab: All Laboratories
 Species: Sprague-Dawley Rats
 Strain: SD
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ALL ROUTES
Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

	Male		Female
#Uterus:			
Squamous Cell Papilloma			
		0/53 (0%)	1/53 (2%)
		0/53 (0%)	0/53 (0%)
		0/50 (0%)	0/53 (0%)
Overall Incidence	Total	2/473 (0.42%)	Mean 0.42% SD 0.83%
.....			
#Vagina:			
Polyp			
		0/53 (0%)	0/53 (0%)
		0/53 (0%)	1/52 (2%)
		0/50 (0%)	0/53 (0%)
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21% SD 0.64%
.....			
#Vagina:			
Sarcoma			
		0/53 (0%)	0/53 (0%)
		0/53 (0%)	0/53 (0%)
		0/50 (0%)	1/53 (2%)
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21% SD 0.63%
.....			
#Vagina:			
Schwannoma Malignant			
		0/53 (0%)	0/53 (0%)
		0/53 (0%)	0/53 (0%)
		0/50 (0%)	1/53 (2%)
Overall Incidence	Total	1/473 (0.21%)	Mean 0.21% SD 0.63%

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

Version: Nov2008

Contract/Lab: All Laboratories

Species: Sprague-Dawley Rats

Strain: SD

Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups

Route: ALL ROUTES

Vehicle: ALL VEHICLES

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Report Date: 11/13/2008

					Male						Female			
#Vagina:														
Squamous Cell Carcinoma														
					1/53	(2%)	0/53	(0%)	1/52	(2%)				
					0/53	(0%)	0/53	(0%)	0/53	(0%)				
					0/50	(0%)	0/53	(0%)	0/53	(0%)				
Overall Incidence					Total	2/473	(0.42%)	Mean	0.42%	SD	0.84%			
.....														
#Vagina:														
Squamous Cell Papilloma														
					0/53	(0%)	0/53	(0%)	0/52	(0%)				
					0/53	(0%)	1/53	(2%)	0/53	(0%)				
					0/50	(0%)	0/53	(0%)	0/53	(0%)				
Overall Incidence					Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%			
.....														
#Zymbal's Gland:														
Carcinoma														
					0/53	(0%)	0/53	(0%)	0/52	(0%)				
					0/53	(0%)	0/53	(0%)	1/53	(2%)				
					1/50	(2%)	0/53	(0%)	0/53	(0%)				
Overall Incidence	Total	1/50	(2%)	Mean	2%	SD	0%	Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%
.....														
#Zymbal's Gland:														
Carcinoma or Adenoma														
					0/53	(0%)	0/53	(0%)	0/52	(0%)				
					0/53	(0%)	0/53	(0%)	1/53	(2%)				
					1/50	(2%)	0/53	(0%)	0/53	(0%)				
Overall Incidence	Total	1/50	(2%)	Mean	2%	SD	0%	Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied