

NTP Historical Controls Report

All Routes And Vehicles

Sprague-Dawley Rats

November 2008

# REPORT DESCRIPTION

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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:

<b>Male</b>			<b>Female</b>		
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
<b>Male</b>							
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)
<b>Female</b>							
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)

		Male			Female		
<b>#All Organs:</b>							
<b>Benign Tumors</b>							
					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%)
<b>Overall Incidence</b>	Total	40/50 (80%)	Mean 80%	SD 0%	Total 415/473 (87.74%)	Mean 87.68%	SD 6.46%
.....							
<b>#All Organs:</b>							
<b>Malignant Tumors</b>							
					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%)
<b>Overall Incidence</b>	Total	9/50 (18%)	Mean 18%	SD 0%	Total 126/473 (26.64%)	Mean 26.64%	SD 3.75%
.....							
<b>#All Organs:</b>							
<b>Malignant and Benign Tumors</b>							
					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%)
<b>Overall Incidence</b>	Total	44/50 (88%)	Mean 88%	SD 0%	Total 443/473 (93.66%)	Mean 93.62%	SD 4.23%
.....							
<b>#All Organs:</b>							
<b>Hemangioma</b>							
					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%)
<b>Overall Incidence</b>	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					
<b>#All Organs:</b>										
<b>Hemangiosarcoma</b>										
					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%)
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	4/473	(0.85%)	Mean 0.84%	SD 1.37%
.....										
<b>#All Organs:</b>										
<b>Hemangiosarcoma or Hemangioma</b>										
					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%)
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	5/473	(1.06%)	Mean 1.05%	SD 1.37%
.....										
<b>#All Organs:</b>										
<b>Histiocytic Sarcoma</b>										
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.44%	SD 0.87%
.....										
<b>#All Organs:</b>										
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>										
					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%)
<b>Overall Incidence</b>	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				
<b>#All Organs:</b>															
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>															
					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%)
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean 2%	SD 0%	Total	6/473	(1.27%)	Mean 1.27%	SD 1.9%					
.....															
<b>#All Organs:</b>															
<b>Osteosarcoma</b>															
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
<b>#All Organs:</b>															
<b>Osteosarcoma or Osteoma</b>															
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
<b>*Adrenal Cortex:</b>															
<b>Adenoma</b>															
					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%)
<b>Overall Incidence</b>	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			
<b>*Adrenal Cortex: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	3/471 (0.64%)	<b>Mean</b> 0.63%	<b>SD</b> 0.95%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Benign</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	5/50 (10%)	<b>Mean</b> 10%	<b>SD</b> 0%	<b>Total</b>	34/470 (7.23%)	<b>Mean</b> 7.24%	<b>SD</b> 3.44%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Complex</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	1/470 (0.21%)	<b>Mean</b> 0.21%	<b>SD</b> 0.63%	
.....									
<b>*Adrenal Medulla: Pheochromocytoma Malignant</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	1/470 (0.21%)	<b>Mean</b> 0.21%	<b>SD</b> 0.63%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
<b>*Adrenal Medulla:</b>									
<b>Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
						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%)
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%	Total	36/470 (7.66%)	Mean 7.66%	SD 3.33%	
.....									
<b>*Bone Marrow:</b>									
<b>Lipoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Bone:</b>									
<b>Osteosarcoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Bone:</b>									
<b>Osteosarcoma or Osteoma</b>									
						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%)
<b>Overall Incidence</b>	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					
<b>*Brain:</b>										
<b>Astrocytoma Benign</b>										
					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%)
<b>Overall Incidence</b>	<b>Total</b>	1/50	(2%)	<b>Mean 2%</b>	<b>SD 0%</b>	<b>Total</b>	0/473	(0%)	<b>Mean 0%</b>	<b>SD 0%</b>
.....										
<b>*Brain:</b>										
<b>Astrocytoma Malignant</b>										
					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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50	(0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	2/473	(0.42%)	<b>Mean 0.42%</b>	<b>SD 1.26%</b>
.....										
<b>*Brain:</b>										
<b>Medulloblastoma Mal</b>										
					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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50	(0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	1/473	(0.21%)	<b>Mean 0.21%</b>	<b>SD 0.63%</b>
.....										
<b>*Brain:</b>										
<b>Oligodendroglioma Malignant</b>										
					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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50	(0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	1/473	(0.21%)	<b>Mean 0.21%</b>	<b>SD 0.63%</b>

\*: 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			
<b>*Brain:</b>									
<b>Oligodendroglioma, Glioma, or Astrocytoma</b>									
						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%)	
<b>Overall Incidence</b>	<b>Total</b>	1/50 (2%)	<b>Mean 2%</b>	<b>SD 0%</b>	<b>Total</b>	3/473 (0.63%)	<b>Mean 0.63%</b>	<b>SD 1.89%</b>	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>Adenoma</b>									
						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%)	
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	1/465 (0.22%)	<b>Mean 0.21%</b>	<b>SD 0.63%</b>	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>Carcinoma or Adenoma</b>									
						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%)	
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	1/465 (0.22%)	<b>Mean 0.21%</b>	<b>SD 0.63%</b>	
.....									
<b>#Ear:</b>									
<b>Neural Crest Tumor</b>									
						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%)	
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	1/473 (0.21%)	<b>Mean 0.21%</b>	<b>SD 0.63%</b>	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
<b>#Eye:</b>									
<b>Schwannoma Malignant</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%	
.....									
<b>*Heart:</b>									
<b>Hemangiosarcoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/471 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
<b>*Heart:</b>									
<b>Schwannoma Malignant</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/471 (0.64%)	Mean 0.63%	SD 1.33%	
.....									
<b>#Intestine Large: Cecum:</b>									
<b>Leiomyoma</b>									
						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%)
<b>Overall Incidence</b>	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			
<b>#Intestine Large: Colon/Rectum: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Intestine Large: Colon/Rectum: Carcinoma or Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Intestine Small: Duodenum: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
<b>#Intestine Small: Jejunum: Leiomyosarcoma</b>									
						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%)
<b>Overall Incidence</b>	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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Report Date: 11/13/2008

		Male				Female			
<b>#Intestine Small: Site Unspecified: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
<b>#Intestine Small: Site Unspecified: Carcinoma or Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
<b>#Intestine Small: Site Unspecified: Leiomyosarcoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
<b>*Islets, Pancreatic: Adenoma</b>									
						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%)
<b>Overall Incidence</b>	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			
<b>*Islets, Pancreatic: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/469 (0.64%)	Mean 0.64%	SD 0.96%	
.....									
<b>*Islets, Pancreatic: Carcinoma or Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%	Total	8/469 (1.71%)	Mean 1.7%	SD 1.78%	
.....									
<b>*Kidney: Renal Tubule: Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/472 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
<b>*Kidney: Renal Tubule: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	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

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

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female		
<b>*Lung:</b>							
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%	Total 2/471 (0.42%)	Mean 0.42%	SD 0.84%
.....							
<b>#Lymph Node, Mesenteric:</b>							
<b>Hemangiosarcoma</b>							
					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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%
.....							
<b>#Mammary Gland:</b>							
<b>Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 12/473 (2.54%)	Mean 2.53%	SD 1.63%
.....							
<b>#Mammary Gland:</b>							
<b>Carcinoma</b>							
					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%)
<b>Overall Incidence</b>	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

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			
<b>#Mammary Gland: Carcinoma or Adenoma</b>									
						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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	57/473 (12.05%)	Mean 12.02%	SD 4.27%	
.....									
<b>#Mammary Gland: Fibroadenoma</b>									
						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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	319/473 (67.44%)	Mean 67.37%	SD 9.96%	
.....									
<b>#Mammary Gland: Fibroma, Fibroadenoma or Adenoma</b>									
						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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	323/473 (68.29%)	Mean 68.21%	SD 9.88%	
.....									
<b>#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma</b>									
						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%)	
<b>Overall Incidence</b>	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			
<b>#Mesentery:</b>									
<b>Schwannoma Malignant</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%	
.....									
<b>#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):</b>									
<b>Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	4/473 (0.85%)	Mean 0.84%	SD 0.99%	
.....									
<b>#Oral Mucosa:</b>									
<b>Squamous Cell Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	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

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Report Date: 11/13/2008

	Male		Female	
<hr/>				
*Ovary:				
Cystadenoma				
		0/53 (0%)	0/52 (0%)	0/52 (0%)
		0/53 (0%)	0/53 (0%)	0/51 (0%)
		0/50 (0%)	0/52 (0%)	1/53 (2%)
Overall Incidence		Total 1/469 (0.21%)	Mean 0.21%	SD 0.63%
<hr/>				
*Ovary:				
Granulosa Cell Tumor Malignant				
		1/53 (2%)	0/52 (0%)	0/52 (0%)
		1/53 (2%)	0/53 (0%)	0/51 (0%)
		1/50 (2%)	0/52 (0%)	0/53 (0%)
Overall Incidence		Total 3/469 (0.64%)	Mean 0.64%	SD 0.96%
<hr/>				
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		1/53 (2%)	0/52 (0%)	0/52 (0%)
		1/53 (2%)	0/53 (0%)	0/51 (0%)
		1/50 (2%)	0/52 (0%)	0/53 (0%)
Overall Incidence		Total 3/469 (0.64%)	Mean 0.64%	SD 0.96%
<hr/>				
*Ovary:				
Luteoma				
		0/53 (0%)	0/52 (0%)	1/52 (2%)
		1/53 (2%)	1/53 (2%)	0/51 (0%)
		0/50 (0%)	0/52 (0%)	0/53 (0%)
Overall Incidence		Total 3/469 (0.64%)	Mean 0.63%	SD 0.95%
<hr/>				

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
<b>*Pancreas:</b>									
<b>Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	9/50 (18%)	Mean 18%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.65%	
.....									
<b>*Pancreas:</b>									
<b>Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
<b>*Pancreas:</b>									
<b>Carcinoma or Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	9/50 (18%)	Mean 18%	SD 0%	Total	2/468 (0.43%)	Mean 0.44%	SD 0.87%	
.....									
<b>*Parathyroid Gland:</b>									
<b>Adenoma</b>									
						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%)
<b>Overall Incidence</b>	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			
<b>#Peripheral Nerve:</b>									
<b>Schwannoma Malignant</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	1/473 (0.21%)	<b>Mean</b> 0.22%	<b>SD</b> 0.67%	
.....									
<b>#Peripheral Nerve:</b>									
<b>Schwannoma: Benign, Malignant, NOS</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	1/473 (0.21%)	<b>Mean</b> 0.22%	<b>SD</b> 0.67%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Adenoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	13/50 (26%)	<b>Mean</b> 26%	<b>SD</b> 0%	<b>Total</b>	183/471 (38.85%)	<b>Mean</b> 38.72%	<b>SD</b> 11.26%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	3/471 (0.64%)	<b>Mean</b> 0.64%	<b>SD</b> 1.36%	

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male			Female		
<b>*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total 186/471 (39.49%)	Mean 39.36%	SD 11.14%
.....							
<b>*Pituitary Gland: Pars Intermedia: Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 5/471 (1.06%)	Mean 1.07%	SD 1.39%
.....							
<b>*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 5/471 (1.06%)	Mean 1.07%	SD 1.39%
.....							
<b>*Prostate: Adenoma</b>							
		5/50 (10%)					
<b>Overall Incidence</b>	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			
<b>*Prostate:</b>								
<b>Carcinoma or Adenoma</b>								
		5/50 (10%)						
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%				
.....								
<b>*Salivary Glands:</b>								
<b>Schwannoma Malignant</b>								
		1/50 (2%)			0/53 (0%)	0/53 (0%)	0/51 (0%)	
					0/53 (0%)	0/53 (0%)	0/51 (0%)	
					0/50 (0%)	0/51 (0%)	0/51 (0%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/466 (0%)	Mean 0%	SD 0%
.....								
<b>#Skeletal Muscle:</b>								
<b>Fibrous Histiocytoma</b>								
		0/50 (0%)			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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%
.....								
<b>#Skeletal Muscle:</b>								
<b>Rhabdomyosarcoma</b>								
		0/50 (0%)			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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 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			
<b>#Skeletal Muscle:</b>									
<b>Rhabdomyosarcoma or Rhabdomyoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.22%	SD 0.67%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma or Basosquamous Tumor Benign</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma</b>									
						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%)
<b>Overall Incidence</b>	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			
<b>#Skin:</b>									
<b>Basal Cell Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma</b>									
						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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
<b>#Skin:</b>									
<b>Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma</b>									
						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%)
<b>Overall Incidence</b>	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		
<b>#Skin:</b>							
<b>Fibroma</b>							
					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%)
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%	Total 8/473 (1.69%)	Mean 1.69%	SD 1.49%
.....							
<b>#Skin:</b>							
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma</b>							
					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%)
<b>Overall Incidence</b>	Total	5/50 (10%)	Mean 10%	SD 0%	Total 9/473 (1.9%)	Mean 1.89%	SD 1.64%
.....							
<b>#Skin:</b>							
<b>Fibrosarcoma</b>							
					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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total 1/473 (0.21%)	Mean 0.21%	SD 0.63%
.....							
<b>#Skin:</b>							
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma</b>							
					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%)
<b>Overall Incidence</b>	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			
<b>#Skin:</b>									
<b>Hemangiosarcoma</b>									
						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%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
<b>#Skin:</b>									
<b>Keratoacanthoma</b>									
						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%)	
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.84%	
.....									
<b>#Skin:</b>									
<b>Neural Crest Tumor</b>									
						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%)	
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/473 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>									
						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%)	
<b>Overall Incidence</b>	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				
<b>#Skin:</b>															
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>															
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.42%	SD 0.84%					
.....															
<b>#Skin:</b>															
<b>Schwannoma Malignant</b>															
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	2/473	(0.42%)	Mean 0.42%	SD 0.84%					
.....															
<b>#Skin:</b>															
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>															
					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%)
<b>Overall Incidence</b>	Total	0/50	(0%)	Mean 0%	SD 0%	Total	1/473	(0.21%)	Mean 0.21%	SD 0.63%					
.....															
<b>#Skin:</b>															
<b>Squamous Cell Papilloma</b>															
					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%)
<b>Overall Incidence</b>	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			
<b>#Skin:</b>									
<b>Squamous Cell Papilloma or Papilloma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	1/473 (0.21%)	<b>Mean</b> 0.21%	<b>SD</b> 0.63%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	2/50 (4%)	<b>Mean</b> 4%	<b>SD</b> 0%	<b>Total</b>	3/473 (0.63%)	<b>Mean</b> 0.63%	<b>SD</b> 0.95%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	2/50 (4%)	<b>Mean</b> 4%	<b>SD</b> 0%	<b>Total</b>	3/473 (0.63%)	<b>Mean</b> 0.63%	<b>SD</b> 0.95%	
.....									
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	<b>Total</b>	0/50 (0%)	<b>Mean</b> 0%	<b>SD</b> 0%	<b>Total</b>	2/473 (0.42%)	<b>Mean</b> 0.42%	<b>SD</b> 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: 32

Report Date: 11/13/2008

		Male				Female			
<b>#Stomach, Forestomach:</b>									
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>									
						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%)	
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/473 (0.42%)	Mean 0.42%	SD 0.83%	
.....									
<b>*Testes:</b>									
<b>Adenoma</b>									
		2/50 (4%)							
<b>Overall Incidence</b>	Total	2/50 (4%)	Mean 4%	SD 0%					
.....									
<b>*Thymus:</b>									
<b>Thymoma Benign</b>									
						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%)	
<b>Overall Incidence</b>	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/461 (0.22%)	Mean 0.21%	SD 0.63%	
.....									
<b>*Thymus:</b>									
<b>Thymoma: Benign, Malignant, NOS</b>									
						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%)	
<b>Overall Incidence</b>	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		
<b>*Thyroid Gland: C-Cell: Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total 119/468 (25.43%)	Mean 25.42%	SD 7.63%
.....							
<b>*Thyroid Gland: C-Cell: Carcinoma</b>							
					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%)
<b>Overall Incidence</b>	Total	1/50 (2%)	Mean 2%	SD 0%	Total 18/468 (3.85%)	Mean 3.82%	SD 2.48%
.....							
<b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b>							
					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%)
<b>Overall Incidence</b>	Total	13/50 (26%)	Mean 26%	SD 0%	Total 135/468 (28.85%)	Mean 28.82%	SD 6.5%
.....							
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>							
					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%)
<b>Overall Incidence</b>	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			
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/468 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/468 (0.64%)	Mean 0.64%	SD 0.96%	
.....									
<b>#Tooth: Fibrosarcoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Tooth: Neurofibrosarcoma</b>									
						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%)
<b>Overall Incidence</b>	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			
<b>#Tooth:</b>									
<b>Odontoma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/473 (0.21%)	Mean 0.21%	SD 0.64%	
.....									
<b>*Urinary Bladder:</b>									
<b>Carcinoma or Papilloma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>*Urinary Bladder:</b>									
<b>Papilloma</b>									
						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%)
<b>Overall Incidence</b>	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/469 (0.21%)	Mean 0.21%	SD 0.63%	
.....									
<b>#Uterus:</b>									
<b>Adenoma</b>									
						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%)
<b>Overall Incidence</b>	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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	Male	Female
<b>#Uterus:</b>		
<b>Carcinoma</b>		
	0/53 (0%)	1/53 (2%)      2/52 (4%)
	1/53 (2%)	1/53 (2%)      0/53 (0%)
	1/50 (2%)	0/53 (0%)      0/53 (0%)
<b>Overall Incidence</b>	Total 6/473 (1.27%)	Mean 1.28%      SD 1.36%
.....		
<b>#Uterus:</b>		
<b>Fibroma</b>		
	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%)
<b>Overall Incidence</b>	Total 1/473 (0.21%)	Mean 0.21%      SD 0.63%
.....		
<b>#Uterus:</b>		
<b>Leiomyoma</b>		
	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%)
<b>Overall Incidence</b>	Total 1/473 (0.21%)	Mean 0.21%      SD 0.63%
.....		
<b>#Uterus:</b>		
<b>Leiomyosarcoma</b>		
	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%)
<b>Overall Incidence</b>	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
<b>#Uterus:</b>		
<b>Polyp Stromal</b>		
	8/53 (15%)	4/53 (8%)
	11/53 (21%)	9/53 (17%)
	8/50 (16%)	7/53 (13%)
<b>Overall Incidence</b>	Total 65/473 (13.74%)	Mean 13.74% SD 5.66%
.....		
<b>#Uterus:</b>		
<b>Sarcoma Stromal or Polyp Stromal</b>		
	8/53 (15%)	4/53 (8%)
	11/53 (21%)	9/53 (17%)
	8/50 (16%)	7/53 (13%)
<b>Overall Incidence</b>	Total 65/473 (13.74%)	Mean 13.74% SD 5.66%
.....		
<b>#Uterus:</b>		
<b>Schwannoma Malignant</b>		
	0/53 (0%)	1/53 (2%)
	1/53 (2%)	0/53 (0%)
	0/50 (0%)	0/53 (0%)
<b>Overall Incidence</b>	Total 4/473 (0.85%)	Mean 0.84% SD 1%
.....		
<b>#Uterus:</b>		
<b>Squamous Cell Carcinoma</b>		
	1/53 (2%)	0/53 (0%)
	0/53 (0%)	0/53 (0%)
	1/50 (2%)	0/53 (0%)
<b>Overall Incidence</b>	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
<b>#Uterus:</b>		
<b>Squamous Cell Papilloma</b>		
	0/53 (0%)	1/53 (2%)
	0/53 (0%)	0/53 (0%)
	0/50 (0%)	0/53 (0%)
<b>Overall Incidence</b>	Total 2/473 (0.42%)	Mean 0.42% SD 0.83%
.....		
<b>#Vagina:</b>		
<b>Polyp</b>		
	0/53 (0%)	0/53 (0%)
	0/53 (0%)	1/52 (2%)
	0/50 (0%)	0/53 (0%)
<b>Overall Incidence</b>	Total 1/473 (0.21%)	Mean 0.21% SD 0.64%
.....		
<b>#Vagina:</b>		
<b>Sarcoma</b>		
	0/53 (0%)	0/53 (0%)
	0/53 (0%)	0/53 (0%)
	0/50 (0%)	1/53 (2%)
<b>Overall Incidence</b>	Total 1/473 (0.21%)	Mean 0.21% SD 0.63%
.....		
<b>#Vagina:</b>		
<b>Schwannoma Malignant</b>		
	0/53 (0%)	0/53 (0%)
	0/53 (0%)	0/53 (0%)
	0/50 (0%)	1/53 (2%)
<b>Overall Incidence</b>	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			
<b>#Vagina:</b>														
<b>Squamous Cell Carcinoma</b>														
					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%)				
<b>Overall Incidence</b>					Total	2/473	(0.42%)	Mean	0.42%	SD	0.84%			
.....														
<b>#Vagina:</b>														
<b>Squamous Cell Papilloma</b>														
					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%)				
<b>Overall Incidence</b>					Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%			
.....														
<b>#Zymbal's Gland:</b>														
<b>Carcinoma</b>														
					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%)				
<b>Overall Incidence</b>	Total	1/50	(2%)	Mean	2%	SD	0%	Total	1/473	(0.21%)	Mean	0.21%	SD	0.63%
.....														
<b>#Zymbal's Gland:</b>														
<b>Carcinoma or Adenoma</b>														
					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%)				
<b>Overall Incidence</b>	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