



National Toxicology Program  
Department of Health and Human Services

# NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

November 2024

# 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.

This report combines data from all of the historical control studies into one section. To see this data broken up by route and vehicle, please refer to 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 for these studies, there are blank spaces where the tumor rates would normally be found, so that the male and female rates for the remaining studies can be easily compared.

# NOMENCLATURE CHANGES

---

The following changes to tissue or morphology nomenclature are seen in recent historical control reports:

Skin "Malignant Fibrous Histiocytoma" is now labeled as "Pleomorphic Fibrosarcoma" (changed on 2024 report).

The All Organs "Malignant Lymphoma" pool label now includes "Large Granular" (changed on 2024 report).

"Carcinoma" is now labeled as "Adenocarcinoma" for several organs, including harderian gland, intestine, mammary gland, salivary gland, and uterus (changed on 2022 report).

Small Intestine "Site Unspecified" is now labeled as "Any Site" (changed on 2022 report).

## 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	050706203	06/13/16	728	50(1)	21(681)	578.9	1020 Long Multiwalled Carbon Nanotubes
Battelle Columbus Laboratory	052030203	02/23/15	730	50(1)	22(660)	566.4	alpha-Pinene
Battelle Columbus Laboratory	050005803	07/03/12	730	50(2)	15(656)	628.4	Black Cohosh
Battelle Columbus Laboratory	051018801	02/17/11	733	50(2)	32(675)	525.8	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051018802	06/27/11	729	50(2)	25(648)	593.4	Di(2-ethylhexyl) Phthalate
Battelle Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
Battelle Columbus Laboratory	052032305	05/07/12	729	50(2)	29(669)	597.1	Resveratrol
Battelle Columbus Laboratory	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	051105403	07/05/15	732	50(2)	16(650)	657.1	Sulfolane
Battelle Columbus Laboratory	052071203	12/12/11	729	50(2)	25(652)	589.0	Tris(Chloropropyl)phosphate
<b>Female</b>							
Battelle Columbus Laboratory	050706203	06/13/16	730	50(1)	29(683)	376.0	1020 Long Multiwalled Carbon Nanotubes
Battelle Columbus Laboratory	052030203	02/23/15	731	50(1)	28(668)	350.6	alpha-Pinene
Battelle Columbus Laboratory	050005803	07/02/12	729	50(5)	28(679)	426.6	Black Cohosh
Battelle Columbus Laboratory	051018801	02/18/11	736	50(4)	33(691)	329.5	Di(2-ethylhexyl) Phthalate
Battelle Columbus Laboratory	051018802	06/28/11	732	50(4)	31(684)	376.1	Di(2-ethylhexyl) Phthalate
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation
Battelle Columbus Laboratory	052032305	05/08/12	730	50(5)	34(690)	394.3	Resveratrol
Battelle Columbus Laboratory	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	051105403	07/05/15	734	50(4)	21(670)	438.1	Sulfolane
Battelle Columbus Laboratory	052071203	12/13/11	731	50(4)	22(629)	380.1	Tris(Chloropropyl)phosphate

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 5  
 Report Date: 11/07/2024

		Male				Female			
<b>#All Organs:</b>									
<b>Benign Tumors</b>									
		33/50 (66%)	24/50 (48%)	30/50 (60%)	43/50 (86%)	39/50 (78%)	44/50 (88%)		
		27/50 (54%)	28/50 (56%)	30/50 (60%)	37/50 (74%)	41/50 (82%)	39/50 (78%)		
		49/90 (54%)	33/50 (66%)	29/50 (58%)	82/90 (91%)	43/50 (86%)	39/50 (78%)		
		29/50 (58%)	25/50 (50%)		43/50 (86%)	41/50 (82%)			
<b>Overall Incidence</b>	Total	337/590 (57.12%)	Mean 57.31%	SD 5.72%	Total	491/590 (83.22%)	Mean 82.65%	SD 5.24%	
.....									
<b>#All Organs:</b>									
<b>Malignant Tumors</b>									
		6/50 (12%)	20/50 (40%)	10/50 (20%)	8/50 (16%)	16/50 (32%)	7/50 (14%)		
		13/50 (26%)	15/50 (30%)	12/50 (24%)	16/50 (32%)	14/50 (28%)	11/50 (22%)		
		24/90 (27%)	13/50 (26%)	14/50 (28%)	37/90 (41%)	10/50 (20%)	17/50 (34%)		
		8/50 (16%)	9/50 (18%)		15/50 (30%)	10/50 (20%)			
<b>Overall Incidence</b>	Total	144/590 (24.41%)	Mean 24.24%	SD 7.63%	Total	161/590 (27.29%)	Mean 26.28%	SD 8.46%	
.....									
<b>#All Organs:</b>									
<b>Malignant and Benign Tumors</b>									
		35/50 (70%)	36/50 (72%)	33/50 (66%)	44/50 (88%)	45/50 (90%)	46/50 (92%)		
		32/50 (64%)	36/50 (72%)	37/50 (74%)	41/50 (82%)	44/50 (88%)	41/50 (82%)		
		57/90 (63%)	39/50 (78%)	36/50 (72%)	89/90 (99%)	45/50 (90%)	47/50 (94%)		
		32/50 (64%)	30/50 (60%)		45/50 (90%)	46/50 (92%)			
<b>Overall Incidence</b>	Total	403/590 (68.31%)	Mean 68.67%	SD 5.52%	Total	533/590 (90.34%)	Mean 89.72%	SD 4.88%	
.....									
<b>#All Organs:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	Total	3/590 (0.51%)	Mean 0.55%	SD 0.93%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 6  
 Report Date: 11/07/2024

		Male				Female			
<b>#All Organs:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/90 (3%)	0/50 (0%)	1/50 (2%)		3/90 (3%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	7/590 (1.19%)	Mean 1.03%	SD 1.53%	Total	4/590 (0.68%)	Mean 0.48%	SD 1.12%	
.....									
<b>#All Organs:</b>									
<b>Hemangiosarcoma or Hemangioma</b>									
		0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/90 (3%)	0/50 (0%)	1/50 (2%)	3/90 (3%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	9/590 (1.53%)	Mean 1.39%	SD 1.47%	Total	7/590 (1.19%)	Mean 1.03%	SD 1.53%	
.....									
<b>#All Organs:</b>									
<b>Histiocytic Sarcoma</b>									
		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	4/590 (0.68%)	Mean 0.73%	SD 1.01%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#All Organs:</b>									
<b>Leukemia: Granulocytic</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 7  
 Report Date: 11/07/2024

		Male				Female			
<b>#All Organs:</b>									
<b>Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)		0/50 (0%)	2/50 (4%)			
<b>Overall Incidence</b>	Total	5/590 (0.85%)		Mean 0.91%	SD 1.87%	Total 4/590 (0.68%)		Mean 0.73%	SD 1.35%
<hr/>									
<b>#All Organs:</b>									
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, Large Granular, or Undifferentiated Cell Type</b>									
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/90 (2%)	1/50 (2%)	1/50 (2%)	5/90 (6%)	1/50 (2%)	1/50 (2%)	2/50 (4%)	
		0/50 (0%)	2/50 (4%)		2/50 (4%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	11/590 (1.86%)		Mean 1.84%	SD 1.67%	Total 12/590 (2.03%)		Mean 1.78%	SD 2%
<hr/>									
<b>#All Organs:</b>									
<b>Malignant Schwannoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/50 (6%)	6/50 (12%)	0/50 (0%)	1/50 (2%)	3/50 (6%)	2/50 (4%)		
		3/90 (3%)	0/50 (0%)	1/50 (2%)	4/90 (4%)	1/50 (2%)	2/50 (4%)		
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	13/590 (2.2%)		Mean 2.12%	SD 3.82%	Total 14/590 (2.37%)		Mean 2.22%	SD 2.13%
<hr/>									
<b>#All Organs:</b>									
<b>Mesothelioma: Benign, Malignant, NOS</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	10/590 (1.69%)		Mean 1.66%	SD 1.51%	Total 0/590 (0%)		Mean 0%	SD 0%

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

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 8  
 Report Date: 11/07/2024

		Male				Female			
<b>#All Organs:</b>									
<b>Mesothelioma: Malignant</b>									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	10/590 (1.69%)	Mean 1.66%	SD 1.51%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)	
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	3/50 (6%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	6/590 (1.02%)	Mean 1.01%	SD 1.84%	Total	8/589 (1.36%)	Mean 1.37%	SD 2.2%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%	
.....									
<b>*Adrenal Cortex:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	2/50 (4%)	
		1/50 (2%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	0/50 (0%)		2/90 (2%)	3/50 (6%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	7/590 (1.19%)	Mean 1.19%	SD 1.83%	Total	10/589 (1.7%)	Mean 1.66%	SD 2.51%	

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 9  
 Report Date: 11/07/2024

		Male				Female			
<b>*Adrenal Medulla:</b>									
<b>  Ganglioneuroma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)	
		0/88 (0%)	0/50 (0%)	1/50 (2%)		0/86 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/584 (0.17%)	Mean 0.18%	SD 0.6%	
-----									
<b>*Adrenal Medulla:</b>									
<b>  Pheochromocytoma Benign</b>									
		9/50 (18%)	6/50 (12%)	14/50 (28%)		2/50 (4%)	3/50 (6%)	3/50 (6%)	
		4/50 (8%)	5/50 (10%)	12/50 (24%)		1/50 (2%)	0/50 (0%)	0/49 (0%)	
		10/88 (11%)	4/50 (8%)	10/50 (20%)		1/86 (1%)	3/50 (6%)	1/50 (2%)	
		10/50 (20%)	6/50 (12%)			1/49 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	90/588 (15.31%)	Mean 15.58%	SD 6.78%	Total	15/584 (2.57%)	Mean 2.65%	SD 2.45%	
-----									
<b>*Adrenal Medulla:</b>									
<b>  Pheochromocytoma Complex</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/88 (1%)	0/50 (0%)	0/50 (0%)		0/86 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/588 (0.34%)	Mean 0.29%	SD 0.66%	Total	0/584 (0%)	Mean 0%	SD 0%	
-----									
<b>*Adrenal Medulla:</b>									
<b>  Pheochromocytoma Malignant</b>									
		0/50 (0%)	6/50 (12%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/88 (1%)	1/50 (2%)	2/50 (4%)		0/86 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	13/588 (2.21%)	Mean 2.29%	SD 3.58%	Total	4/584 (0.68%)	Mean 0.73%	SD 1.35%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 10  
 Report Date: 11/07/2024

		Male				Female			
<b>*Adrenal Medulla:</b>									
<b>  Pheochromocytoma: Benign, Complex, Malignant, NOS</b>									
		9/50 (18%)	12/50 (24%)	14/50 (28%)	2/50 (4%)	5/50 (10%)	3/50 (6%)		
		5/50 (10%)	6/50 (12%)	14/50 (28%)	1/50 (2%)	0/50 (0%)	0/49 (0%)		
		11/88 (13%)	5/50 (10%)	12/50 (24%)	1/86 (1%)	3/50 (6%)	2/50 (4%)		
		10/50 (20%)	6/50 (12%)		2/49 (4%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	104/588 (17.69%)	Mean 18.05%	SD 7.11%	Total	19/584 (3.25%)	Mean 3.39%	SD 3.16%	
.....									
<b>#Bone:</b>									
<b>  Hemangiosarcoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Bone:</b>									
<b>  Osteosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Bone:</b>									
<b>  Osteosarcoma or Osteoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 11  
 Report Date: 11/07/2024

		Male				Female							
<b>*Brain:</b>													
<b>Astrocytoma</b>													
		0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/589 (0.17%)		Mean 0.19%		SD 0.62%		Total	0/590 (0%)		Mean 0%	SD 0%	
.....													
<b>*Brain:</b>													
<b>Glioma</b>													
		0/50	(0%)	1/49	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/589 (0.17%)		Mean 0.19%		SD 0.62%		Total	0/590 (0%)		Mean 0%	SD 0%	
.....													
<b>*Brain:</b>													
<b>Glioma Malignant</b>													
		1/50	(2%)	0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)		
		4/50	(8%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	1/50	(2%)		
		0/90	(0%)	0/50	(0%)	2/50	(4%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	10/589 (1.7%)		Mean 1.82%		SD 2.6%		Total	1/590 (0.17%)		Mean 0.18%	SD 0.6%	
.....													
<b>*Brain:</b>													
<b>Granular Cell Tumor Benign</b>													
		2/50	(4%)	1/49	(2%)	3/50	(6%)	1/50	(2%)	1/50	(2%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)	0/50	(0%)	2/50	(4%)	1/50	(2%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	11/589 (1.87%)		Mean 1.92%		SD 2.38%		Total	6/590 (1.02%)		Mean 1.01%	SD 1.34%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 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: 11/07/2024

		Male				Female			
<b>*Brain:</b>									
<b>Granular Cell Tumor Malignant</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Meningioma Benign</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/589 (0%)	Mean 0%	SD 0%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>Meningioma Malignant</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Brain:</b>									
<b>Meningioma: Benign, Malignant, NOS</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 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: 11/07/2024

		Male				Female			
<b>*Brain:</b>									
<b>  Oligodendroglioma Malignant</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	1/589 (0.17%)	Mean 0.18%	SD 0.6%	<b>Total</b>	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>*Brain:</b>									
<b>  Oligodendroglioma, Glioma, or Astrocytoma</b>									
		1/50 (2%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/90 (0%)	0/50 (0%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	13/589 (2.21%)	Mean 2.37%	SD 2.51%	<b>Total</b>	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Brain:</b>									
<b>  Schwannoma Malignant</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	0/589 (0%)	Mean 0%	SD 0%	<b>Total</b>	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Clitoral/Preputial Gland:</b>									
<b>  Adenocarcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/46 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	1/587 (0.17%)	Mean 0.19%	SD 0.62%	<b>Total</b>	0/575 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 14  
 Report Date: 11/07/2024

		Male				Female			
<b>*Clitoral/Preputial Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/46 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	0/587 (0%)	Mean 0%	SD 0%	<b>Total</b>	0/575 (0%)	Mean 0%	SD 0%	
-----									
<b>*Clitoral/Preputial Gland:</b>									
<b>Adenoma or Adenocarcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/46 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	1/587 (0.17%)	Mean 0.19%	SD 0.62%	<b>Total</b>	0/575 (0%)	Mean 0%	SD 0%	
-----									
<b>*Clitoral/Preputial Gland:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	1/49 (2%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	1/48 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/48 (0%)	0/46 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	2/587 (0.34%)	Mean 0.36%	SD 0.81%	<b>Total</b>	3/575 (0.52%)	Mean 0.56%	SD 0.96%	
-----									
<b>*Clitoral/Preputial Gland:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/49 (0%)	
		0/49 (0%)	1/50 (2%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)	
		0/88 (0%)	1/50 (2%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/46 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	2/587 (0.34%)	Mean 0.36%	SD 0.81%	<b>Total</b>	1/575 (0.17%)	Mean 0.19%	SD 0.62%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 15  
 Report Date: 11/07/2024

		Male				Female			
<b>*Epididymis:</b>									
<b>Sarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/49	(0%)	1/50	(2%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	1/589 (0.17%)		Mean 0.18%		SD 0.6%			
.....									
<b>#Eye:</b>									
<b>Leiomyoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)
								Mean	0%
								SD	0%
.....									
<b>#Harderian Gland:</b>									
<b>Schwannoma Malignant</b>									
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)
								Mean	0%
								SD	0%
.....									
<b>*Heart:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	2/50	(4%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)
<b>Overall Incidence</b>	Total	5/590 (0.85%)		Mean 0.91%		SD 2.07%		Total	4/588 (0.68%)
								Mean	0.73%
								SD	1.35%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 16  
 Report Date: 11/07/2024

		Male				Female							
<b>#Intestine Large: Cecum:</b>													
<b>Leiomyosarcoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			1/50	(2%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total 1/590 (0.17%)		Mean 0.18%		SD 0.6%	
-----													
<b>#Intestine Large: Cecum:</b>													
<b>Liposarcoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	1/50	(2%)		
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total 1/590 (0.17%)		Mean 0.18%		SD 0.6%	
-----													
<b>#Intestine Large: Colon/Rectum:</b>													
<b>Granular Cell Tumor Benign</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total 1/590 (0.17%)		Mean 0.1%		SD 0.34%	
-----													
<b>#Intestine Large: Colon/Rectum:</b>													
<b>Leiomyoma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total 0/590 (0%)		Mean 0%		SD 0%	

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 17  
 Report Date: 11/07/2024

		Male				Female					
<b>#Intestine Small: Any Site:</b>											
<b>Adenocarcinoma</b>											
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/90	(2%)	1/50	(2%)	1/50	(2%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	9/590 (1.53%)		Mean 1.47%		SD 1.3%		Total		0/590 (0%)	
										Mean 0%	
										SD 0%	
.....											
<b>#Intestine Small: Any Site:</b>											
<b>Adenoma or Adenocarcinoma</b>											
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/90	(2%)	1/50	(2%)	1/50	(2%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	9/590 (1.53%)		Mean 1.47%		SD 1.3%		Total		0/590 (0%)	
										Mean 0%	
										SD 0%	
.....											
<b>#Intestine Small: Any Site:</b>											
<b>Leiomyosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total		1/590 (0.17%)	
										Mean 0.1%	
										SD 0.34%	
.....											
<b>#Intestine Small: Any Site:</b>											
<b>Leiomyosarcoma or Leiomyoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total		2/590 (0.34%)	
										Mean 0.28%	
										SD 0.66%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 18  
 Report Date: 11/07/2024

		Male				Female			
<b>#Intestine Small: Jejunum:</b>									
<b>Adenocarcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/90 (2%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	9/590 (1.53%)	Mean 1.47%	SD 1.3%	Total	0/590 (0%)	Mean 0%	SD 0%	
-----									
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
-----									
<b>#Intestine Small: Jejunum:</b>									
<b>Leiomyosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%	
-----									
<b>*Islets, Pancreatic:</b>									
<b>Adenoma</b>									
		3/50 (6%)	1/50 (2%)	4/50 (8%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/49 (6%)	2/50 (4%)	8/50 (16%)	1/50 (2%)	3/49 (6%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		5/90 (6%)	2/50 (4%)	2/50 (4%)	5/90 (6%)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (6%)	4/50 (8%)	4/50 (8%)	0/48 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)
<b>Overall Incidence</b>	Total	37/589 (6.28%)	Mean 6.33%	SD 3.67%	Total	15/586 (2.56%)	Mean 2.33%	SD 2.11%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 19  
 Report Date: 11/07/2024

		Male				Female			
<b>*Islets, Pancreatic:</b>									
<b>  Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)	
		8/90 (9%)	3/50 (6%)	1/50 (2%)		2/90 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>12/589 (2.04%)</b>	<b>Mean 1.54%</b>	<b>SD 3.05%</b>	<b>Total</b>	<b>4/586 (0.68%)</b>	<b>Mean 0.57%</b>	<b>SD 0.97%</b>	
.....									
<b>*Islets, Pancreatic:</b>									
<b>  Carcinoma or Adenoma</b>									
		3/50 (6%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		3/49 (6%)	2/50 (4%)	8/50 (16%)		1/50 (2%)	3/49 (6%)	2/50 (4%)	
		13/90 (14%)	5/50 (10%)	3/50 (6%)		7/90 (8%)	2/50 (4%)	2/50 (4%)	
		3/50 (6%)	4/50 (8%)			0/48 (0%)	0/49 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>49/589 (8.32%)</b>	<b>Mean 7.87%</b>	<b>SD 4.21%</b>	<b>Total</b>	<b>19/586 (3.24%)</b>	<b>Mean 2.9%</b>	<b>SD 2.56%</b>	
.....									
<b>*Kidney: Pelvis and Urothelium:</b>									
<b>  Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>0/590 (0%)</b>	<b>Mean 0%</b>	<b>SD 0%</b>	<b>Total</b>	<b>0/589 (0%)</b>	<b>Mean 0%</b>	<b>SD 0%</b>	
.....									
<b>*Kidney: Renal Tubule:</b>									
<b>  Adenoma</b>									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/90 (3%)	0/50 (0%)	2/50 (4%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>9/590 (1.53%)</b>	<b>Mean 1.39%</b>	<b>SD 1.72%</b>	<b>Total</b>	<b>2/589 (0.34%)</b>	<b>Mean 0.28%</b>	<b>SD 0.66%</b>	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 20  
 Report Date: 11/07/2024

		Male				Female			
<b>*Kidney: Renal Tubule: Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%	
.....									
<b>*Kidney: Renal Tubule: Carcinoma or Adenoma</b>									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/90 (3%)	0/50 (0%)	2/50 (4%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	9/590 (1.53%)	Mean 1.39%	SD 1.72%	Total	4/589 (0.68%)	Mean 0.57%	SD 0.97%	
.....									
<b>*Kidney: Renal Tubule: Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Kidney: Renal Tubule: Lipoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.28%	SD 0.66%	Total	0/589 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 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: 11/07/2024

		Male				Female						
<b>*Kidney: Renal Tubule: Liposarcoma</b>												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)	
		0/50	(0%)	1/50	(2%)			0/49	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/589 (0%)		Mean 0%	SD 0%
.....												
<b>*Kidney: Renal Tubule: Oncocytoma Benign</b>												
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		1/90	(1%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean 0.28%		SD 0.66%		Total	0/589 (0%)		Mean 0%	SD 0%
.....												
<b>*Kidney: Renal Tubule: Polyp Adenomatous</b>												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)			0/49	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/589 (0%)		Mean 0%	SD 0%
.....												
<b>#Lacrimal Gland: Carcinoma</b>												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)	
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)		Mean 0.18%	SD 0.6%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 22  
 Report Date: 11/07/2024

		Male				Female			
<b>*Liver:</b>									
<b>Cholangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	5/50 (10%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/49 (2%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	8/588 (1.36%)	Mean 1.46%	SD 2.98%	
.....									
<b>*Liver:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	2/50 (4%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)		7/90 (8%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)	1/50 (2%)			0/49 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	3/590 (0.51%)	Mean 0.55%	SD 0.93%	Total	16/588 (2.72%)	Mean 2.35%	SD 2.45%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 23  
 Report Date: 11/07/2024

		Male				Female			
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatoblastoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma or Hepatocellular Adenoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)	7/90 (8%)	2/50 (4%)	1/50 (2%)		
		0/50 (0%)	1/50 (2%)		0/49 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	4/590 (0.68%)	Mean 0.73%	SD 1.01%	Total	16/588 (2.72%)	Mean 2.35%	SD 2.45%	
.....									
<b>*Liver:</b>									
<b>Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)	7/90 (8%)	2/50 (4%)	1/50 (2%)		
		0/50 (0%)	1/50 (2%)		0/49 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	4/590 (0.68%)	Mean 0.73%	SD 1.01%	Total	16/588 (2.72%)	Mean 2.35%	SD 2.45%	
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Adenoma</b>									
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	5/590 (0.85%)	Mean 0.83%	SD 1.33%	Total	0/588 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 24  
 Report Date: 11/07/2024

		Male				Female			
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	2/590 (0.34%)		Mean 0.36%	SD 0.81%	Total 0/588 (0%)		Mean 0%	SD 0%
.....									
<b>*Lung:</b>									
<b>Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma</b>									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	7/590 (1.19%)		Mean 1.19%	SD 1.6%	Total 0/588 (0%)		Mean 0%	SD 0%
.....									
<b>#Lymph Node, Mesenteric:</b>									
<b>Hemangiosarcoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	1/590 (0.17%)		Mean 0.18%	SD 0.6%	Total 0/590 (0%)		Mean 0%	SD 0%
.....									
<b>#Mammary Gland:</b>									
<b>Adenocarcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		4/50 (8%)	5/50 (10%)	3/50 (6%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		8/50 (16%)	1/50 (2%)	5/50 (10%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		10/90 (11%)	2/50 (4%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)		
<b>Overall Incidence</b>	<b>Total</b>	1/590 (0.17%)		Mean 0.18%	SD 0.6%	Total 42/590 (7.12%)		Mean 6.83%	SD 4.59%

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 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: 11/07/2024

		Male				Female			
<b>#Mammary Gland:</b>									
<b>Adenolipoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	0/590 (0%)	Mean 0%	SD 0%	
-----									
<b>#Mammary Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	4/50 (8%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		8/90 (9%)	1/50 (2%)	3/50 (6%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	22/590 (3.73%)	Mean 3.35%	SD 3.02%	
-----									
<b>#Mammary Gland:</b>									
<b>Adenoma or Adenocarcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		6/50 (12%)	6/50 (12%)	4/50 (8%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		8/50 (16%)	2/50 (4%)	9/50 (18%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		16/90 (18%)	3/50 (6%)	5/50 (10%)	
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	62/590 (10.51%)	Mean 9.98%	SD 5.7%	
-----									
<b>#Mammary Gland:</b>									
<b>Fibroadenoma</b>									
		0/50 (0%)	1/50 (2%)	3/50 (6%)		31/50 (62%)	28/50 (56%)	29/50 (58%)	
		0/50 (0%)	2/50 (4%)	2/50 (4%)		25/50 (50%)	28/50 (56%)	20/50 (40%)	
		2/90 (2%)	0/50 (0%)	0/50 (0%)		63/90 (70%)	28/50 (56%)	30/50 (60%)	
		2/50 (4%)	2/50 (4%)			32/50 (64%)	29/50 (58%)		
<b>Overall Incidence</b>	Total	14/590 (2.37%)	Mean 2.38%	SD 2.15%	Total	343/590 (58.14%)	Mean 57.27%	SD 7.71%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 26  
 Report Date: 11/07/2024

		Male				Female			
<b>#Mammary Gland:</b>									
<b>Fibroma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	3/50 (6%)		33/50 (66%)	29/50 (58%)	29/50 (58%)	
		0/50 (0%)	2/50 (4%)	2/50 (4%)		25/50 (50%)	29/50 (58%)	23/50 (46%)	
		2/90 (2%)	0/50 (0%)	0/50 (0%)		64/90 (71%)	28/50 (56%)	32/50 (64%)	
		2/50 (4%)	2/50 (4%)			33/50 (66%)	29/50 (58%)		
<b>Overall Incidence</b>	Total	14/590 (2.37%)	Mean 2.38%	SD 2.15%	Total	354/590 (60%)	Mean 59.19%	SD 7.3%	
.....									
<b>#Mammary Gland:</b>									
<b>Fibroma, Fibroadenoma, Adenocarcinoma, or Adenoma</b>									
		0/50 (0%)	1/50 (2%)	3/50 (6%)		35/50 (70%)	33/50 (66%)	30/50 (60%)	
		0/50 (0%)	3/50 (6%)	2/50 (4%)		29/50 (58%)	30/50 (60%)	27/50 (54%)	
		2/90 (2%)	0/50 (0%)	0/50 (0%)		66/90 (73%)	29/50 (58%)	34/50 (68%)	
		2/50 (4%)	2/50 (4%)			33/50 (66%)	30/50 (60%)		
<b>Overall Incidence</b>	Total	15/590 (2.54%)	Mean 2.57%	SD 2.38%	Total	376/590 (63.73%)	Mean 63.03%	SD 5.97%	
.....									
<b>#Nerve Trigeminal:</b>									
<b>Schwannoma Malignant</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 27  
 Report Date: 11/07/2024

		Male				Female			
<b>#Oral Mucosa:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%	SD 0.6%	Total 1/590 (0.17%)		Mean 0.1%	SD 0.34%
.....									
<b>#Oral Mucosa, Tongue, Pharynx, or Gingiva:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean 0.36%	SD 0.81%	Total 2/590 (0.34%)		Mean 0.2%	SD 0.67%
.....									
<b>#Oral Mucosa, Tongue, Pharynx, or Gingiva:</b>									
<b>Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean 0.36%	SD 0.81%	Total 3/590 (0.51%)		Mean 0.38%	SD 0.86%
.....									
<b>*Ovary:</b>									
<b>Adenocarcinoma, Cystadenoma, or Cystadenocarcinoma</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						1/90 (1%)	0/50 (0%)	0/50 (0%)	
						0/48 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total					Total 1/588 (0.17%)		Mean 0.1%	SD 0.34%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 28  
 Report Date: 11/07/2024

	Male		Female			
<b>*Ovary:</b>						
<b>Adenoma</b>						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.18%		SD 0.6%	
.....						
<b>*Ovary:</b>						
<b>Cystadenoma</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.1%		SD 0.34%	
.....						
<b>*Ovary:</b>						
<b>Cystadenoma or Cystadenocarcinoma</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.1%		SD 0.34%	
.....						
<b>*Ovary:</b>						
<b>Granulosa-Theca Tumor Benign</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.18%		SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 29  
 Report Date: 11/07/2024

	Male		Female			
<b>*Ovary:</b>						
<b>Granulosa-Theca Tumor Malignant</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/48 (0%)	0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>1/588 (0.17%)</b>	<b>Mean</b>	<b>0.18%</b>	<b>SD</b>	<b>0.6%</b>
.....						
<b>*Ovary:</b>						
<b>Granulosa Cell Tumor Benign</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	1/50 (2%)	3/50 (6%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	<b>6/588 (1.02%)</b>	<b>Mean</b>	<b>1.01%</b>	<b>SD</b>	<b>1.84%</b>
.....						
<b>*Ovary:</b>						
<b>Granulosa Cell Tumor Malignant</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)	1/50 (2%)	1/50 (2%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	<b>5/588 (0.85%)</b>	<b>Mean</b>	<b>0.75%</b>	<b>SD</b>	<b>1.04%</b>
.....						
<b>*Ovary:</b>						
<b>Granulosa Cell Tumor, Luteoma, Thecoma, or Sertoli Cell Tumor (Benign, Malignant, NOS)</b>						
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/50 (4%)	2/50 (4%)	4/50 (8%)		
		4/90 (4%)	1/50 (2%)	1/50 (2%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	<b>15/588 (2.55%)</b>	<b>Mean</b>	<b>2.4%</b>	<b>SD</b>	<b>2.53%</b>

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 30  
 Report Date: 11/07/2024

	Male		Female			
<b>*Ovary:</b>						
<b>Granulosa Cell Tumor: Benign, Malignant, NOS</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	2/50 (4%)	3/50 (6%)		
		3/90 (3%)	1/50 (2%)	1/50 (2%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	11/588 (1.87%)	Mean 1.76%	SD 2.03%		
.....						
<b>*Ovary:</b>						
<b>Luteoma</b>						
		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	2/588 (0.34%)	Mean 0.36%	SD 0.81%		
.....						
<b>*Ovary:</b>						
<b>Schwannoma Malignant</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/588 (0%)	Mean 0%	SD 0%		
.....						
<b>*Ovary:</b>						
<b>Sertoli Cell Tumor Benign</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/90 (1%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.1%	SD 0.34%		

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 31  
 Report Date: 11/07/2024

		Male				Female			
<b>*Ovary:</b>									
<b>Thecoma Benign</b>									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
						0/90 (0%)	0/50 (0%)	0/50 (0%)	
						0/48 (0%)	0/50 (0%)		
<b>Overall Incidence</b>					<b>Total</b>	1/588 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Pancreas:</b>									
<b>Adenocarcinoma</b>									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		1/90 (1%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	3/589 (0.51%)	Mean 0.46%	SD 0.83%	<b>Total</b>	0/586 (0%)	Mean 0%	SD 0%	
.....									
<b>*Pancreas:</b>									
<b>Adenoma</b>									
		0/50 (0%)	1/50 (2%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/49 (2%)	10/50 (20%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		18/90 (20%)	8/50 (16%)	14/50 (28%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		4/50 (8%)	9/50 (18%)			0/48 (0%)	0/49 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	71/589 (12.05%)	Mean 11.46%	SD 9.67%	<b>Total</b>	1/586 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Pancreas:</b>									
<b>Adenoma or Adenocarcinoma</b>									
		0/50 (0%)	1/50 (2%)	7/50 (14%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/49 (2%)	10/50 (20%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)	
		18/90 (20%)	8/50 (16%)	14/50 (28%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		4/50 (8%)	9/50 (18%)			0/48 (0%)	0/49 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	72/589 (12.22%)	Mean 11.64%	SD 9.7%	<b>Total</b>	1/586 (0.17%)	Mean 0.18%	SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 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: 11/07/2024

		Male				Female			
<b>*Parathyroid Gland:</b>									
<b>Adenoma</b>									
		3/49 (6%)	0/45 (0%)	0/49 (0%)	1/47 (2%)	0/48 (0%)	0/46 (0%)		
		0/43 (0%)	0/42 (0%)	0/48 (0%)	0/42 (0%)	0/42 (0%)	0/45 (0%)		
		1/83 (1%)	1/49 (2%)	0/43 (0%)	0/87 (0%)	0/48 (0%)	0/46 (0%)		
		0/44 (0%)	0/49 (0%)		1/43 (2%)	0/44 (0%)			
<b>Overall Incidence</b>	Total	5/544 (0.92%)	Mean 0.85%	SD 1.87%	Total	2/538 (0.37%)	Mean 0.4%	SD 0.9%	
.....									
<b>#Peripheral Nerve:</b>									
<b>Paranglioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Peripheral Nerve:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Pharynx:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 33  
 Report Date: 11/07/2024

		Male				Female			
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Adenoma</b>									
		9/50 (18%)	11/49 (22%)	12/50 (24%)		20/50 (40%)	23/50 (46%)	20/50 (40%)	
		3/50 (6%)	4/50 (8%)	11/50 (22%)		13/49 (27%)	15/49 (31%)	18/50 (36%)	
		17/89 (19%)	10/50 (20%)	8/50 (16%)		43/90 (48%)	21/50 (42%)	16/50 (32%)	
		9/50 (18%)	7/50 (14%)			14/50 (28%)	11/50 (22%)		
<b>Overall Incidence</b>	Total	101/588 (17.18%)	Mean 17.05%	SD 5.75%	Total	214/588 (36.39%)	Mean 35.54%	SD 8.36%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma</b>									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/49 (2%)	0/50 (0%)	
		0/89 (0%)	0/50 (0%)	1/50 (2%)		1/90 (1%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/588 (0.34%)	Mean 0.37%	SD 0.82%	Total	8/588 (1.36%)	Mean 1.38%	SD 2.38%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Carcinoma or Adenoma</b>									
		9/50 (18%)	12/49 (24%)	12/50 (24%)		21/50 (42%)	27/50 (54%)	20/50 (40%)	
		3/50 (6%)	4/50 (8%)	11/50 (22%)		13/49 (27%)	16/49 (33%)	18/50 (36%)	
		17/89 (19%)	10/50 (20%)	9/50 (18%)		44/90 (49%)	21/50 (42%)	17/50 (34%)	
		9/50 (18%)	7/50 (14%)			14/50 (28%)	11/50 (22%)		
<b>Overall Incidence</b>	Total	103/588 (17.52%)	Mean 17.42%	SD 5.96%	Total	222/588 (37.76%)	Mean 36.92%	SD 9.66%	
.....									
<b>*Pituitary Gland: Pars Distalis or Unspecified Site:</b>									
<b>Schwannoma Malignant</b>									
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		0/89 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 34  
 Report Date: 11/07/2024

		Male				Female			
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>Adenoma</b>									
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/89 (0%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	4/588 (0.68%)	Mean 0.73%	SD 1.01%	Total	2/588 (0.34%)	Mean 0.36%	SD 0.81%	
.....									
<b>*Pituitary Gland: Pars Intermedia:</b>									
<b>Carcinoma or Adenoma</b>									
		0/50 (0%)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/89 (0%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	4/588 (0.68%)	Mean 0.73%	SD 1.01%	Total	2/588 (0.34%)	Mean 0.36%	SD 0.81%	
.....									
<b>*Pituitary Gland: Pars Nervosa:</b>									
<b>Schwannoma Malignant</b>									
		0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/89 (0%)	0/50 (0%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%	
.....									
<b>*Prostate:</b>									
<b>Adenoma</b>									
		1/50 (2%)	1/50 (2%)	0/50 (0%)					
		1/50 (2%)	0/50 (0%)	0/50 (0%)					
		2/90 (2%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)						
<b>Overall Incidence</b>	Total	5/590 (0.85%)	Mean 0.75%	SD 1.04%					

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

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 35  
 Report Date: 11/07/2024

		Male				Female			
<b>*Prostate:</b>									
<b>Adenoma or Adenocarcinoma</b>									
		1/50	(2%)	1/50	(2%)	0/50	(0%)		
		1/50	(2%)	0/50	(0%)	0/50	(0%)		
		2/90	(2%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	5/590 (0.85%)		Mean 0.75%		SD 1.04%			
.....									
<b>*Salivary Glands:</b>									
<b>Schwannoma Malignant</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	2/50	(4%)	0/50	(0%)	0/49	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean 0.36%		SD 1.21%		Total	0/588 (0%)
								Mean	0%
								SD	0%
.....									
<b>#Seminal Vesicle:</b>									
<b>Hemangiosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	1/50	(2%)		
		0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%			
.....									
<b>#Skeletal Muscle:</b>									
<b>Fibrosarcoma</b>									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total	1/590 (0.17%)
								Mean	0.18%
								SD	0.6%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 36  
 Report Date: 11/07/2024

		Male				Female					
<b>#Skeletal Muscle:</b>											
<b>Hemangioma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total		1/590 (0.17%)	
										Mean 0.18%	
										SD 0.6%	
.....											
<b>#Skeletal Muscle:</b>											
<b>Hemangiosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total		0/590 (0%)	
										Mean 0%	
										SD 0%	
.....											
<b>#Skeletal Muscle:</b>											
<b>Liposarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total		1/590 (0.17%)	
										Mean 0.18%	
										SD 0.6%	
.....											
<b>#Skeletal Muscle:</b>											
<b>Sarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total		0/590 (0%)	
										Mean 0%	
										SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 37  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Basal Cell Adenoma</b>									
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.28%	SD 0.66%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Basal Cell Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	Total	3/590 (0.51%)	Mean 0.55%	SD 1.29%	
.....									
<b>#Skin:</b>									
<b>Basal or Squamous Cell Carcinoma, Basosquamous Tumor (Malignant or Benign), Basal Cell Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma, Adenoma, Carcinoma, Sebaceous Gland Adenoma, or Sebaceous Gland Adenocarcinoma</b>									
		7/50 (14%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	4/50 (8%)	5/50 (10%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		9/90 (10%)	5/50 (10%)	1/50 (2%)	0/90 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	37/590 (6.27%)	Mean 6%	SD 4.65%	Total	5/590 (0.85%)	Mean 0.91%	SD 1.87%	
.....									
<b>#Skin:</b>									
<b>Basal or Squamous Cell Carcinoma, Basosquamous Tumor (Malignant), or Sebaceous Gland Adenocarcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	Total	4/590 (0.68%)	Mean 0.73%	SD 1.01%	Total	4/590 (0.68%)	Mean 0.73%	SD 1.35%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 38  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Basosquamous Tumor (Benign), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma, or Sebaceous Gland Adenoma</b>									
		7/50 (14%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/50 (6%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		9/90 (10%)	4/50 (8%)	1/50 (2%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
<b>Overall Incidence</b>	<b>Total</b>	<b>37/590 (6.27%)</b>	<b>Mean 6%</b>	<b>SD 4.29%</b>	<b>Total</b>	<b>1/590 (0.17%)</b>	<b>Mean 0.18%</b>	<b>SD 0.6%</b>	
-----									
<b>#Skin:</b>									
<b>Fibroma</b>									
		3/50 (6%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/90 (2%)	2/50 (4%)	3/50 (6%)		2/90 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	4/50 (8%)			0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>26/590 (4.41%)</b>	<b>Mean 4.57%</b>	<b>SD 2.82%</b>	<b>Total</b>	<b>5/590 (0.85%)</b>	<b>Mean 0.75%</b>	<b>SD 1.04%</b>	
-----									
<b>#Skin:</b>									
<b>Fibroma or Myxoma</b>									
		3/50 (6%)	0/50 (0%)	4/50 (8%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/90 (2%)	2/50 (4%)	3/50 (6%)		2/90 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		2/50 (4%)	4/50 (8%)			0/50 (0%)	1/50 (2%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>26/590 (4.41%)</b>	<b>Mean 4.57%</b>	<b>SD 2.82%</b>	<b>Total</b>	<b>5/590 (0.85%)</b>	<b>Mean 0.75%</b>	<b>SD 1.04%</b>	
-----									
<b>#Skin:</b>									
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Pleomorphic Fibrosarcoma</b>									
		3/50 (6%)	5/50 (10%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		5/90 (6%)	3/50 (6%)	3/50 (6%)		5/90 (6%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
		3/50 (6%)	4/50 (8%)			1/50 (2%)	2/50 (4%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>39/590 (6.61%)</b>	<b>Mean 6.69%</b>	<b>SD 2.59%</b>	<b>Total</b>	<b>13/590 (2.2%)</b>	<b>Mean 1.96%</b>	<b>SD 1.91%</b>	

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

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 39  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Pleomorphic Fibrosarcoma, or Hemangiopericytoma</b>									
		3/50 (6%)	5/50 (10%)	6/50 (12%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		3/50 (6%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		5/90 (6%)	3/50 (6%)	3/50 (6%)		5/90 (6%)	0/50 (0%)	3/50 (6%)	
		3/50 (6%)	4/50 (8%)			1/50 (2%)	2/50 (4%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>39/590 (6.61%)</b>	<b>Mean 6.69%</b>	<b>SD 2.59%</b>	<b>Total</b>	<b>14/590 (2.37%)</b>	<b>Mean 2.14%</b>	<b>SD 2.2%</b>	
-----									
<b>#Skin:</b>									
<b>Fibrosarcoma</b>									
		0/50 (0%)	5/50 (10%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/90 (1%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>8/590 (1.36%)</b>	<b>Mean 1.37%</b>	<b>SD 2.97%</b>	<b>Total</b>	<b>4/590 (0.68%)</b>	<b>Mean 0.73%</b>	<b>SD 1.01%</b>	
-----									
<b>#Skin:</b>									
<b>Fibrosarcoma, Sarcoma, Myxosarcoma, or Pleomorphic Fibrosarcoma</b>									
		0/50 (0%)	5/50 (10%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		3/90 (3%)	1/50 (2%)	0/50 (0%)		3/90 (3%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>13/590 (2.2%)</b>	<b>Mean 2.12%</b>	<b>SD 2.99%</b>	<b>Total</b>	<b>8/590 (1.36%)</b>	<b>Mean 1.21%</b>	<b>SD 1.22%</b>	
-----									
<b>#Skin:</b>									
<b>Hemangioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	<b>Total</b>	<b>1/590 (0.17%)</b>	<b>Mean 0.18%</b>	<b>SD 0.6%</b>	<b>Total</b>	<b>0/590 (0%)</b>	<b>Mean 0%</b>	<b>SD 0%</b>	

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

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 40  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Hemangiopericytoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Keratoacanthoma</b>									
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		5/90 (6%)	2/50 (4%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	2/50 (4%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	23/590 (3.9%)	Mean 3.78%	SD 2.05%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Lipoma</b>									
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		3/50 (6%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		2/90 (2%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	9/590 (1.53%)	Mean 1.47%	SD 2.03%	Total	3/590 (0.51%)	Mean 0.55%	SD 0.93%	
.....									
<b>#Skin:</b>									
<b>Liposarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 41  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Neurofibrosarcoma or Schwannoma (malignant or NOS)</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 1.21%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 1.21%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Osteosarcoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Papilloma</b>									
		3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	3/590 (0.51%)	Mean 0.55%	SD 1.81%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 42  
 Report Date: 11/07/2024

		Male				Female									
<b>#Skin:</b>															
<b>Pilomatrixoma</b>															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total		0/590 (0%)		Mean 0%		SD 0%	
.....															
<b>#Skin:</b>															
<b>Pleomorphic Fibrosarcoma</b>															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)				
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total		1/590 (0.17%)		Mean 0.1%		SD 0.34%	
.....															
<b>#Skin:</b>															
<b>Sarcoma</b>															
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)				
		2/90	(2%)	0/50	(0%)	0/50	(0%)	2/90	(2%)	0/50	(0%)				
		1/50	(2%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	4/590 (0.68%)		Mean 0.57%		SD 0.97%		Total		3/590 (0.51%)		Mean 0.38%		SD 0.86%	
.....															
<b>#Skin:</b>															
<b>Schwannoma Malignant</b>															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)				
		0/50	(0%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	1/50	(2%)				
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)				
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)				
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean 0.36%		SD 1.21%		Total		1/590 (0.17%)		Mean 0.18%		SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 43  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	2/50 (4%)	0/50 (0%)	
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	4/590 (0.68%)	Mean 0.73%	SD 1.01%	Total	4/590 (0.68%)	Mean 0.73%	SD 1.35%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)	2/50 (4%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	6/590 (1.02%)	Mean 0.93%	SD 1.39%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma or Papilloma</b>									
		3/50 (6%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/90 (2%)	2/50 (4%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	9/590 (1.53%)	Mean 1.47%	SD 2.03%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 44  
 Report Date: 11/07/2024

		Male				Female			
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, or Keratoacanthoma</b>									
		6/50 (12%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	2/50 (4%)	4/50 (8%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		7/90 (8%)	4/50 (8%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	32/590 (5.42%)	Mean 5.25%	SD 3.59%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin:</b>									
<b>Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma</b>									
		6/50 (12%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	3/50 (6%)	4/50 (8%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		7/90 (8%)	4/50 (8%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		4/50 (8%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	34/590 (5.76%)	Mean 5.62%	SD 3.65%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>#Skin:</b>									
<b>Trichoepithelioma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Skin: Sebaceous Gland:</b>									
<b>Adenoma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)	Mean 0.28%	SD 0.66%	Total	0/590 (0%)	Mean 0%	SD 0%	

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

#: Denominator is number of animals necropsied

		Male				Female					
<b>*Spleen:</b>											
<b>Hemangiosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/49	(2%)
		3/90	(3%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/49	(0%)	0/49	(0%)
<b>Overall Incidence</b>	Total	3/590 (0.51%)		Mean 0.3%		SD 1.01%		Total 2/587 (0.34%)		Mean 0.29%	
										SD 0.67%	
<b>#Stomach, Forestomach:</b>											
<b>Papilloma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total 2/590 (0.34%)		Mean 0.36%	
										SD 0.81%	
<b>#Stomach, Forestomach:</b>											
<b>Sarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	0/590 (0%)		Mean 0%		SD 0%		Total 1/590 (0.17%)		Mean 0.1%	
										SD 0.34%	
<b>#Stomach, Forestomach:</b>											
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/90	(1%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.1%		SD 0.34%		Total 0/590 (0%)		Mean 0%	
										SD 0%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 46  
 Report Date: 11/07/2024

		Male				Female							
<b>#Stomach, Forestomach:</b>													
<b>Squamous Cell Papilloma</b>													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/90	(1%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.1%		SD 0.34%		Total	0/590 (0%)		Mean 0%	SD 0%	
.....													
<b>#Stomach, Glandular:</b>													
<b>Sarcoma</b>													
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%		Total	0/590 (0%)		Mean 0%	SD 0%	
.....													
<b>*Testis:</b>													
<b>Adenoma</b>													
		2/50	(4%)	1/50	(2%)	1/50	(2%)						
		7/50	(14%)	3/49	(6%)	0/50	(0%)						
		2/90	(2%)	0/50	(0%)	1/50	(2%)						
		0/50	(0%)	0/50	(0%)								
<b>Overall Incidence</b>	Total	17/589 (2.89%)		Mean 2.94%		SD 4.14%							
.....													
<b>*Thymus:</b>													
<b>Schwannoma Malignant</b>													
		0/50	(0%)	0/50	(0%)	0/46	(0%)	1/50	(2%)	0/47	(0%)	0/49	(0%)
		0/48	(0%)	0/47	(0%)	0/48	(0%)	0/49	(0%)	0/46	(0%)	0/50	(0%)
		0/88	(0%)	0/48	(0%)	0/48	(0%)	0/87	(0%)	0/50	(0%)	0/47	(0%)
		0/48	(0%)	0/49	(0%)			0/43	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	0/570 (0%)		Mean 0%		SD 0%		Total	1/568 (0.18%)		Mean 0.18%	SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 47  
 Report Date: 11/07/2024

		Male				Female			
<b>*Thymus:</b>									
<b>Thymoma Benign</b>									
		0/50 (0%)	0/50 (0%)	0/46 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)	
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/50 (0%)	
		0/88 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)	
		0/48 (0%)	0/49 (0%)			0/43 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/570 (0%)	Mean 0%	SD 0%	Total	1/568 (0.18%)	Mean 0.1%	SD 0.35%	
.....									
<b>*Thymus:</b>									
<b>Thymoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/46 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)	
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/50 (0%)	
		0/88 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)	
		0/48 (0%)	0/49 (0%)			0/43 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/570 (0%)	Mean 0%	SD 0%	Total	1/568 (0.18%)	Mean 0.1%	SD 0.35%	
.....									
<b>*Thymus:</b>									
<b>Thymoma: Benign, Malignant, NOS</b>									
		0/50 (0%)	0/50 (0%)	0/46 (0%)		0/50 (0%)	0/47 (0%)	0/49 (0%)	
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/50 (0%)	
		0/88 (0%)	0/48 (0%)	0/48 (0%)		2/87 (2%)	0/50 (0%)	0/47 (0%)	
		0/48 (0%)	0/49 (0%)			0/43 (0%)	0/50 (0%)		
<b>Overall Incidence</b>	Total	0/570 (0%)	Mean 0%	SD 0%	Total	2/568 (0.35%)	Mean 0.21%	SD 0.69%	
.....									
<b>*Thyroid Gland: C-Cell:</b>									
<b>Adenoma</b>									
		12/49 (24%)	7/50 (14%)	11/50 (22%)		10/50 (20%)	12/50 (24%)	9/50 (18%)	
		13/50 (26%)	10/50 (20%)	2/50 (4%)		12/50 (24%)	8/49 (16%)	2/50 (4%)	
		8/89 (9%)	8/50 (16%)	4/50 (8%)		6/90 (7%)	16/50 (32%)	5/50 (10%)	
		8/50 (16%)	9/50 (18%)			6/50 (12%)	10/50 (20%)		
<b>Overall Incidence</b>	Total	92/588 (15.65%)	Mean 16.13%	SD 6.99%	Total	96/589 (16.3%)	Mean 17%	SD 8.32%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 48  
 Report Date: 11/07/2024

		Male				Female			
<b>*Thyroid Gland: C-Cell: Carcinoma</b>									
		0/49 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	
		2/50 (4%)	1/50 (2%)	1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		2/89 (2%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	2/50 (4%)	2/50 (4%)	
		0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)			
<b>Overall Incidence</b>	Total	8/588 (1.36%)	Mean 1.3%	SD 1.36%	Total	9/589 (1.53%)	Mean 1.64%	SD 1.75%	
.....									
<b>*Thyroid Gland: C-Cell: Carcinoma or Adenoma</b>									
		12/49 (24%)	8/50 (16%)	11/50 (22%)	11/50 (22%)	13/50 (26%)	9/50 (18%)		
		14/50 (28%)	10/50 (20%)	3/50 (6%)	14/50 (28%)	8/49 (16%)	2/50 (4%)		
		10/89 (11%)	8/50 (16%)	4/50 (8%)	6/90 (7%)	16/50 (32%)	7/50 (14%)		
		8/50 (16%)	9/50 (18%)		7/50 (14%)	12/50 (24%)			
<b>Overall Incidence</b>	Total	97/588 (16.5%)	Mean 16.88%	SD 6.71%	Total	105/589 (17.83%)	Mean 18.64%	SD 8.76%	
.....									
<b>*Thyroid Gland: Follicular Cell: Adenoma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/89 (0%)	2/50 (4%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/45 (0%)	0/50 (0%)		0/45 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	2/583 (0.34%)	Mean 0.36%	SD 1.21%	Total	1/584 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
<b>*Thyroid Gland: Follicular Cell: Carcinoma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)	
		0/89 (0%)	0/50 (0%)	0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/45 (0%)	0/50 (0%)		0/45 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/583 (0%)	Mean 0%	SD 0%	Total	1/584 (0.17%)	Mean 0.1%	SD 0.34%	

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

#: Denominator is number of animals necropsied



Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 49  
 Report Date: 11/07/2024

		Male				Female			
<b>*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma</b>									
		0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/89 (0%)	2/50 (4%)	0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/45 (0%)	0/50 (0%)		0/45 (0%)	1/50 (2%)			
<b>Overall Incidence</b>	Total	2/583 (0.34%)	Mean 0.36%	SD 1.21%	Total	2/584 (0.34%)	Mean 0.28%	SD 0.66%	
.....									
<b>#Tissue NOS: Schwannoma Malignant</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)	1/90 (1%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%	
.....									
<b>#Tongue: Fibrosarcoma</b>									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
.....									
<b>#Tongue: Papilloma</b>									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	0/590 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 50  
 Report Date: 11/07/2024

		Male				Female					
<b>#Tongue:</b>											
<b>Squamous Cell Carcinoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	<b>Total</b>	0/590 (0%)		Mean 0%		SD 0%		<b>Total</b> 1/590 (0.17%)		Mean 0.1%	
										SD 0.34%	
.....											
<b>#Tongue:</b>											
<b>Squamous Cell Carcinoma or Papilloma Squamous</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	<b>Total</b>	0/590 (0%)		Mean 0%		SD 0%		<b>Total</b> 1/590 (0.17%)		Mean 0.1%	
										SD 0.34%	
.....											
<b>#Tooth:</b>											
<b>Odontoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)
<b>Overall Incidence</b>	<b>Total</b>	1/590 (0.17%)		Mean 0.18%		SD 0.6%		<b>Total</b> 0/590 (0%)		Mean 0%	
										SD 0%	
.....											
<b>*Urinary Bladder:</b>											
<b>Leiomyosarcoma</b>											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/89	(0%)	0/50	(0%)	0/50	(0%)	1/88	(1%)	0/49	(0%)
		0/50	(0%)	0/50	(0%)			0/46	(0%)	0/50	(0%)
<b>Overall Incidence</b>	<b>Total</b>	0/589 (0%)		Mean 0%		SD 0%		<b>Total</b> 1/583 (0.17%)		Mean 0.1%	
										SD 0.34%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 51  
 Report Date: 11/07/2024

	Male		Female			
<b>*Uterus:</b>						
<b>Adenocarcinoma</b>						
		0/50 (0%)	1/50 (2%)	2/50 (4%)		
		2/50 (4%)	3/50 (6%)	1/50 (2%)		
			2/50 (4%)	3/50 (6%)		
		5/49 (10%)	3/50 (6%)			
<b>Overall Incidence</b>	Total	22/499 (4.41%)	Mean	4.42%	SD	2.84%
.....						
<b>*Uterus:</b>						
<b>Adenocarcinoma or Adenoma</b>						
		0/50 (0%)	1/50 (2%)	2/50 (4%)		
		2/50 (4%)	3/50 (6%)	1/50 (2%)		
			4/50 (8%)	3/50 (6%)		
		5/49 (10%)	3/50 (6%)			
<b>Overall Incidence</b>	Total	24/499 (4.81%)	Mean	4.82%	SD	3.05%
.....						
<b>*Uterus:</b>						
<b>Adenoma</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
			2/50 (4%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	Total	2/499 (0.4%)	Mean	0.4%	SD	1.26%
.....						
<b>*Uterus:</b>						
<b>Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Papilloma</b>						
		0/50 (0%)	1/50 (2%)	4/50 (8%)		
		2/50 (4%)	3/50 (6%)	2/50 (4%)		
			4/50 (8%)	5/50 (10%)		
		7/49 (14%)	3/50 (6%)			
<b>Overall Incidence</b>	Total	31/499 (6.21%)	Mean	6.23%	SD	4.11%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 52  
 Report Date: 11/07/2024

	Male		Female			
<b>*Uterus:</b>						
<b>Deciduoma Benign</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	1/50	(2%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	0/49	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total 1/499 (0.2%)		Mean 0.2%		SD 0.63%	
.....						
<b>*Uterus:</b>						
<b>Granular Cell Tumor Benign</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	1/50	(2%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	1/49	(2%)	0/50	(0%)		
<b>Overall Incidence</b>	Total 2/499 (0.4%)		Mean 0.4%		SD 0.85%	
.....						
<b>*Uterus:</b>						
<b>Hemangioma</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	0/49	(0%)	1/50	(2%)		
<b>Overall Incidence</b>	Total 1/499 (0.2%)		Mean 0.2%		SD 0.63%	
.....						
<b>*Uterus:</b>						
<b>Polyp Stromal</b>						
	1/50	(2%)	5/50	(10%)	9/50	(18%)
	5/50	(10%)	8/50	(16%)	7/50	(14%)
			2/50	(4%)	5/50	(10%)
	4/49	(8%)	5/50	(10%)		
<b>Overall Incidence</b>	Total 51/499 (10.22%)		Mean 10.22%		SD 4.93%	

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 53  
 Report Date: 11/07/2024

	Male		Female			
<b>*Uterus:</b>						
<b>Sarcoma</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	1/50	(2%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	0/49	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/499 (0.2%)	Mean	0.2%	SD	0.63%
.....						
<b>*Uterus:</b>						
<b>Sarcoma Stromal</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	1/50	(2%)
	0/49	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	1/499 (0.2%)	Mean	0.2%	SD	0.63%
.....						
<b>*Uterus:</b>						
<b>Sarcoma Stromal or Polyp Stromal</b>						
	1/50	(2%)	5/50	(10%)	9/50	(18%)
	5/50	(10%)	8/50	(16%)	7/50	(14%)
			2/50	(4%)	6/50	(12%)
	4/49	(8%)	5/50	(10%)		
<b>Overall Incidence</b>	Total	52/499 (10.42%)	Mean	10.42%	SD	4.96%
.....						
<b>*Uterus:</b>						
<b>Schwannoma Malignant</b>						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
	0/50	(0%)	1/50	(2%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	1/49	(2%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	2/499 (0.4%)	Mean	0.4%	SD	0.85%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 54  
 Report Date: 11/07/2024

	Male		Female			
<b>*Uterus:</b>						
<b>Sq Cell Carcinoma or Papilloma Squamous</b>						
		0/50 (0%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		
			0/50 (0%)	2/50 (4%)		
		2/49 (4%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	7/499 (1.4%)	<b>Mean</b>	1.41%	<b>SD</b>	1.91%
.....						
<b>*Uterus:</b>						
<b>Squamous Cell Carcinoma</b>						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		
			0/50 (0%)	2/50 (4%)		
		2/49 (4%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	6/499 (1.2%)	<b>Mean</b>	1.21%	<b>SD</b>	1.7%
.....						
<b>*Uterus:</b>						
<b>Squamous Cell Papilloma</b>						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
			0/50 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	1/499 (0.2%)	<b>Mean</b>	0.2%	<b>SD</b>	0.63%
.....						
<b>#Vagina:</b>						
<b>Granular Cell Tumor Benign</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/47 (0%)	0/50 (0%)			
<b>Overall Incidence</b>	<b>Total</b>	1/587 (0.17%)	<b>Mean</b>	0.18%	<b>SD</b>	0.6%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 55  
 Report Date: 11/07/2024

					Male		Female				
<b>#Vagina:</b>											
<b>Polyp</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/90	(0%)	0/50	(0%)	1/50	(2%)	
					0/47	(0%)	0/50	(0%)			
<b>Overall Incidence</b>					Total	1/587	(0.17%)	Mean	0.18%	SD	0.6%
.....											
<b>#Vagina:</b>											
<b>Sarcoma</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/90	(0%)	0/50	(0%)	0/50	(0%)	
					0/47	(0%)	1/50	(2%)			
<b>Overall Incidence</b>					Total	1/587	(0.17%)	Mean	0.18%	SD	0.6%
.....											
<b>#Vagina:</b>											
<b>Schwannoma Malignant</b>											
					0/50	(0%)	0/50	(0%)	0/50	(0%)	
					0/50	(0%)	1/50	(2%)	1/50	(2%)	
					1/90	(1%)	1/50	(2%)	0/50	(0%)	
					0/47	(0%)	0/50	(0%)			
<b>Overall Incidence</b>					Total	4/587	(0.68%)	Mean	0.65%	SD	0.93%
.....											
<b>#Zymbal's Gland:</b>											
<b>Adenoma</b>											
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	0/50	(0%)
		1/50	(2%)	0/50	(0%)			0/50	(0%)		
<b>Overall Incidence</b>	Total	2/590 (0.34%)		Mean	0.36%	SD	0.81%	Total	0/590 (0%)	Mean	0%
										SD	0%

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

#: Denominator is number of animals necropsied

Version: Nov2024  
 Contract/Lab: All Laboratories  
 Species: RATS  
 Strain: Harlan Sprague-Dawley  
 Length of Study: CHRONIC

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

Page: 56  
 Report Date: 11/07/2024

		Male				Female							
<b>#Zymbal's Gland:</b>													
<b>Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Papilloma</b>													
		0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)	1/50	(2%)	0/90	(0%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	10/590 (1.69%)		Mean 1.82%		SD 1.89%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%
.....													
<b>#Zymbal's Gland:</b>													
<b>Carcinoma</b>													
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	1/50	(2%)	1/50	(2%)	0/90	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
<b>Overall Incidence</b>	Total	8/590 (1.36%)		Mean 1.45%		SD 1.29%		Total	1/590 (0.17%)		Mean 0.18%		SD 0.6%
.....													

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

#: Denominator is number of animals necropsied