



National Toxicology Program
Department of Health and Human Services

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

December 2020

REPORT DESCRIPTION

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

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

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

Male

M1
M2
M3
M4
M5

Female

F1
F2
F3
F4
F5

the data would be shown as:

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

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

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

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	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 Columbus Laboratory	051098701	08/30/10	729	49(2)	27(672)	628.3	Dibutyl Phthalate
Battelle Columbus Laboratory	051026001	11/08/10	729	50(2)	30(706)	615.3	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052000603	03/14/07	727	50(3)	20(644)	584.8	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
Battelle Columbus Laboratory	052061401	10/27/08	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	07/27/09	743	50(2)	36(684)	609.5	Perfluorooctanoic Acid
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	052071203	12/12/11	729	50(2)	25(652)	589.0	Tris(Chloropropyl)phosphate
Female							
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 Columbus Laboratory	051098701	08/31/10	730	50(4)	29(668)	397.3	Dibutyl Phthalate
Battelle Columbus Laboratory	051026001	11/09/10	730	50(4)	30(657)	379.6	2-Hydroxy-4-methoxybenzophenone
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene
Battelle Columbus Laboratory	052061401	10/28/08	744	50(4)	23(649)	385.9	Perfluorooctanoic Acid
Battelle Columbus Laboratory	052061402	N/A	N/A	0(0)	0(0)	N/A	Perfluorooctanoic Acid
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	052071203	12/13/11	731	50(4)	22(629)	380.1	Tris(Chloropropyl)phosphate

Version: Dec2020
 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: 4
 Report Date: 12/30/2020

		Male				Female			
#All Organs:									
Benign Tumors									
		30/50 (60%)	27/50 (54%)	28/50 (56%)	44/50 (88%)	37/50 (74%)	41/50 (82%)		
		35/49 (71%)	38/50 (76%)	27/50 (54%)	40/50 (80%)	41/50 (82%)	40/50 (80%)		
		30/50 (60%)		32/50 (64%)	39/50 (78%)	39/50 (78%)			
		49/90 (54%)	33/50 (66%)	29/50 (58%)	82/90 (91%)	43/50 (86%)	39/50 (78%)		
		25/50 (50%)			41/50 (82%)				
Overall Incidence	Total	383/639 (59.94%)	Mean 60.32%	SD 7.75%	Total	526/640 (82.19%)	Mean 81.59%	SD 4.8%	

#All Organs:									
Malignant Tumors									
		10/50 (20%)	13/50 (26%)	15/50 (30%)	7/50 (14%)	16/50 (32%)	14/50 (28%)		
		14/49 (29%)	11/50 (22%)	12/50 (24%)	13/50 (26%)	15/50 (30%)	19/50 (38%)		
		12/50 (24%)		9/50 (18%)	11/50 (22%)	14/50 (28%)			
		24/90 (27%)	13/50 (26%)	14/50 (28%)	37/90 (41%)	10/50 (20%)	17/50 (34%)		
		9/50 (18%)			10/50 (20%)				
Overall Incidence	Total	156/639 (24.41%)	Mean 24.27%	SD 4.04%	Total	183/640 (28.59%)	Mean 27.76%	SD 7.93%	

#All Organs:									
Malignant and Benign Tumors									
		33/50 (66%)	32/50 (64%)	36/50 (72%)	46/50 (92%)	41/50 (82%)	44/50 (88%)		
		41/49 (84%)	42/50 (84%)	33/50 (66%)	44/50 (88%)	47/50 (94%)	46/50 (92%)		
		37/50 (74%)		37/50 (74%)	41/50 (82%)	47/50 (94%)			
		57/90 (63%)	39/50 (78%)	36/50 (72%)	89/90 (99%)	45/50 (90%)	47/50 (94%)		
		30/50 (60%)			46/50 (92%)				
Overall Incidence	Total	453/639 (70.89%)	Mean 71.42%	SD 7.84%	Total	583/640 (91.09%)	Mean 90.57%	SD 4.96%	

#All Organs:									
Hemangioma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/49 (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%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%	

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

		Male				Female									
#All Organs:															
Hemangiosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)		
		0/49	(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%)	0/50	(0%)				
		3/90	(3%)	0/50	(0%)	1/50	(2%)	3/90	(3%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)						
Overall Incidence	Total	5/639 (0.78%)		Mean 0.61%		SD 1.15%		Total		5/640 (0.78%)		Mean 0.61%		SD 1.15%	
#All Organs:															
Hemangiosarcoma or Hemangioma															
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	2/50	(4%)		
		0/49	(0%)	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%)				
		3/90	(3%)	0/50	(0%)	1/50	(2%)	3/90	(3%)	1/50	(2%)	0/50	(0%)		
		0/50	(0%)					1/50	(2%)						
Overall Incidence	Total	7/639 (1.1%)		Mean 0.94%		SD 1.22%		Total		8/640 (1.25%)		Mean 1.11%		SD 1.49%	
#All Organs:															
Histiocytic Sarcoma															
		1/50	(2%)	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%)	0/50	(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%)		
		1/50	(2%)					0/50	(0%)						
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%		SD 0.78%		Total		1/640 (0.16%)		Mean 0.17%		SD 0.58%	
#All Organs:															
Leukemia: Granulocytic															
		1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		0/49	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	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%)						
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%		SD 0.78%		Total		1/640 (0.16%)		Mean 0.17%		SD 0.58%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#All Organs:									
Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/50 (6%)		3/50 (6%)		0/50 (0%)	1/50 (2%)		
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				2/50 (4%)			
Overall Incidence	Total	8/639 (1.25%)		Mean 1.33%	SD 2.31%	Total 5/640 (0.78%)		Mean 0.83%	SD 1.34%

#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	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%)	1/50 (2%)		
		2/90 (2%)	1/50 (2%)	1/50 (2%)		5/90 (6%)	1/50 (2%)	2/50 (4%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	10/639 (1.56%)		Mean 1.52%	SD 1.52%	Total 11/640 (1.72%)		Mean 1.46%	SD 1.84%

#All Organs:									
Malignant Schwannoma									
		0/50 (0%)	3/50 (6%)	6/50 (12%)		1/50 (2%)	1/50 (2%)	3/50 (6%)	
		3/49 (6%)	1/50 (2%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)		1/50 (2%)		2/50 (4%)	0/50 (0%)		
		3/90 (3%)	0/50 (0%)	1/50 (2%)		4/90 (4%)	1/50 (2%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	20/639 (3.13%)		Mean 3.12%	SD 3.56%	Total 18/640 (2.81%)		Mean 2.7%	SD 2%

#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)		1/50 (2%)		0/50 (0%)	0/50 (0%)		
		2/90 (2%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	14/639 (2.19%)		Mean 2.19%	SD 1.03%	Total 0/640 (0%)		Mean 0%	SD 0%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)		1/50 (2%)		0/50 (0%)	0/50 (0%)		
		2/90 (2%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	14/639 (2.19%)	Mean 2.19%	SD 1.03%	Total	0/640 (0%)	Mean 0%	SD 0%	

#All Organs:									
Osteosarcoma									
		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%)	0/50 (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%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	2/640 (0.31%)	Mean 0.33%	SD 0.78%	

#All Organs:									
Osteosarcoma or Osteoma									
		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%)	0/50 (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%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	2/640 (0.31%)	Mean 0.33%	SD 0.78%	

*Adrenal Cortex:									
Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)	
		3/50 (6%)		0/50 (0%)		0/50 (0%)	2/50 (4%)	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%)			
Overall Incidence	Total	8/639 (1.25%)	Mean 1.26%	SD 2.3%	Total	11/640 (1.72%)	Mean 1.76%	SD 2.49%	

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

		Male				Female			
*Adrenal Cortex:									
 Carcinoma									
		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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%

*Adrenal Medulla:									
 Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/50 (0%)	0/50 (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%)			
Overall Incidence	Total	1/637 (0.16%)		Mean 0.17%	SD 0.58%	Total 1/635 (0.16%)		Mean 0.17%	SD 0.58%

*Adrenal Medulla:									
 Pheochromocytoma Benign									
		14/50 (28%)	4/50 (8%)	5/50 (10%)		3/50 (6%)	1/50 (2%)	0/50 (0%)	
		7/49 (14%)	9/50 (18%)	5/50 (10%)		0/50 (0%)	3/50 (6%)	0/50 (0%)	
		12/50 (24%)		8/50 (16%)		0/49 (0%)	1/50 (2%)		
		10/88 (11%)	4/50 (8%)	10/50 (20%)		1/86 (1%)	3/50 (6%)	1/50 (2%)	
		6/50 (12%)				0/50 (0%)			
Overall Incidence	Total	94/637 (14.76%)		Mean 14.97%	SD 6.44%	Total 13/635 (2.05%)		Mean 2.1%	SD 2.5%

*Adrenal Medulla:									
 Pheochromocytoma Complex									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (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%)	0/50 (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%)			
Overall Incidence	Total	3/637 (0.47%)		Mean 0.43%	SD 0.8%	Total 0/635 (0%)		Mean 0%	SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	3/50 (6%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
		2/50 (4%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	
		1/88 (1%)	1/50 (2%)	2/50 (4%)	0/86 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	13/637 (2.04%)		Mean 2.1%	SD 2.01%	Total	3/635 (0.47%)		Mean 0.5% SD 1.24%

*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		14/50 (28%)	5/50 (10%)	6/50 (12%)	3/50 (6%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		8/49 (16%)	12/50 (24%)	8/50 (16%)	0/50 (0%)	5/50 (10%)	0/50 (0%)	5/50 (10%)	0/50 (0%)
		14/50 (28%)		8/50 (16%)	0/49 (0%)	1/50 (2%)		1/50 (2%)	
		11/88 (13%)	5/50 (10%)	12/50 (24%)	1/86 (1%)	3/50 (6%)		3/50 (6%)	2/50 (4%)
		6/50 (12%)			0/50 (0%)			0/50 (0%)	
Overall Incidence	Total	109/637 (17.11%)		Mean 17.4%	SD 6.8%	Total	16/635 (2.52%)		Mean 2.6% SD 3.25%

#Bone:									
Osteosarcoma									
		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%)	0/50 (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%)		1/50 (2%)	
		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%)	
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	1/640 (0.16%)		Mean 0.17% SD 0.58%

#Bone:									
Osteosarcoma or Osteoma									
		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%)	0/50 (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%)		1/50 (2%)	
		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%)	
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	1/640 (0.16%)		Mean 0.17% SD 0.58%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Brain:									
 Glioma Malignant									
		1/50 (2%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/49 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
		2/50 (4%)		1/50 (2%)		1/50 (2%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	12/589 (2.04%)	Mean 2.19%	SD 2.61%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	

*Brain:									
 Granular Cell Tumor Benign									
		3/50 (6%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
		0/49 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)		
		0/50 (0%)		2/50 (4%)		0/50 (0%)	0/50 (0%)		
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	12/589 (2.04%)	Mean 2.1%	SD 2.46%	Total	5/590 (0.85%)	Mean 0.83%	SD 1.33%	

*Brain:									
 Granular Cell Tumor Malignant									
		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%)		
		0/50 (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%)			
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	

*Brain:									
 Meningioma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/589 (0.17%)	Mean 0.19%	SD 0.62%	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			
*Brain:									
Meningioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
*Brain:									
Meningioma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/49 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/589 (0.34%)	Mean 0.37%	SD 0.82%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
.....									
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		1/50 (2%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		2/49 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
		2/50 (4%)		1/50 (2%)		1/50 (2%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	12/589 (2.04%)	Mean 2.19%	SD 2.61%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%	
.....									
*Brain:									
Schwannoma Malignant									
		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%)		
		0/50 (0%)		1/50 (2%)		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%)			
Overall Incidence	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: Dec2020
 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: 12/30/2020

		Male				Female			
*Clitoral/Preputial Gland: Adenoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		1/49 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (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%)				0/46 (0%)			
Overall Incidence	Total	1/635 (0.16%)	Mean 0.17%	SD 0.59%	Total	0/626 (0%)	Mean 0%	SD 0%	

*Clitoral/Preputial Gland: Carcinoma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)		
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)				0/46 (0%)			
Overall Incidence	Total	2/635 (0.31%)	Mean 0.34%	SD 0.79%	Total	1/626 (0.16%)	Mean 0.17%	SD 0.58%	

*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)	
		1/49 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)		
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)				0/46 (0%)			
Overall Incidence	Total	3/635 (0.47%)	Mean 0.51%	SD 0.92%	Total	1/626 (0.16%)	Mean 0.17%	SD 0.58%	

*Clitoral/Preputial Gland: Squamous Cell Carcinoma									
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/49 (2%)	0/49 (0%)	0/50 (0%)	
		1/49 (2%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)		0/50 (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%)	
		1/50 (2%)				0/46 (0%)			
Overall Incidence	Total	2/635 (0.31%)	Mean 0.34%	SD 0.79%	Total	2/626 (0.32%)	Mean 0.34%	SD 0.8%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Clitoral/Preputial Gland:									
Squamous Cell Papilloma									
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/49 (0%)	1/49 (2%)	0/50 (0%)	
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)	
		0/50 (0%)		0/50 (0%)		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%)				0/46 (0%)			
Overall Incidence	Total	2/635 (0.31%)		Mean 0.33%	SD 0.78%	Total 1/626 (0.16%)		Mean 0.17%	SD 0.59%
.....									
*Epididymis:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)					
		0/49 (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%)							
Overall Incidence	Total	1/638 (0.16%)		Mean 0.17%	SD 0.58%				
.....									
#Eye:									
Leiomyoma									
		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%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 0/640 (0%)		Mean 0%	SD 0%
.....									
*Heart:									
Schwannoma Malignant									
		0/50 (0%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/49 (0%)	
		2/49 (4%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/49 (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%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	9/639 (1.41%)		Mean 1.51%	SD 2.12%	Total 4/638 (0.63%)		Mean 0.67%	SD 1.3%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female						
#Intestine Large: Cecum:												
Liposarcoma												
		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%)	0/50	(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%)			
Overall Incidence	Total	0/639 (0%)		Mean 0%		SD 0%		Total	1/640 (0.16%)		Mean 0.17%	SD 0.58%
<hr/>												
#Intestine Large: Colon/Rectum:												
Granular Cell Tumor Benign												
		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%)	0/50	(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%)			
Overall Incidence	Total	0/639 (0%)		Mean 0%		SD 0%		Total	1/640 (0.16%)		Mean 0.09%	SD 0.32%
<hr/>												
#Intestine Large: Colon/Rectum:												
Leiomyoma												
		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%)	0/50	(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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%		SD 0.58%		Total	0/640 (0%)		Mean 0%	SD 0%
<hr/>												
#Intestine Small: Jejunum:												
Carcinoma												
		0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)	
		0/49	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)			1/50	(2%)	0/50	(0%)	1/50	(2%)	
		2/90	(2%)	1/50	(2%)	1/50	(2%)	0/90	(0%)	0/50	(0%)	
		0/50	(0%)					0/50	(0%)			
Overall Incidence	Total	9/639 (1.41%)		Mean 1.35%		SD 1.31%		Total	1/640 (0.16%)		Mean 0.17%	SD 0.58%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		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%)		0/50 (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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%

#Intestine Small: Site Unspecified:									
Carcinoma									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (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%)		0/50 (0%)	1/50 (2%)	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%)			
Overall Incidence	Total	9/639 (1.41%)		Mean 1.35%	SD 1.31%	Total 1/640 (0.16%)		Mean 0.17%	SD 0.58%

#Intestine Small: Site Unspecified:									
Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (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%)		0/50 (0%)	1/50 (2%)	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%)			
Overall Incidence	Total	9/639 (1.41%)		Mean 1.35%	SD 1.31%	Total 1/640 (0.16%)		Mean 0.17%	SD 0.58%

#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		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%)		0/50 (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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Islets, Pancreatic:									
Adenoma									
		4/50 (8%)	3/49 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	3/49 (6%)	
		4/49 (8%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		8/50 (16%)		5/50 (10%)		1/50 (2%)	1/50 (2%)		
		5/90 (6%)	2/50 (4%)	2/50 (4%)		5/90 (6%)	2/50 (4%)	1/50 (2%)	
		4/50 (8%)				0/49 (0%)			
Overall Incidence	Total	44/638 (6.9%)	Mean 6.99%	SD 3.48%	Total	16/638 (2.51%)	Mean 2.31%	SD 2.01%	

*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/49 (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%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)		0/50 (0%)		1/50 (2%)	0/50 (0%)		
		8/90 (9%)	3/50 (6%)	1/50 (2%)		2/90 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	12/638 (1.88%)	Mean 1.41%	SD 2.94%	Total	5/638 (0.78%)	Mean 0.69%	SD 1.01%	

*Islets, Pancreatic:									
Carcinoma or Adenoma									
		4/50 (8%)	3/49 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	3/49 (6%)	
		4/49 (8%)	3/50 (6%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)	
		8/50 (16%)		5/50 (10%)		2/50 (4%)	1/50 (2%)		
		13/90 (14%)	5/50 (10%)	3/50 (6%)		7/90 (8%)	2/50 (4%)	2/50 (4%)	
		4/50 (8%)				0/49 (0%)			
Overall Incidence	Total	56/638 (8.78%)	Mean 8.39%	SD 3.76%	Total	21/638 (3.29%)	Mean 2.99%	SD 2.31%	

*Kidney: Pelvis and Transitional Epithelium:									
Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (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%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%	

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

		Male				Female						
*Kidney: Renal Tubule: Adenoma												
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		1/49	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)			1/50	(2%)	1/50	(2%)	0/50	(0%)	
		3/90	(3%)	0/50	(0%)	2/50	(4%)	1/90	(1%)	0/50	(0%)	
		0/50	(0%)					0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	9/639 (1.41%)		Mean 1.28%		SD 1.46%		Total	2/640 (0.31%)		Mean 0.26%	SD 0.63%
*Kidney: Renal Tubule: Carcinoma												
		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%)	0/50	(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%)	
Overall Incidence	Total	1/639 (0.16%)		Mean 0.09%		SD 0.32%		Total	1/640 (0.16%)		Mean 0.09%	SD 0.32%
*Kidney: Renal Tubule: Carcinoma or Adenoma												
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		1/49	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)			1/50	(2%)	1/50	(2%)	0/50	(0%)	
		3/90	(3%)	0/50	(0%)	2/50	(4%)	2/90	(2%)	0/50	(0%)	
		0/50	(0%)					0/50	(0%)	0/50	(0%)	
Overall Incidence	Total	9/639 (1.41%)		Mean 1.28%		SD 1.46%		Total	3/640 (0.47%)		Mean 0.35%	SD 0.82%
*Kidney: Renal Tubule: Hemangioma												
		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%)	0/50	(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%)	
Overall Incidence	Total	0/639 (0%)		Mean 0%		SD 0%		Total	1/640 (0.16%)		Mean 0.17%	SD 0.58%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Kidney: Renal Tubule: Lipoma									
		1/50 (2%)	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%)	0/50 (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%)			
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%	

*Kidney: Renal Tubule: Liposarcoma									
		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%)		0/50 (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%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 0.78%	Total	0/640 (0%)	Mean 0%	SD 0%	

*Kidney: Renal Tubule: Nephroblastoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)		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%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%	

*Kidney: Renal Tubule: Oncocytoma Benign									
		1/50 (2%)	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%)	0/50 (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%)			
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Kidney: Renal Tubule:									
Polyp Adenomatous									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	0/640 (0%)		Mean 0% SD 0%

#Lacrimal Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)		0/50 (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%)			
Overall Incidence	Total	0/639 (0%)		Mean 0%	SD 0%	Total	1/640 (0.16%)		Mean 0.17% SD 0.58%

*Liver:									
Cholangiocarcinoma									
		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%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	0/639 (0%)		Mean 0% SD 0%

*Liver:									
Cholangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/49 (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%)		0/50 (0%)	1/50 (2%)		
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	4/639 (0.63%)		Mean 0.67% SD 0.99%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Liver:									
Hemangioma									
		0/50 (0%)	1/50 (2%)	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%)	0/50 (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%)				
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 0/639 (0%)		Mean 0%	SD 0%

*Liver:									
Hepatocellular Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/49 (2%)		
		0/49 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)		0/50 (0%)	2/50 (4%)	2/50 (4%)			
		0/90 (0%)	0/50 (0%)	1/50 (2%)	7/90 (8%)	2/50 (4%)	1/50 (2%)		
		1/50 (2%)			1/50 (2%)				
Overall Incidence	Total	3/639 (0.47%)		Mean 0.5%	SD 0.9%	Total 20/639 (3.13%)		Mean 2.82%	SD 2.28%

*Liver:									
Hepatocellular Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (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%)	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%)				
Overall Incidence	Total	2/639 (0.31%)		Mean 0.34%	SD 0.79%	Total 1/639 (0.16%)		Mean 0.17%	SD 0.58%

*Liver:									
Hepatocellular Carcinoma or Hepatoblastoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (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%)	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%)				
Overall Incidence	Total	2/639 (0.31%)		Mean 0.34%	SD 0.79%	Total 1/639 (0.16%)		Mean 0.17%	SD 0.58%

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

Version: Dec2020
 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: 12/30/2020

		Male					Female									
*Liver:																
Hepatocellular Carcinoma or Hepatocellular Adenoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	1/49	(2%)			
		1/49	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	2/50	(4%)			
		0/50	(0%)			0/50	(0%)	2/50	(4%)	3/50	(6%)					
		0/90	(0%)	0/50	(0%)	1/50	(2%)	7/90	(8%)	2/50	(4%)	1/50	(2%)			
		1/50	(2%)					1/50	(2%)							
Overall Incidence	Total	5/639 (0.78%)			Mean	0.84%	SD	1.03%	Total	21/639 (3.29%)			Mean	2.98%	SD	2.44%
.....																
*Liver:																
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	1/49	(2%)			
		1/49	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	2/50	(4%)			
		0/50	(0%)			0/50	(0%)	2/50	(4%)	3/50	(6%)					
		0/90	(0%)	0/50	(0%)	1/50	(2%)	7/90	(8%)	2/50	(4%)	1/50	(2%)			
		1/50	(2%)					1/50	(2%)							
Overall Incidence	Total	5/639 (0.78%)			Mean	0.84%	SD	1.03%	Total	21/639 (3.29%)			Mean	2.98%	SD	2.44%
.....																
*Lung:																
Alveolar/Bronchiolar Adenoma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)			
		1/49	(2%)	0/50	(0%)	0/49	(0%)	0/50	(0%)	0/49	(0%)	1/50	(2%)			
		0/50	(0%)			0/50	(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%)							
Overall Incidence	Total	4/638 (0.63%)			Mean	0.6%	SD	0.91%	Total	1/638 (0.16%)			Mean	0.17%	SD	0.58%
.....																
*Lung:																
Alveolar/Bronchiolar Carcinoma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/49	(0%)			
		0/49	(0%)	1/50	(2%)	0/49	(0%)	0/50	(0%)	0/49	(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%)			
		1/50	(2%)					0/50	(0%)							
Overall Incidence	Total	3/638 (0.47%)			Mean	0.5%	SD	0.9%	Total	0/638 (0%)			Mean	0%	SD	0%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
		1/49 (2%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
		1/90 (1%)	1/50 (2%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	7/638 (1.1%)		Mean 1.1%	SD 1.31%	Total 1/638 (0.16%)		Mean 0.17%	SD 0.58%

*Lung:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (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%)				0/50 (0%)			
Overall Incidence	Total	0/638 (0%)		Mean 0%	SD 0%	Total 1/638 (0.16%)		Mean 0.17%	SD 0.58%

*Lung:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (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%)			
Overall Incidence	Total	1/638 (0.16%)		Mean 0.17%	SD 0.58%	Total 0/638 (0%)		Mean 0%	SD 0%

#Lymph Node, Mesenteric:									
Hemangiosarcoma									
		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%)	1/50 (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%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 0/640 (0%)		Mean 0%	SD 0%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Mammary Gland:									
Adenolipoma									
		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%)		0/50 (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%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Mammary Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)	
		0/50 (0%)		0/50 (0%)		4/50 (8%)	1/50 (2%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		8/90 (9%)	1/50 (2%)	3/50 (6%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	22/640 (3.44%)	Mean 3.07%	SD 3.27%	

#Mammary Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	8/50 (16%)	1/50 (2%)	
		0/49 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	7/50 (14%)	3/50 (6%)	
		0/50 (0%)		0/50 (0%)		5/50 (10%)	3/50 (6%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		10/90 (11%)	2/50 (4%)	2/50 (4%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 1.24%	Total	49/640 (7.66%)	Mean 7.43%	SD 4.53%	

#Mammary Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		4/50 (8%)	8/50 (16%)	2/50 (4%)	
		0/49 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	7/50 (14%)	6/50 (12%)	
		0/50 (0%)		0/50 (0%)		9/50 (18%)	4/50 (8%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		16/90 (18%)	3/50 (6%)	5/50 (10%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 1.24%	Total	69/640 (10.78%)	Mean 10.31%	SD 5.29%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Mammary Gland:									
Fibroadenoma									
		3/50 (6%)	0/50 (0%)	2/50 (4%)		29/50 (58%)	25/50 (50%)	28/50 (56%)	
		1/49 (2%)	2/50 (4%)	1/50 (2%)		33/50 (66%)	32/50 (64%)	29/50 (58%)	
		2/50 (4%)		2/50 (4%)		20/50 (40%)	21/50 (42%)		
		2/90 (2%)	0/50 (0%)	0/50 (0%)		63/90 (70%)	28/50 (56%)	30/50 (60%)	
		2/50 (4%)				29/50 (58%)			
Overall Incidence	Total	17/639 (2.66%)	Mean 2.69%	SD 1.96%	Total	367/640 (57.34%)	Mean 56.5%	SD 8.91%	

#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		3/50 (6%)	0/50 (0%)	2/50 (4%)		29/50 (58%)	25/50 (50%)	29/50 (58%)	
		1/49 (2%)	2/50 (4%)	1/50 (2%)		33/50 (66%)	32/50 (64%)	30/50 (60%)	
		2/50 (4%)		2/50 (4%)		23/50 (46%)	22/50 (44%)		
		2/90 (2%)	0/50 (0%)	0/50 (0%)		64/90 (71%)	28/50 (56%)	32/50 (64%)	
		2/50 (4%)				29/50 (58%)			
Overall Incidence	Total	17/639 (2.66%)	Mean 2.69%	SD 1.96%	Total	376/640 (58.75%)	Mean 57.93%	SD 8.09%	

#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		3/50 (6%)	0/50 (0%)	3/50 (6%)		30/50 (60%)	29/50 (58%)	30/50 (60%)	
		1/49 (2%)	3/50 (6%)	1/50 (2%)		35/50 (70%)	36/50 (72%)	32/50 (64%)	
		2/50 (4%)		2/50 (4%)		27/50 (54%)	25/50 (50%)		
		2/90 (2%)	0/50 (0%)	0/50 (0%)		66/90 (73%)	29/50 (58%)	34/50 (68%)	
		2/50 (4%)				30/50 (60%)			
Overall Incidence	Total	19/639 (2.97%)	Mean 3.02%	SD 2.33%	Total	403/640 (62.97%)	Mean 62.28%	SD 7.28%	

#Mammary Gland:									
Myoepithelioma									
		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%)	0/50 (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%)				0/50 (0%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Nose:									
Carcinoma									
		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%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	1/50 (2%)		
		0/89 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/638 (0%)	Mean 0%	SD 0%	Total	1/638 (0.16%)	Mean 0.17%	SD 0.58%	
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (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%)		
		0/90 (0%)	1/50 (2%)	0/50 (0%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 0.91%	Total	2/640 (0.31%)	Mean 0.19%	SD 0.64%	
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (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%)		
		0/90 (0%)	1/50 (2%)	0/50 (0%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 0.91%	Total	2/640 (0.31%)	Mean 0.19%	SD 0.64%	
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (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%)		
		0/90 (0%)	1/50 (2%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.5%	SD 0.91%	Total	1/640 (0.16%)	Mean 0.09%	SD 0.32%	

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

Version: Dec2020
 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: 12/30/2020

	Male			Female		
*Ovary:						
Cystadenoma						
		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%)
		0/50	(0%)			
Overall Incidence	Total	1/640 (0.16%)		Mean	0.09%	SD 0.32%
.....						
*Ovary:						
Granulosa Cell Tumor Benign						
		0/50	(0%)	1/50	(2%)	1/50 (2%)
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		3/50	(6%)	1/50	(2%)	
		1/90	(1%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)			
Overall Incidence	Total	7/640 (1.09%)		Mean	1.09%	SD 1.78%
.....						
*Ovary:						
Granulosa Cell Tumor Malignant						
		0/50	(0%)	0/50	(0%)	1/50 (2%)
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		0/50	(0%)	0/50	(0%)	
		2/90	(2%)	1/50	(2%)	1/50 (2%)
		0/50	(0%)			
Overall Incidence	Total	5/640 (0.78%)		Mean	0.69%	SD 1.01%
.....						
*Ovary:						
Granulosa Cell Tumor: Benign, Malignant, NOS						
		0/50	(0%)	1/50	(2%)	2/50 (4%)
		0/50	(0%)	0/50	(0%)	0/50 (0%)
		3/50	(6%)	1/50	(2%)	
		3/90	(3%)	1/50	(2%)	1/50 (2%)
		0/50	(0%)			
Overall Incidence	Total	12/640 (1.88%)		Mean	1.78%	SD 1.93%

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

Version: Dec2020
 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: 12/30/2020

	Male		Female			
*Ovary:						
Granulosa-Theca Tumor Benign						
		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%)	0/50 (0%)	
		1/50 (2%)				
Overall Incidence	Total	2/640 (0.31%)	Mean	0.33%	SD	0.78%
<hr/>						
*Ovary:						
Granulosa-Theca Tumor Malignant						
		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%)	0/50 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/640 (0.16%)	Mean	0.17%	SD	0.58%
<hr/>						
*Ovary:						
Luteoma						
		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%)	0/50 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/640 (0.16%)	Mean	0.17%	SD	0.58%
<hr/>						
*Ovary:						
Schwannoma Malignant						
		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%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				
Overall Incidence	Total	1/640 (0.16%)	Mean	0.17%	SD	0.58%

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

Version: Dec2020
 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: 12/30/2020

					Male						Female			
*Ovary:														
Sertoli Cell Tumor Benign														
					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%)				
					0/50	(0%)								
Overall Incidence					Total	1/640	(0.16%)	Mean	0.09%	SD	0.32%			
.....														
*Ovary:														
Thecoma Benign														
					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%)								
Overall Incidence					Total	1/640	(0.16%)	Mean	0.17%	SD	0.58%			
.....														
*Ovary:														
Tubulostromal Carcinoma														
					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%)				
					0/50	(0%)								
Overall Incidence					Total	1/640	(0.16%)	Mean	0.17%	SD	0.58%			
.....														
*Pancreas:														
Adenoma														
		6/50	(12%)	1/49	(2%)	10/50	(20%)	0/50	(0%)	0/50	(0%)	0/49	(0%)	
		4/49	(8%)	5/50	(10%)	5/50	(10%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)			3/50	(6%)	0/50	(0%)	0/50	(0%)			
		18/90	(20%)	8/50	(16%)	14/50	(28%)	0/90	(0%)	0/50	(0%)	0/50	(0%)	
		9/50	(18%)					0/49	(0%)					
Overall Incidence	Total	83/638 (13.01%)		Mean	12.52%	SD	8.17%	Total	0/638	(0%)	Mean	0%	SD	0%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Pancreas:									
Carcinoma									
		1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		2/49 (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%)		
		1/90 (1%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	5/638 (0.78%)	Mean 0.77%	SD 1.31%	Total	0/638 (0%)	Mean 0%	SD 0%	

*Pancreas:									
Carcinoma or Adenoma									
		7/50 (14%)	1/49 (2%)	10/50 (20%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		6/49 (12%)	5/50 (10%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)		3/50 (6%)		0/50 (0%)	0/50 (0%)		
		18/90 (20%)	8/50 (16%)	14/50 (28%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		9/50 (18%)				0/49 (0%)			
Overall Incidence	Total	86/638 (13.48%)	Mean 13.02%	SD 8.06%	Total	0/638 (0%)	Mean 0%	SD 0%	

*Parathyroid Gland:									
Adenoma									
		0/49 (0%)	0/43 (0%)	0/42 (0%)		0/46 (0%)	0/42 (0%)	0/42 (0%)	
		0/48 (0%)	0/49 (0%)	0/43 (0%)		0/45 (0%)	1/41 (2%)	0/47 (0%)	
		0/48 (0%)		0/41 (0%)		0/45 (0%)	0/47 (0%)		
		1/83 (1%)	1/49 (2%)	0/43 (0%)		0/87 (0%)	0/48 (0%)	0/46 (0%)	
		0/49 (0%)				0/44 (0%)			
Overall Incidence	Total	2/587 (0.34%)	Mean 0.27%	SD 0.66%	Total	1/580 (0.17%)	Mean 0.2%	SD 0.7%	

#Peripheral Nerve:									
Paraganglioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.59%	Total	0/640 (0%)	Mean 0%	SD 0%	

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

		Male				Female			
#Peripheral Nerve:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.59%	Total	0/640 (0%)	Mean 0%	SD 0%	

#Peripheral Nerve:									
Schwannoma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.59%	Total	0/640 (0%)	Mean 0%	SD 0%	

*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		12/50 (24%)	3/50 (6%)	4/50 (8%)		20/50 (40%)	13/49 (27%)	15/49 (31%)	
		15/48 (31%)	14/50 (28%)	5/50 (10%)		12/50 (24%)	19/50 (38%)	18/50 (36%)	
		11/50 (22%)		5/50 (10%)		18/50 (36%)	22/50 (44%)		
		17/89 (19%)	10/50 (20%)	8/50 (16%)		43/90 (48%)	21/50 (42%)	16/50 (32%)	
		7/50 (14%)				11/50 (22%)			
Overall Incidence	Total	111/637 (17.43%)	Mean 17.36%	SD 8.09%	Total	228/638 (35.74%)	Mean 34.91%	SD 8.09%	

*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/49 (2%)	
		0/48 (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%)		
		0/89 (0%)	0/50 (0%)	1/50 (2%)		1/90 (1%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/637 (0.16%)	Mean 0.17%	SD 0.58%	Total	4/638 (0.63%)	Mean 0.6%	SD 0.91%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
*Pituitary Gland: Pars Distalis or Unspecified Site:									
 Carcinoma or Adenoma									
		12/50 (24%)	3/50 (6%)	4/50 (8%)	20/50 (40%)	13/49 (27%)	16/49 (33%)		
		15/48 (31%)	14/50 (28%)	5/50 (10%)	13/50 (26%)	19/50 (38%)	18/50 (36%)		
		11/50 (22%)		5/50 (10%)	18/50 (36%)	22/50 (44%)			
		17/89 (19%)	10/50 (20%)	9/50 (18%)	44/90 (49%)	21/50 (42%)	17/50 (34%)		
		7/50 (14%)			11/50 (22%)				
Overall Incidence	Total	112/637 (17.58%)	Mean 17.53%	SD 8.08%	Total	232/638 (36.36%)	Mean 35.51%	SD 7.89%	

*Pituitary Gland: Pars Intermedia:									
 Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)		
		0/48 (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%)		
		0/89 (0%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	5/637 (0.78%)	Mean 0.83%	SD 1.34%	Total	1/638 (0.16%)	Mean 0.17%	SD 0.58%	

*Pituitary Gland: Pars Intermedia:									
 Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)		
		0/48 (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%)		
		0/89 (0%)	1/50 (2%)	1/50 (2%)	0/90 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	5/637 (0.78%)	Mean 0.83%	SD 1.34%	Total	1/638 (0.16%)	Mean 0.17%	SD 0.58%	

*Pituitary Gland: Pars Nervosa:									
 Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/49 (0%)		
		0/48 (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%)		
		0/89 (0%)	0/50 (0%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/637 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/638 (0%)	Mean 0%	SD 0%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female							
*Prostate:													
Adenoma													
		0/50	(0%)	1/50	(2%)	0/50	(0%)						
		1/49	(2%)	0/50	(0%)	0/50	(0%)						
		0/50	(0%)			3/50	(6%)						
		2/90	(2%)	0/50	(0%)	0/50	(0%)						
		0/50	(0%)										
Overall Incidence	Total	7/639 (1.1%)		Mean 1.02%		SD 1.82%							

*Prostate:													
Carcinoma or Adenoma													
		0/50	(0%)	1/50	(2%)	0/50	(0%)						
		1/49	(2%)	0/50	(0%)	0/50	(0%)						
		0/50	(0%)			3/50	(6%)						
		2/90	(2%)	0/50	(0%)	0/50	(0%)						
		0/50	(0%)										
Overall Incidence	Total	7/639 (1.1%)		Mean 1.02%		SD 1.82%							

*Salivary Glands:													
Schwannoma Malignant													
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)	0/49	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)	0/49	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)			0/49	(0%)	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%)					0/50	(0%)				
Overall Incidence	Total	3/638 (0.47%)		Mean 0.5%		SD 1.24%		Total	0/635 (0%)	Mean 0%		SD 0%	

#Seminal Vesicle:													
Hemangiosarcoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)						
		0/49	(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%)										
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%		SD 0.58%							

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skeletal Muscle:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	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%)		0/50 (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%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skeletal Muscle:									
Liposarcoma									
		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%)	0/50 (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%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skeletal Muscle:									
Sarcoma									
		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%)	0/50 (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%)				0/50 (0%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skin:									
Basal Cell Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/49 (2%)	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%)		
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.43%	SD 0.81%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female							
#Skin:													
Basal Cell Adenoma or Basosquamous Tumor Benign													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)		
		1/49	(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%)		
		1/90	(1%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	1/50	(2%)		
		0/50	(0%)					0/50	(0%)				
Overall Incidence	Total	3/639 (0.47%)		Mean 0.43%		SD 0.81%		Total	1/640 (0.16%)		Mean 0.17%		
											SD 0.58%		
#Skin:													
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma													
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/49	(2%)	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%)
		1/90	(1%)	0/50	(0%)	0/50	(0%)	0/90	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)				
Overall Incidence	Total	4/639 (0.63%)		Mean 0.6%		SD 0.91%		Total	1/640 (0.16%)		Mean 0.17%		
											SD 0.58%		
#Skin:													
Basal Cell Carcinoma													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)	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%)				
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%		SD 0.78%		Total	3/640 (0.47%)		Mean 0.5%		
											SD 1.24%		
#Skin:													
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)													
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49	(0%)	0/50	(0%)	1/50	(2%)	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%)				
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%		SD 0.78%		Total	3/640 (0.47%)		Mean 0.5%		
											SD 1.24%		

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	1/50 (2%)		0/50 (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%)	0/50 (0%)
		1/90 (1%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	3/50 (6%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	6/639 (0.94%)		Mean 0.93%	SD 1%	4/640 (0.62%)		Mean 0.67%	SD 1.78%

#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		1/50 (2%)	1/50 (2%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		9/49 (18%)	4/50 (8%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		4/50 (8%)		6/50 (12%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		8/90 (9%)	5/50 (10%)	1/50 (2%)		0/90 (0%)	3/50 (6%)	0/50 (0%)	
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	52/639 (8.14%)		Mean 8.1%	SD 4.83%	5/640 (0.78%)		Mean 0.83%	SD 1.8%

#Skin:									
Fibroma									
		4/50 (8%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		3/49 (6%)	3/50 (6%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)		1/50 (2%)		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%)	
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	33/639 (5.16%)		Mean 5.36%	SD 2.85%	5/640 (0.78%)		Mean 0.69%	SD 1.01%

#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma									
		6/50 (12%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	
		4/49 (8%)	3/50 (6%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	
		1/50 (2%)		2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		5/90 (6%)	3/50 (6%)	3/50 (6%)		5/90 (6%)	0/50 (0%)	3/50 (6%)	
		4/50 (8%)				2/50 (4%)			
Overall Incidence	Total	44/639 (6.89%)		Mean 6.98%	SD 3.27%	16/640 (2.5%)		Mean 2.3%	SD 2.17%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		6/50 (12%)	3/50 (6%)	3/50 (6%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		4/49 (8%)	3/50 (6%)	7/50 (14%)	1/50 (2%)	0/50 (0%)	2/50 (4%)		
		1/50 (2%)		2/50 (4%)	0/50 (0%)	1/50 (2%)			
		5/90 (6%)	3/50 (6%)	3/50 (6%)	5/90 (6%)	0/50 (0%)	2/50 (4%)		
		4/50 (8%)			2/50 (4%)				
Overall Incidence	Total	44/639 (6.89%)	Mean 6.98%	SD 3.27%	Total	15/640 (2.34%)	Mean 2.13%	SD 1.92%	

#Skin:									
Fibrosarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
		1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		1/90 (1%)	1/50 (2%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	6/639 (0.94%)	Mean 0.93%	SD 1%	Total	4/640 (0.62%)	Mean 0.67%	SD 0.98%	

#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)		
		1/49 (2%)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	1/50 (2%)		
		1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)			
		3/90 (3%)	1/50 (2%)	0/50 (0%)	3/90 (3%)	0/50 (0%)	1/50 (2%)		
		0/50 (0%)			1/50 (2%)				
Overall Incidence	Total	11/639 (1.72%)	Mean 1.61%	SD 1.6%	Total	10/640 (1.56%)	Mean 1.44%	SD 1.13%	

#Skin:									
Hemangioma									
		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%)	0/50 (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%)				
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Hemangiopericytoma									
		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%)		0/50 (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%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skin:									
Hemangiosarcoma									
		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%)		0/50 (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%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skin:									
Keratoacanthoma									
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		8/49 (16%)	2/50 (4%)	4/50 (8%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)		5/50 (10%)		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%)	
		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	36/639 (5.63%)	Mean 5.66%	SD 4.15%	Total	0/640 (0%)	Mean 0%	SD 0%	

#Skin:									
Lipoma									
		2/50 (4%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	2/50 (4%)	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%)	
		2/90 (2%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	10/639 (1.56%)	Mean 1.52%	SD 2.12%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Liposarcoma									
		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%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	0/640 (0%)		Mean 0% SD 0%

#Skin:									
Malignant Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	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%)		1/90 (1%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%	SD 0.78%	Total	2/640 (0.31%)		Mean 0.26% SD 0.63%

#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%	SD 1.15%	Total	3/640 (0.47%)		Mean 0.5% SD 0.9%

#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/639 (0.31%)		Mean 0.33%	SD 1.15%	Total	3/640 (0.47%)		Mean 0.5% SD 0.9%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Osteosarcoma									
		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%)		0/50 (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%)			
Overall Incidence	Total	0/639 (0%)	Mean 0%	SD 0%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skin:									
Pilomatrixoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/49 (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%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.51%	SD 1.77%	Total	0/640 (0%)	Mean 0%	SD 0%	

#Skin:									
Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (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%)		
		2/90 (2%)	0/50 (0%)	0/50 (0%)		2/90 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	3/639 (0.47%)	Mean 0.35%	SD 0.82%	Total	4/640 (0.62%)	Mean 0.52%	SD 0.94%	

#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	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%)	
		0/90 (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%)			
Overall Incidence	Total	2/639 (0.31%)	Mean 0.33%	SD 1.15%	Total	3/640 (0.47%)	Mean 0.5%	SD 0.9%	

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

		Male					Female									
#Skin:																
Squamous Cell Carcinoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
		0/49	(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%)	0/50	(0%)			
		0/50	(0%)					0/50	(0%)							
Overall Incidence	Total	2/639 (0.31%)			Mean	0.33%	SD	0.78%	Total	1/640 (0.16%)			Mean	0.17%	SD	0.58%
#Skin:																
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma																
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	1/50	(2%)			
		0/49	(0%)	0/50	(0%)	2/50	(4%)	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%)							
Overall Incidence	Total	4/639 (0.63%)			Mean	0.67%	SD	1.3%	Total	4/640 (0.62%)			Mean	0.67%	SD	1.3%
#Skin:																
Squamous Cell Papilloma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/49	(0%)	2/50	(4%)	1/50	(2%)	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%)			
		1/50	(2%)					0/50	(0%)							
Overall Incidence	Total	9/639 (1.41%)			Mean	1.35%	SD	1.57%	Total	0/640 (0%)			Mean	0%	SD	0%
#Skin:																
Squamous Cell Papilloma or Papilloma																
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)			
		0/49	(0%)	2/50	(4%)	1/50	(2%)	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%)			
		1/50	(2%)					0/50	(0%)							
Overall Incidence	Total	9/639 (1.41%)			Mean	1.35%	SD	1.57%	Total	0/640 (0%)			Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		1/50 (2%)	1/50 (2%)	3/50 (6%)	0/50 (0%)	0/50 (0%)	1/50 (2%)		
		8/49 (16%)	4/50 (8%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		4/50 (8%)		5/50 (10%)	0/50 (0%)	0/50 (0%)			
		7/90 (8%)	4/50 (8%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)		
		3/50 (6%)			0/50 (0%)				
Overall Incidence	Total	46/639 (7.2%)	Mean 7.18%	SD 4.1%	Total	1/640 (0.16%)	Mean 0.17%	SD 0.58%	

#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		1/50 (2%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		8/49 (16%)	4/50 (8%)	5/50 (10%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		4/50 (8%)		5/50 (10%)	0/50 (0%)	0/50 (0%)			
		7/90 (8%)	4/50 (8%)	1/50 (2%)	0/90 (0%)	0/50 (0%)	0/50 (0%)		
		3/50 (6%)			0/50 (0%)				
Overall Incidence	Total	45/639 (7.04%)	Mean 7.01%	SD 4.2%	Total	0/640 (0%)	Mean 0%	SD 0%	

#Skin:									
Trichoepithelioma									
		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%)	0/50 (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%)				
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)	Mean 0%	SD 0%	

#Skin: Sebaceous Gland:									
Adenoma									
		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%)	0/50 (0%)	0/50 (0%)		
		1/50 (2%)		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%)				
Overall Incidence	Total	2/639 (0.31%)	Mean 0.26%	SD 0.63%	Total	0/640 (0%)	Mean 0%	SD 0%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female						
#Skin: Sebaceous Gland:												
Carcinoma or Adenoma												
		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%)	0/50	(0%)	
		1/50	(2%)			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%)	
Overall Incidence	Total	2/639 (0.31%)		Mean 0.26%		SD 0.63%		Total	0/640 (0%)		Mean 0%	SD 0%
<hr/>												
#Spinal Cord:												
Astrocytoma Malignant												
		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%)	0/50	(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%)	
Overall Incidence	Total	0/639 (0%)		Mean 0%		SD 0%		Total	1/640 (0.16%)		Mean 0.17%	SD 0.58%
<hr/>												
*Spleen:												
Hemangiosarcoma												
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	1/49	(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%)	0/50	(0%)	
		3/90	(3%)	0/50	(0%)	0/50	(0%)	1/90	(1%)	0/50	(0%)	
		0/50	(0%)			0/50	(0%)	0/49	(0%)	0/50	(0%)	
Overall Incidence	Total	3/639 (0.47%)		Mean 0.28%		SD 0.96%		Total	2/638 (0.31%)		Mean 0.26%	SD 0.64%
<hr/>												
#Stomach, Forestomach:												
Sarcoma												
		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%)	0/50	(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%)	
Overall Incidence	Total	0/639 (0%)		Mean 0%		SD 0%		Total	1/640 (0.16%)		Mean 0.09%	SD 0.32%

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		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%)	1/50 (2%)		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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total 1/640 (0.16%)		Mean 0.17%	SD 0.58%

#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		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%)	1/50 (2%)		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%)	
		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%)			
Overall Incidence	Total	2/639 (0.31%)		Mean 0.26%	SD 0.63%	Total 1/640 (0.16%)		Mean 0.17%	SD 0.58%

#Stomach, Forestomach:									
Squamous Cell Papilloma									
		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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.09%	SD 0.32%	Total 0/640 (0%)		Mean 0%	SD 0%

*Testis:									
Adenoma									
		1/50 (2%)	7/50 (14%)	3/49 (6%)					
		2/49 (4%)	1/50 (2%)	3/49 (6%)					
		0/50 (0%)		0/50 (0%)					
		2/90 (2%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)							
Overall Incidence	Total	20/637 (3.14%)		Mean 3.21%	SD 4.05%				

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

		Male				Female			
*Thymus:									
Thymoma Benign									
		0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)	
		0/48 (0%)	0/46 (0%)	1/46 (2%)		0/49 (0%)	0/49 (0%)	0/47 (0%)	
		0/48 (0%)		0/48 (0%)		0/50 (0%)	0/49 (0%)		
		0/88 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)	
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	1/610 (0.16%)	Mean 0.18%	SD 0.63%	Total	1/622 (0.16%)	Mean 0.1%	SD 0.33%	

*Thymus:									
Thymoma Malignant									
		0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)	
		0/48 (0%)	0/46 (0%)	0/46 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)	
		0/48 (0%)		0/48 (0%)		0/50 (0%)	0/49 (0%)		
		0/88 (0%)	0/48 (0%)	0/48 (0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)	
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	0/610 (0%)	Mean 0%	SD 0%	Total	1/622 (0.16%)	Mean 0.1%	SD 0.33%	

*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/46 (0%)	0/48 (0%)	0/47 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)	
		0/48 (0%)	0/46 (0%)	1/46 (2%)		0/49 (0%)	0/49 (0%)	0/47 (0%)	
		0/48 (0%)		0/48 (0%)		0/50 (0%)	0/49 (0%)		
		0/88 (0%)	0/48 (0%)	0/48 (0%)		2/87 (2%)	0/50 (0%)	0/47 (0%)	
		0/49 (0%)				0/50 (0%)			
Overall Incidence	Total	1/610 (0.16%)	Mean 0.18%	SD 0.63%	Total	2/622 (0.32%)	Mean 0.19%	SD 0.66%	

*Thyroid Gland: C-Cell:									
Adenoma									
		11/50 (22%)	13/50 (26%)	10/50 (20%)		9/50 (18%)	12/50 (24%)	8/49 (16%)	
		8/49 (16%)	7/50 (14%)	13/50 (26%)		12/50 (24%)	5/50 (10%)	11/49 (22%)	
		2/50 (4%)		11/49 (22%)		2/50 (4%)	9/50 (18%)		
		8/89 (9%)	8/50 (16%)	4/50 (8%)		6/90 (7%)	16/50 (32%)	5/50 (10%)	
		9/50 (18%)				10/50 (20%)			
Overall Incidence	Total	104/637 (16.33%)	Mean 16.81%	SD 7.08%	Total	105/638 (16.46%)	Mean 17.12%	SD 8.19%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Dec2020
 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: 45
 Report Date: 12/30/2020

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		1/50 (2%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	2/50 (4%)	0/49 (0%)		
		1/49 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/49 (0%)		
		1/50 (2%)		0/49 (0%)	0/50 (0%)	1/50 (2%)			
		2/89 (2%)	0/50 (0%)	0/50 (0%)	0/90 (0%)	0/50 (0%)	2/50 (4%)		
		0/50 (0%)			2/50 (4%)				
Overall Incidence	Total	9/637 (1.41%)		Mean 1.36%	SD 1.32%	Total 9/638 (1.41%)		Mean 1.5%	SD 1.73%

*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		11/50 (22%)	14/50 (28%)	10/50 (20%)	9/50 (18%)	14/50 (28%)	8/49 (16%)		
		8/49 (16%)	8/50 (16%)	13/50 (26%)	13/50 (26%)	6/50 (12%)	11/49 (22%)		
		3/50 (6%)		11/49 (22%)	2/50 (4%)	9/50 (18%)			
		10/89 (11%)	8/50 (16%)	4/50 (8%)	6/90 (7%)	16/50 (32%)	7/50 (14%)		
		9/50 (18%)			12/50 (24%)				
Overall Incidence	Total	109/637 (17.11%)		Mean 17.5%	SD 6.75%	Total 113/638 (17.71%)		Mean 18.45%	SD 8.49%

*Thyroid Gland: Follicular Cell: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (0%)		
		1/49 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/49 (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%)			1/50 (2%)				
Overall Incidence	Total	3/637 (0.47%)		Mean 0.5%	SD 1.25%	Total 1/638 (0.16%)		Mean 0.17%	SD 0.58%

*Thyroid Gland: Follicular Cell: Carcinoma									
		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%)	0/50 (0%)	0/49 (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%)			0/50 (0%)				
Overall Incidence	Total	0/637 (0%)		Mean 0%	SD 0%	Total 1/638 (0.16%)		Mean 0.09%	SD 0.32%

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

		Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (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%)				1/50 (2%)			
Overall Incidence	Total	3/637 (0.47%)		Mean 0.5%	SD 1.25%	Total 2/638 (0.31%)		Mean 0.26%	SD 0.63%
.....									
#Tissue NOS: Schwannoma Malignant									
		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%)	0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.09%	SD 0.32%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%
.....									
#Tongue: Squamous Cell Carcinoma									
		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%)	0/50 (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%)			
Overall Incidence	Total	0/639 (0%)		Mean 0%	SD 0%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%
.....									
#Tongue: Squamous Cell Carcinoma or Papilloma Squamous									
		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%)	0/50 (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%)			
Overall Incidence	Total	0/639 (0%)		Mean 0%	SD 0%	Total 1/640 (0.16%)		Mean 0.09%	SD 0.32%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Tooth:									
Odontoma									
		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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)		Mean 0.17%	SD 0.58%	Total	0/640 (0%)		Mean 0% SD 0%

*Urinary Bladder:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/49 (0%)	0/49 (0%)
		0/50 (0%)		0/49 (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%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/637 (0%)		Mean 0%	SD 0%	Total	1/635 (0.16%)		Mean 0.09% SD 0.33%

#Uterus:									
Adenocarcinoma									
						2/50 (4%)	2/50 (4%)	3/50 (6%)	
							5/50 (10%)	5/50 (10%)	
						1/50 (2%)	1/50 (2%)		
							2/50 (4%)	3/50 (6%)	
Overall Incidence	Total					27/500 (5.4%)		Mean 5.4%	SD 2.84%

#Uterus:									
Adenocarcinoma or Adenoma									
						2/50 (4%)	2/50 (4%)	3/50 (6%)	
							5/50 (10%)	5/50 (10%)	
						1/50 (2%)	2/50 (4%)		
							4/50 (8%)	3/50 (6%)	
Overall Incidence	Total					30/500 (6%)		Mean 6%	SD 2.67%

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

Version: Dec2020
 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: 12/30/2020

	Male		Female			
#Uterus:						
Adenoma						
	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%)				
Overall Incidence	Total	3/500 (0.6%)	Mean	0.6%	SD	1.35%
.....						
#Uterus:						
Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Papilloma						
	4/50	(8%)	2/50	(4%)	3/50	(6%)
			5/50	(10%)	5/50	(10%)
	2/50	(4%)	2/50	(4%)		
			4/50	(8%)	5/50	(10%)
	3/50	(6%)				
Overall Incidence	Total	35/500 (7%)	Mean	7%	SD	2.54%
.....						
#Uterus:						
Deciduoma Benign						
	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%)				
Overall Incidence	Total	1/500 (0.2%)	Mean	0.2%	SD	0.63%
.....						
#Uterus:						
Granular Cell Tumor Benign						
	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%)				
Overall Incidence	Total	1/500 (0.2%)	Mean	0.2%	SD	0.63%

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

Version: Dec2020
 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: 12/30/2020

	Male		Female			
#Uterus:						
Hemangioma						
		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%)	
Overall Incidence	Total	1/500 (0.2%)	Mean 0.2%		SD 0.63%	
.....						
#Uterus:						
Papilloma						
		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%)	
Overall Incidence	Total	1/500 (0.2%)	Mean 0.2%		SD 0.63%	
.....						
#Uterus:						
Polyp Stromal						
		9/50 (18%)	5/50 (10%)	8/50 (16%)	10/50 (20%)	
		7/50 (14%)	16/50 (32%)	5/50 (10%)	5/50 (10%)	
		5/50 (10%)	2/50 (4%)	5/50 (10%)	5/50 (10%)	
Overall Incidence	Total	75/500 (15%)	Mean 15%		SD 7.62%	
.....						
#Uterus:						
Sarcoma						
		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%)	
Overall Incidence	Total	1/500 (0.2%)	Mean 0.2%		SD 0.63%	

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

Version: Dec2020
 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: 12/30/2020

	Male		Female			
#Uterus:						
Sarcoma Stromal						
	0/50	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	2/50	(4%)
	0/50	(0%)	1/50	(2%)		
			0/50	(0%)	1/50	(2%)
Overall Incidence	Total 4/500 (0.8%)		Mean 0.8%		SD 1.4%	
.....						
#Uterus:						
Sarcoma Stromal or Polyp Stromal						
	9/50	(18%)	5/50	(10%)	8/50	(16%)
			8/50	(16%)	12/50	(24%)
	7/50	(14%)	16/50	(32%)		
			2/50	(4%)	6/50	(12%)
	5/50	(10%)				
Overall Incidence	Total 78/500 (15.6%)		Mean 15.6%		SD 7.88%	
.....						
#Uterus:						
Schwannoma Malignant						
	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%)				
Overall Incidence	Total 1/500 (0.2%)		Mean 0.2%		SD 0.63%	
.....						
#Uterus:						
Sq Cell Carcinoma or Papilloma Squamous						
	2/50	(4%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	1/50	(2%)	0/50	(0%)		
			0/50	(0%)	2/50	(4%)
	0/50	(0%)				
Overall Incidence	Total 5/500 (1%)		Mean 1%		SD 1.7%	

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

Version: Dec2020
 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: 12/30/2020

	Male		Female			
#Uterus:						
Squamous Cell Carcinoma						
	1/50	(2%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/50	(0%)
	1/50	(2%)	0/50	(0%)		
			0/50	(0%)	2/50	(4%)
	0/50	(0%)				
Overall Incidence	Total 4/500 (0.8%)		Mean 0.8%		SD 1.4%	
.....						
#Vagina:						
Granular Cell Tumor Benign						
	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%)				
Overall Incidence	Total 1/640 (0.16%)		Mean 0.17%		SD 0.58%	
.....						
#Vagina:						
Polyp						
	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%)	1/50	(2%)
	0/50	(0%)				
Overall Incidence	Total 2/640 (0.31%)		Mean 0.33%		SD 0.78%	
.....						
#Vagina:						
Sarcoma						
	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%)				
Overall Incidence	Total 1/640 (0.16%)		Mean 0.17%		SD 0.58%	

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

Version: Dec2020
 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: 12/30/2020

		Male				Female			
#Vagina:									
Schwannoma Malignant									
						0/50 (0%)		0/50 (0%)	1/50 (2%)
						0/50 (0%)		0/50 (0%)	1/50 (2%)
						1/50 (2%)		0/50 (0%)	
						1/90 (1%)		1/50 (2%)	0/50 (0%)
						0/50 (0%)			
Overall Incidence					Total	5/640 (0.78%)		Mean 0.76%	SD 0.97%

#Zymbal's Gland:									
Adenoma									
		1/50 (2%)	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%)		0/50 (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%)			
Overall Incidence	Total	1/639 (0.16%)	Mean 0.17%	SD 0.58%	Total	0/640 (0%)		Mean 0%	SD 0%

#Zymbal's Gland:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		1/49 (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%)		0/50 (0%)	
		0/90 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	6/639 (0.94%)	Mean 1%	SD 1.05%	Total	0/640 (0%)		Mean 0%	SD 0%

#Zymbal's Gland:									
Carcinoma or Adenoma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	0/50 (0%)
		1/49 (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%)		0/50 (0%)	
		0/90 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)		0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	7/639 (1.1%)	Mean 1.17%	SD 1.34%	Total	0/640 (0%)		Mean 0%	SD 0%

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