

# **NTP Historical Controls Report**

# All Routes and Vehicles

# Harlan Sprague-Dawley RATS

October 2022

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	М3	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.

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

				Stu	dy 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 Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
Battelle Columbus Laboratory	052032305	05/07/12	729	50(2)	29(669)	597.1	Resveratrol
Battelle Columbus Laboratory	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071203	12/12/11	729	50(2)	25(652)	589.0	Tris(Chloropropyl)phosphate
Batelle Columbus	051105403	07/05/15	732	50(2)	16(650)	657.1	Sulfolane
					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 Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation
Battelle Columbus Laboratory	052032305	05/08/12	730	50(5)	34(690)	394.3	Resveratrol
Battelle Columbus Laboratory	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate
Battelle Columbus Laboratory	052071203	12/13/11	731	50(4)	22(629)	380.1	Tris(Chloropropyl)phosphate
Batelle Columbus	051105403	07/05/15	734	50(4)	21(670)	438.1	Sulfolane

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

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			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%)	30/50 (60%)		40/50 (80%)	41/50 (82%)	39/50 (78%)
		49/90 (54%)	33/50 (66%)	29/50 (58%)		82/90 (91%)	43/50 (86%)	39/50 (78%)
		25/50 (50%)	29/50 (58%)			41/50 (82%)	43/50 (86%)	
verall Incidence	Total	353/589 (59.93%)	Mean 60.35%	SD 7.82%	Total	490/590 (83.05%)	Mean 82.46%	SD 4.99%
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%)	11/50 (22%)
		24/90 (27%)	13/50 (26%)	14/50 (28%)		37/90 (41%)	10/50 (20%)	17/50 (34%)
		9/50 (18%)	8/50 (16%)			10/50 (20%)	15/50 (30%)	
Overall Incidence	Total	143/589 (24.28%)	Mean 24.11%	SD 4.56%	Total	165/590 (27.97%)	Mean 27.01%	SD 7.65%
All Organs: Malignant and Benign								
• •		33/50 (66%)	32/50 (64%)	36/50 (72%)		46/50 (92%)	41/50 (82%)	44/50 (88%)
		41/49 (84%)	42/50 (84%)	37/50 (74%)		44/50 (88%)	47/50 (94%)	41/50 (82%)
		57/90 (63%)	39/50 (78%)	36/50 (72%)		89/90 (99%)	45/50 (90%)	47/50 (94%)
		30/50 (60%)	32/50 (64%)			46/50 (92%)	45/50 (90%)	
Overall Incidence	Total	415/589 (70.46%)	Mean 71%	SD 8.32%	Total	535/590 (90.68%)	Mean 90.08%	SD 5.05%
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%)	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%)
						4/50 (00/)	0/50 (00/)	
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	

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

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

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			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%)	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%)
Verall Incidence	Total	0/50 (0%)	1/50 (2%)	SD 1.19%	Total	0/50 (0%)	0/50 (0%) Mean 0.48%	SD 1.12%
		5/589 (0.85%)	Mean 0.67%			4/590 (0.68%)		
All Organs: Hemangiosarcoma or Hen	nangioma							
•	•	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%)	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%)			1/50 (2%)	0/50 (0%)	
Verall Incidence	Total	7/589 (1.19%)	Mean 1.03%	SD 1.24%	Total	7/590 (1.19%)	Mean 1.03%	SD 1.53%
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%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
	<b>T</b> - ( - )	1/50 (2%)	1/50 (2%)	00.000/	Takal	0/50 (0%)	0/50 (0%)	00.00/
Verall Incidence	Total	3/589 (0.51%)	Mean 0.55%	SD 0.93%	Total	0/590 (0%)	Mean 0%	SD 0%
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%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Verall Incidence	Total	2/589 (0.34%)	Mean 0.36%	SD 0.81%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%

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

Version: Oct2022 Contract/Lab: All Laborato Species: RATS Strain: Harlan Sprague-Da Length of Study: CHRONI	wley			Tur	nor Inciden	logy Data Ma nce for Select Route: ALI Vehicle: ALI	ted Control / _ ROUTES	Animal Groups			Page: 6 Report Date: 10/05/2022				
		· · · · · ·			Male		· · · · ·				F	emale		· · · · · · · · · · · · · · · · · · ·	
#All Organs: Leukemia: Lymphocytic	c, Monocytic, M	ononuclear, or	Undifferer	ntiated											
		0/50 0/49 0/90 1/50	(0%) (0%) (0%) (2%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 3/50 1/50	(0%) (6%) (2%)		0/50 0/50 0/90 2/50	(0%) (0%) (0%) (4%)	0/50 0/50 1/50 0/50	(0%) (0%) (2%) (0%)	1/50 0/50 0/50	(2%) (0%) (0%)	
Overall Incidence	Total	5/589 (0.85	5%)	Mean 0.	.91%	SD 1.87		Total	4/590 (0.	,		0.73%	SD 1	.35%	
Malignant Lymphoma: I Overall Incidence	Total	0/50 1/49 2/90 2/50 9/589 (1.53	(0%) (2%) (2%) (4%) 3%)	2/50 0/50 1/50 0/50 Mean 1.	(4%) (0%) (2%) (0%) .48%	0/50 0/50 1/50 SD 1.58		Total	0/50 1/50 5/90 0/50 12/590 (2	,		(2%) (0%) (2%) (4%) 1.78%	0/50 0/50 2/50 SD	(0%) (0%) (4%) 2%	
#All Organs: Malignant Schwannoma	à	0/50 3/49 3/90	(0%) (6%) (3%)	3/50 1/50 0/50	(6%) (2%) (0%)	6/50 0/50 1/50	(12%) (0%) (2%)		1/50 2/50 4/90	(2%) (4%) (4%)	1/50 0/50 1/50	(2%) (0%) (2%)	3/50 2/50 2/50	(6%) (4%) (4%)	
Overall Incidence	Total	0/50 17/589 (2.89	(0%) 9%)	0/50 Mean 2.	(0%) .86%	SD 3.83	%	Total	0/50 16/590 (2	(0%) 2.71%)	0/50 Mean	(0%) 2.59%	SD 2	.05%	
#All Organs: Mesothelioma: Benign,		6													
		2/50 1/49 2/90 1/50	(4%) (2%) (2%) (2%)	2/50 1/50 1/50 0/50	(4%) (2%) (2%) (0%)	1/50 1/50 0/50	(2%) (2%) (0%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)	
Overall Incidence	Total	12/589 (2.04	. ,	Mean 2.		SD 1.27	%	Total	0/590 (	0%)	Mea	in 0%	SD	0%	

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

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			Male				Female	
All Organs: Mesothelioma: Malignan	t							
-		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%)
		2/90 (2%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
· · · · · · · · · · · · · · · · · · ·	<b>T</b> . ( . )	1/50 (2%)	0/50 (0%)	00 4 070/	<b>T</b> - ( - 1	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	12/589 (2.04%)	Mean 2.02%	SD 1.27%	Total	0/590 (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%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)
Verall Incidence	Tatal	0/50 (0%)	0/50 (0%)		Tatal	0/50 (0%)	0/50 (0%)	
	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
All Organs: Osteosarcoma or Osteor	na							
		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%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)
Normall In airlan an	Tatal	0/50 (0%)	0/50 (0%)		Tatal	0/50 (0%)	0/50 (0%)	
Verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
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%)	3/50 (6%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	3/50 (6%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	8/589 (1.36%)	Mean 1.37%	SD 2.38%	Total	9/589 (1.53%)	Mean 1.56%	SD 2.5%

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

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

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			Male				Female	
Adrenal Cortex: 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%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%
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%)	0/49 (0%)
		0/88 (0%)	0/50 (0%)	1/50 (2%)		0/86 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/587 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/584 (0.17%)	Mean 0.18%	SD 0.6%
Adrenal Medulla: Pheochromocytoma Ber								
		14/50 (28%)	4/50 (8%)	5/50 (10%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		7/49 (14%)	9/50 (18%)	12/50 (24%)		0/50 (0%)	3/50 (6%)	0/49 (0%)
		10/88 (11%)	4/50 (8%)	10/50 (20%)		1/86 (1%)	3/50 (6%)	1/50 (2%)
		6/50 (12%)	10/50 (20%)			0/50 (0%)	1/49 (2%)	
Overall Incidence	Total	91/587 (15.5%)	Mean 15.79%	SD 6.69%	Total	13/584 (2.23%)	Mean 2.29%	SD 2.53%
Adrenal Medulla: Pheochromocytoma Cor								
-	-	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%)	0/49 (0%)
		1/88 (1%)	0/50 (0%)	0/50 (0%)		0/86 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	. ,		0/50 (0%)	0/49 (0%)	. ,
Overall Incidence	Total	2/587 (0.34%)	Mean 0.29%	SD 0.66%	Total	0/584 (0%)	Mean 0%	SD 0%

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

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

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			Male				Female	
Adrenal Medulla: Pheochromocytoma Mal	ignant							
		0/50 (0%)	1/50 (2%)	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%)	0/49 (0%)
		1/88 (1%)	1/50 (2%)	2/50 (4%)		0/86 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/49 (2%)	
verall Incidence	Total	11/587 (1.87%)	Mean 1.93%	SD 2.02%	Total	4/584 (0.68%)	Mean 0.73%	SD 1.35%
Adrenal Medulla:								
Pheochromocytoma: Be	nign, Complex	x, Malignant, NOS						
		14/50 (28%)	5/50 (10%)	6/50 (12%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		8/49 (16%)	12/50 (24%)	14/50 (28%)		0/50 (0%)	5/50 (10%)	0/49 (0%)
		11/88 (13%)	5/50 (10%)	12/50 (24%)		1/86 (1%)	3/50 (6%)	2/50 (4%)
		6/50 (12%)	10/50 (20%)			0/50 (0%)	2/49 (4%)	
Overall Incidence	Total	103/587 (17.55%)	Mean 17.89%	SD 7.13%	Total	17/584 (2.91%)	Mean 3.02%	SD 3.31%
Bone: 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%)
		0/90 (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	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%
Bone:								
Osteosarcoma or Osteor	na							
		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%)
		0/90 (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	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%

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

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

#### Page: 10 Report Date: 10/05/2022

			Male				Female	
Brain: Glioma Malignant								
enerna manghant		1/50 (2%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/90 (0%)	0/50 (0%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	11/589 (1.87%)	Mean 2.01%	SD 2.69%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%
Brain: Granular Cell Tumor Ber								
	ngn	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%)		0/50 (0%)	1/50 (2%)	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%)	()		0/50 (0%)	0/50 (0%)	()
Overall Incidence	Total	10/589 (1.7%)	Mean 1.74%	SD 2.45%	Total	5/590 (0.85%)	Mean 0.83%	SD 1.33%
Brain:								
Granular Cell Tumor Mal	lignant							
		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%)
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	00.000		0/50 (0%)	0/50 (0%)	<b>65 6 6</b>
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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
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

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

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			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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall 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, Ma	lignant, 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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Verall 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 Malig	griant	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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0,00 (0,0)
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%
Brain:								
Oligodendroglioma, Glio	ma, or Astrocv	toma						
		1/50 (2%)	4/50 (8%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/49 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/90 (0%)	0/50 (0%)	2/50 (4%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	12/589 (2.04%)	Mean 2.19%	SD 2.61%	Total	2/590 (0.34%)	Mean 0.36%	SD 0.81%

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

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

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			Male				Female	
Brain: Schwannoma Malignant						· · · · · · · · · · · · · · · · · · ·		
U		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
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%)
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/46 (0%)	0/48 (0%)	
verall Incidence	Total	1/585 (0.17%)	Mean 0.19%	SD 0.62%	Total	0/574 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenocarcinoma								
		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%)
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/46 (0%)	0/48 (0%)	
verall Incidence	Total	2/585 (0.34%)	Mean 0.37%	SD 0.83%	Total	0/574 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma or Adenocarcino								
		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%)
		0/88 (0%)	0/50 (0%)	0/50 (0%)		0/87 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/46 (0%)	0/48 (0%)	
verall Incidence	Total	3/585 (0.51%)	Mean 0.56%	SD 0.95%	Total	0/574 (0%)	Mean 0%	SD 0%

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

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

					Male						F	emale		
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%)
		0/88	(0%)	0/50	(0%)	0/50	(0%)		0/87	(0%)	1/48	(2%)	0/50	(0%)
	<b>T</b> ( )	1/50	(2%)	0/50	(0%)	00.000	.,	<b>T</b> ( )	0/46	(0%)	0/48	(0%)	0.5	000/
verall Incidence	Total	2/585 (0.34	,	Mean 0		SD 0.829		Total	2/574 (0	,		0.37%	SD 0.	
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%)
		0/88	(0%)	1/50	(2%)	0/50	(0%)		0/87	(0%)	0/48	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/46	(0%)	0/48	(0%)		
Verall Incidence	Total	2/585 (0.34	,	Mean 0	.36%	SD 0.819	%	Total	1/574 (0	.17%)	Mean	0.19%	SD 0.	62%
Epididymis: Sarcoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)							
		0/49	(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	1/588 (0.17	,	Mean 0		SD 0.6%								
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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17	%)	Mean 0	.18%	SD 0.6%	/ 0	Total	0/590 (	0%)	Mea	n 0%	SD	0%

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

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

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			Male				Female	
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%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/90 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	2/50 (4%)
Overall Incidence	Total	8/589 (1.36%)	Mean 1.46%	SD 2.22%	Total	4/587 (0.68%)	Mean 0.73%	SD 1.35%
#Intestine Large: Cecum: Leiomyosarcoma								
		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%)
		0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/90 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
#Intestine Large: Cecum: 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%)
		0/90 (0%) 0/50 (0%)	0/50 (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	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
#Intestine Large: Colon/Rec Granular Cell Tumor Beni	ctum:							
	.9	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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>-</b>	0/50 (0%)	0/50 (0%)	00.0000
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%

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

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

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			Male				Female	
Intestine Large: Colon/Rector Leiomyoma	um:							
		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Adenocarcinoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%)
		2/90 (2%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	9/589 (1.53%)	Mean 1.47%	SD 1.3%	Total	0/590 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%
Intestine Small: Any Site: Adenocarcinoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%)
		2/90 (2%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	9/589 (1.53%)	Mean 1.47%	SD 1.3%	Total	0/590 (0%)	Mean 0%	SD 0%

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

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

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			Male				Female	
Intestine Small: Any Site Adenoma or Adenocard								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		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%)
		2/90 (2%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	9/589 (1.53%)	Mean 1.47%	SD 1.3%	Total	0/590 (0%)	Mean 0%	SD 0%
Intestine Small: Any Site Leiomyosarcoma								
		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%
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%)	8/50 (16%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		5/90 (6%)	2/50 (4%)	2/50 (4%)		5/90 (6%)	2/50 (4%)	1/50 (2%)
		4/50 (8%)	3/50 (6%)			0/49 (0%)	0/48 (0%)	
verall Incidence	Total	40/588 (6.8%)	Mean 6.89%	SD 3.41%	Total	15/586 (2.56%)	Mean 2.33%	SD 2.11%
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%)	1/50 (2%)
		8/90 (9%)	3/50 (6%)	1/50 (2%)		2/90 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	12/588 (2.04%)	Mean 1.54%	SD 3.05%	Total	5/586 (0.85%)	Mean 0.75%	SD 1.04%

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

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

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			Male				Female	
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%)	8/50 (16%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
		13/90 (14%)	5/50 (10%)	3/50 (6%)		7/90 (8%)	2/50 (4%)	2/50 (4%)
		4/50 (8%)	3/50 (6%)			0/49 (0%)	0/48 (0%)	
verall Incidence	Total	52/588 (8.84%)	Mean 8.43%	SD 3.73%	Total	20/586 (3.41%)	Mean 3.08%	SD 2.4%
Kidney: Pelvis and Transitio 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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/589 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		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%)	1/50 (2%)
		3/90 (3%)	0/50 (0%)	2/50 (4%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	8/589 (1.36%)	Mean 1.22%	SD 1.52%	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%
Kidney: Renal Tubule: 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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%

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

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

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			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		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%)	1/50 (2%)
		3/90 (3%)	0/50 (0%)	2/50 (4%)		2/90 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	8/589 (1.36%)	Mean 1.22%	SD 1.52%	Total	3/589 (0.51%)	Mean 0.38%	SD 0.86%
Kidney: Renal Tubule: 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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%
Kidney: Renal Tubule: Lipoma								
		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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%	Total	0/589 (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%)
		0/49 (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%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/589 (0%)	Mean 0%	SD 0%

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

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

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			Male				Female	
Kidney: Renal Tubule: Oncocytoma Benign								
		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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	2/589 (0.34%)	Mean 0.28%	SD 0.66%	Total	0/589 (0%)	Mean 0%	SD 0%
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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/589 (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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
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%)
		0/90 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	3/588 (0.51%)	Mean 0.55%	SD 0.94%

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

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

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				Male						F	emale		
Liver: Hemangioma						·							
-		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%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
	-	``	%) 0/50	(0%)				0/50	(0%)	0/49	(0%)		
verall Incidence	Total	1/589 (0.17%)	Mean	0.18%	SD 0.6%	<b>)</b>	Total	0/588 (	0%)	Mea	in 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%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	2/50	(4%)
		(	%) 0/50	(0%)	1/50	(2%)		7/90	(8%)	2/50	(4%)	1/50	(2%)
		`	%) 0/50	(0%)				1/50	(2%)	0/49	(0%)		
Verall Incidence	Total	2/589 (0.34%)	Mean		SD 0.819		Total	16/588 (2	,		2.35%	SD 2.	.45%
Liver: Hepatocellular Carcinoma													
		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%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		``	%) 0/50	(0%)				0/50	(0%)	0/49	(0%)		
Overall Incidence	Total	2/589 (0.34%)	Mean		SD 0.829		Total	0/588 (	,		in 0%	SD	
Liver: Hepatocellular Carcinoma c													
			%) 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%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0	%) 0/50	(0%)		. ,		0/50	(0%)	0/49	(0%)		. ,
Overall Incidence	Total	2/589 (0.34%)	Mean	0 37%	SD 0.829	6	Total	0/588 (	0%)	Mea	n 0%	SD	0%

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

Version: Oct2022 Contract/Lab: All Laboratori Species: RATS Strain: Harlan Sprague-Daw Length of Study: CHRONIC	ley		Toxico Tumor Incide		Page: 21 Report Date: 10/05/2022			
			Male				Female	
*Liver: Hepatocellular Carcinom	a or Hepatoc	ellular Adenoma						
		0/50 (0%) 1/49 (2%) 0/90 (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%)		0/50 (0%) 0 7/90 (8%) 2	0/50 (0%) 1/4 0/50 (0%) 2/5 2/50 (4%) 1/5 0/49 (0%)	50 (4%)
Overall Incidence	Total	4/589 (0.68%)	Mean 0.73%	SD 1.01%		( )	()	0 2.45%
*Liver: Hepatocellular Carcinom Overall Incidence	Total	ular Adenoma, or Hepat 0/50 (0%) 1/49 (2%) 0/90 (0%) 1/50 (2%) 4/589 (0.68%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.73%	1/50 (2%) 0/50 (0%) 1/50 (2%) SD 1.01%	Total 16/5	0/50  (0%)  0    7/90  (8%)  2    1/50  (2%)  0    588  (2.72%)  1	0/50 (0%) 1/4 0/50 (0%) 2/5 2/50 (4%) 1/5 0/49 (0%) Mean 2.35% SI	50 (4%)
*Lung: Alveolar/Bronchiolar Ade								
		0/50 (0%) 1/49 (2%) 1/90 (1%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)		0/50 (0%) 0 0/90 (0%) 0	0/50 (0%) 0/4 0/49 (0%) 0/5 0/50 (0%) 0/5 0/49 (0%)	50 (0%)
Overall Incidence	Total	4/589 (0.68%)	Mean 0.65%	SD 0.94%	ر Total 0	/587 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Car		0/50 (0%) 0/49 (0%) 0/90 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)		0/50 (0%) 0 0/90 (0%) 0	0/50 (0%) 0/4 0/49 (0%) 0/5 0/50 (0%) 0/5 0/49 (0%)	50 (0%)

SD 0.93%

Total

0/587 (0%)

Mean 0%

SD 0%

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

Total

3/589 (0.51%)

Mean 0.55%

#: Denominator is number of animals necropsied

**Overall Incidence** 

Version: Oct2022 Contract/Lab: All Laborato Species: RATS Strain: Harlan Sprague-Da Length of Study: CHRON	awley		Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES									Page: 22 Report Date: 10/05/2022					
		· · · ·			Male						F	emale					
*Lung: Alveolar/Bronchiolar Carcinoma or A Overall Incidence Total		0/50 1/49 1/90	(0%) (2%) (1%) (2%) %)	0/50 1/50 1/50 0/50 Mean 1	(0%) (2%) (2%) (0%) .2%	0/50 0/50 2/50 SD 1.33'		Total		(0%) (0%) (0%) (0%) 0%)		(0%) (0%) (0%) (0%) n 0%	0/49 0/50 0/50 SD (				
#Mammary Gland: Adenolipoma		0/50 0/49 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 1/50 0/50 0/50	(0%) (2%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)			
Overall Incidence	Total	0/589 (0%)		Mean	0%	SD 0%		Total	1/590 (0.	17%)	Mean	0.18%	SD 0	.6%			

0/90 (0%) 0/50 (0%) 0/50 (0%) 8/90 (9%) 1/50 (2%) 3/50 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) **Overall Incidence** Total 0/589 (0%) Mean 0% SD 0% Total 19/590 (3.22%) Mean 2.81% SD 3.29% ..... ..... ..... #Mammary Gland: Adenocarcinoma 0/50 (0%) 0/50 (0%) 1/50 (2%) 3/50 (6%) 8/50 (16%) 1/50 0/49 (0%) 2/50 (4%) 0/50 (0%) 4/50 (8%) 7/50 (14%) 5/50 (10%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 2/50 10/90 (11%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 44/590 (7.46%) Mean 7.19% **Overall Incidence** Total 3/589 (0.51%) Mean 0.55% SD 1.29% Total SD 5% 

0/50

0/50

(0%)

(0%)

(0%)

(0%)

(2%)

(0%)

1/50

0/50

0/50

0/50

(0%)

(0%)

1/50

4/50

(2%)

(8%)

(6%)

(2%)

(4%)

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

0/50

0/49

(0%)

(0%)

0/50

0/50

#: Denominator is number of animals necropsied

.....

#Mammary Gland: Adenoma

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

## Page: 23 Report Date: 10/05/2022

					Male						I	emale		
#Mammary Gland: Adenoma or Adenocar	cinoma													
		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%)	9/50	(18%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		· · · ·	8%)	3/50	(6%)	5/50	(10%)
		0/50	(0%)	0/50	(0%)				1/50 (2	2%)	2/50	(4%)		
Verall Incidence	Total	3/589 (0.51		Mean 0		SD 1.299		Total	61/590 (10.34	,		n 9.8%	SD 5	5.8%
#Mammary Gland: Fibroadenoma														
		3/50	(6%)	0/50	(0%)	2/50	(4%)		29/50 (5	8%)	25/50	(50%)	28/50	(56%)
		1/49	(2%)	2/50	(4%)	2/50	(4%)		33/50 (6	6%)	32/50	(64%)	20/50	(40%)
		2/90	(2%)	0/50	(0%)	0/50	(0%)		· · · ·	0%)	28/50	(56%)	30/50	(60%)
		2/50	(4%)	2/50	(4%)				29/50 (5	8%)	32/50	(64%)		
Overall Incidence	Total	16/589 (2.72		Mean 2		SD 2.05%		Total	349/590 (59.1	,		58.36%	SD 8	
#Mammary Gland: Fibroma														
		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%)	0/50	(0%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		```	0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				`	0%)	1/50	(2%)		
Overall Incidence	Total	0/589 (0%		Mean		SD 0%		Total	1/590 (0.17%	,		0.18%	SD (	
#Mammary Gland: Fibroma, Fibroadenom														
·····, · ·····		3/50	(6%)	0/50	(0%)	2/50	(4%)		29/50 (5	8%)	25/50	(50%)	29/50	(58%)
		1/49	(2%)	2/50	(4%)	2/50	(4%)		,	6%)	32/50	(64%)	23/50	(46%)
		2/90	(2%)	0/50	(0%)	0/50	(0%)		· · · ·	1%)	28/50	(56%)	32/50	(64%)
		2/50	(4%)	2/50	(4%)		. ,		29/50 (5	, 8%)	33/50	(66%)		. ,
Overall Incidence	Total	16/589 (2.72	2%)	Mean 2	75%	SD 2.05%	6	Total	357/590 (60.5	1%)	Mean	59.74%	SD 7	42%

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

Version: Oct2022 Contract/Lab: All Laborat Species: RATS Strain: Harlan Sprague-D Length of Study: CHRON	awley		Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES									Page: 24 Report Date: 10/05/2022				
					Male						I	emale				
#Mammary Gland:																
Fibroma, Fibroadenon	na, Adenocarcino	•		0/50	(00()	0/50	(00()		00/50	(000()	00/50	(500()	00/50	(000)		
		3/50	(6%)	0/50	(0%)	3/50	(6%)		30/50	(60%)	29/50	(58%)	30/50	(60%)		
		1/49 2/90	(2%) (2%)	3/50 0/50	(6%) (0%)	2/50 0/50	(4%) (0%)		35/50 66/90	(70%) (73%)	36/50 29/50	(72%) (58%)	27/50 34/50	(54%) (68%)		
		2/90	(2 <i>%</i> ) (4%)	2/50	(0%)	0/50	(076)		30/50	(60%)	29/50 33/50	(66%)	54/50	(00 %)		
Overall Incidence	Total	2/30 18/589 (3.0	( )	Mean 3	( )	SD 2.42	0/	Total	379/590 (6	. ,		(00 <i>%)</i> 63.58%	SD 6	52%		
			0 /0)		. 1 1 70	30 2.42	/0	101ai	379/390 (0	4.24 /0) 	Iviean			.JZ /0		
#Oral Cavity (Oral Mucos Squamous Cell Carcin		rynx, Tooth, Gir	ngiva):													
		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%)		
		0/90	(0%)	1/50	(2%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	2/589 (0.34	1%)	Mean 0	.37%	SD 0.82	%	Total	2/590 (0.	34%)	Mea	n 0.2%	SD 0	.67%		
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Pha	• • •	• /													
•		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%)		
		0/90	(0%)	1/50	(2%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	2/589 (0.34	1%)	Mean 0	.37%	SD 0.82	%	Total	2/590 (0.	34%)	Mea	n 0.2%	SD 0	.67%		
#Oral Mucosa: Squamous Cell Carcin	noma															
		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%)		
		0/90	(0%)	1/50	(2%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)		
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)				
• ··· ··																

SD 0.82%

Total

1/590 (0.17%)

Mean 0.1%

SD 0.34%

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

Total

2/589 (0.34%)

Mean 0.37%

#: Denominator is number of animals necropsied

**Overall Incidence** 

Version: Oct2022 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 Dat	e: 10/05/2022
	Male		Female	
*Ovary: Cystadenoma				
Cystadenoma			0/50 (0%)	0/50 (0%)
		( )	0/50 (0%)	0/50 (0%)
		( )	0/50 (0%)	0/50 (0%)
Overall Incidence	Tatal		0/48 (0%)	SD 0.34%
Overall Incidence	Total	1/588 (0.17%)	Mean 0.1%	SD 0.34%
*Ovary: Granulosa Cell Tumor Benign				
ů		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%) (	0/50 (0%)	3/50 (6%)
		( )	0/50 (0%)	0/50 (0%)
		( )	0/48 (0%)	
Overall Incidence	Total		Mean 1.01%	SD 1.84%
*Ovary: Granulosa Cell Tumor Malignant				
5		0/50 (0%) 0	0/50 (0%)	1/50 (2%)
		( )	0/50 (0%)	0/50 (0%)
		( )	1/50 (2%)	1/50 (2%)
		, ,	0/48 (0%)	
Overall Incidence	Total	5/588 (0.85%)	Mean 0.75%	SD 1.04%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
			1/50 (2%)	2/50 (4%)
		( )	0/50 (0%)	3/50 (6%)
		( )	1/50 (2%)	1/50 (2%)
		( )	0/48 (0%)	0.0.000/
Overall Incidence	Total	, ,	Mean 1.76%	SD 2.03%

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC	Toxicology Data Management System Tumor Incidence for Selected Control Animal Group Route: ALL ROUTES Vehicle: ALL VEHICLES	5	Page: 26 Report Date: 10/05/2022 Female				
	Male						
*Ovary:							
Granulosa-Theca Tumor Benign		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	. ,	0/48 (0%) Mean 0.18%	SD 0.6%			
*Ovary: Granulosa-Theca Tumor Malignant							
		0/50 (0%) ( 0/90 (0%) (	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)			
Overall Incidence	Total	1/588 (0.17%)	0/48 (0%) Mean 0.18%	SD 0.6%			
*Ovary:							
Luteoma		0/50 (0%) ( 0/90 (0%) (	1/50 (2%) D/50 (0%) D/50 (0%) D/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	. ,	Mean 0.18%	SD 0.6%			
'Ovary: Schwannoma Malignant							
		1/50 (2%) ( 0/90 (0%) (	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total		Mean 0.18%	SD 0.6%			

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC			Toxicol Tumor Incider	Page: 27 Report Date: 10/05/2022						
			Male			Female				
*Ovary: Sertoli Cell Tumor Benign										
						0/50 (0%) 0/50 (0%) 1/90 (1%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		
Overall Incidence					Total	1/588 (0.17%)	Mean 0.1%	SD 0.34%		
*Ovary: Thecoma Benign										
-						0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)		
Overall Incidence					Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%		
*Pancreas: Adenoma		6/50 (12%)	1/49 (2%)	10/50 (20%)		0/50 (0%)	0/50 (0%)	0/49 (0%)		
		4/49 (8%) 18/90 (20%) 9/50 (18%)	5/50 (10%) 8/50 (16%) 4/50 (8%)	0/50 (0%) 14/50 (28%)		0/50 (0%) 0/90 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	79/588 (13.44%)	Mean 12.93%	SD 8.39%	Total	0/586 (0%)	Mean 0%	SD 0%		
*Pancreas: Adenocarcinoma										
		1/50 (2%) 2/49 (4%) 1/90 (1%) 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%) 0/90 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	5/588 (0.85%)	Mean 0.84%	SD 1.35%	Total	0/586 (0%)	Mean 0%	SD 0%		

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

#### Page: 28 Report Date: 10/05/2022

			Male			Female				
Pancreas: Adenoma or Adenocarcinc	oma									
		7/50 (14%)	1/49 (2%)	10/50 (20%)		0/50 (0%)	0/50 (0%)	0/49 (0%)		
		6/49 (12%)	5/50 (10%)	0/50 (0%)		0/50 (0%)	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%)	4/50 (8%)			0/49 (0%)	0/48 (0%)			
verall Incidence	Total	82/588 (13.95%)	Mean 13.48%	SD 8.24%	Total	0/586 (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%)	0/48 (0%)		0/45 (0%)	1/41 (2%)	0/45 (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%)			0/44 (0%)	1/43 (2%)			
Overall Incidence	Total	2/547 (0.37%)	Mean 0.3%	SD 0.68%	Total	2/529 (0.38%)	Mean 0.43%	SD 0.96%		
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%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/589 (0.17%)	Mean 0.19%	SD 0.62%	Total	0/590 (0%)	Mean 0%	SD 0%		
Peripheral Nerve: Schwannoma Malignant										
-		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%)		
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
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

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

			Male				Female					
#Peripheral Nerve: Schwannoma: Benign, Malignant, NOS												
		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%)				
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/589 (0.17%)	Mean 0.19%	SD 0.62%	Total	0/590 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Di 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%)	11/50 (22%)		12/50 (24%)	19/50 (38%)	18/50 (36%)				
		17/89 (19%)	10/50 (20%)	8/50 (16%)		43/90 (48%)	21/50 (42%)	16/50 (32%)				
		7/50 (14%)	9/50 (18%)			11/50 (22%)	14/50 (28%)					
Overall Incidence	Total	110/587 (18.74%)	Mean 18.76%	SD 7.68%	Total	202/588 (34.35%)	Mean 33.36%	SD 8.1%				
*Pituitary Gland: Pars Di Carcinoma		cified Site:										
		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%)				
		0/89 (0%)	0/50 (0%)	1/50 (2%)		1/90 (1%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/587 (0.17%)	Mean 0.18%	SD 0.6%	Total	4/588 (0.68%)	Mean 0.65%	SD 0.94%				
*Pituitary Gland: Pars Di Carcinoma or Adenom	stalis or Unspe											
		12/50 (24%)	3/50 (6%)	4/50 (8%)		20/50 (40%)	13/49 (27%)	16/49 (33%)				
		15/48 (31%)	14/50 (28%)	11/50 (22%)		13/50 (26%)	19/50 (38%)	18/50 (36%)				
		17/89 (19%)	10/50 (20%)	9/50 (18%)		44/90 (49%)	21/50 (42%)	17/50 (34%)				
Overall Incidence		7/50 (14%)	9/50 (18%)			11/50 (22%)	14/50 (28%) Mean 34.01%					

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

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

			Male			Female				
Pituitary Gland: Pars Inte Adenoma	ermedia:									
		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%)		
		0/89 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
verall Incidence	Total	5/587 (0.85%)	Mean 0.91%	SD 1.38%	Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%		
Pituitary Gland: Pars Inte Carcinoma or Adenoma	ermedia:									
		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%)		
		0/89 (0%)	1/50 (2%)	1/50 (2%)		0/90 (0%)	1/50 (2%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
verall Incidence	Total	5/587 (0.85%)	Mean 0.91%	SD 1.38%	Total	1/588 (0.17%)	Mean 0.18%	SD 0.6%		
Pituitary Gland: Pars Ne Schwannoma Malignan	rvosa:									
		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%)		
		0/89 (0%)	0/50 (0%)	1/50 (2%)		0/90 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Verall Incidence	Total	1/587 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/588 (0%)	Mean 0%	SD 0%		
Prostate: Adenoma										
		0/50 (0%)	1/50 (2%)	0/50 (0%)						
		1/49 (2%)	0/50 (0%)	0/50 (0%)						
		2/90 (2%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)							
Overall Incidence	Total	4/589 (0.68%)	Mean 0.57%	SD 0.98%						

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

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

# Page: 31 Report Date: 10/05/2022

			Male				Female	
Prostate: Adenoma or Adenocarcinc	oma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		1/49 (2%)	0/50 (0%)	0/50 (0%)				
		2/90 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)					
verall Incidence	Total	4/589 (0.68%)	Mean 0.57%	SD 0.98%				
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%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	2/589 (0.34%)	Mean 0.36%	SD 1.21%	Total	0/586 (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%)				
		0/90 (0%)	0/50 (0%)	1/50 (2%)				
		0/50 (0%)	0/50 (0%)					
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%				
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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%

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

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

## Page: 32 Report Date: 10/05/2022

			Male		Female				
Skeletal Muscle: Hemangiosarcoma									
-		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%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
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%)	1/50 (2%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	
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%)	0/50 (0%)	
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%	
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%)	
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	2/589 (0.34%)	Mean 0.29%	SD 0.67%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%	

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

Version: Oct2022 Contract/Lab: All Laborator Species: RATS Strain: Harlan Sprague-Daw Length of Study: CHRONIC	vley		<b>Toxico</b> Tumor Incider	Page: 33 Report Date: 10/05/2022				
			Female					
#Skin:	_							
Basal Cell Adenoma or E	Basosquamou	•	0/50 (00()	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		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%)
		1/49 (2%) 1/90 (1%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/30 (0%)
Overall Incidence	Total	2/589 (0.34%)	Mean 0.29%	SD 0.67%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
		2/369 (0.34%)				1/590 (0.17%)		30 0.0%
#Skin: Basal Cell Adenoma, Ba Overall Incidence	sosquamous 1 Total	Fumor Benign, or Tricho 0/50 (0%) 1/49 (2%) 1/90 (1%) 0/50 (0%) 3/589 (0.51%)	epithelioma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.47%	1/50 (2%) 0/50 (0%) 0/50 (0%) SD 0.84%	Total	0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 1/590 (0.17%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Mean 0.18%	0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0.6%
		( ,				( )		
#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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	3/590 (0.51%)	Mean 0.55%	SD 1.29%
#Skin:								
Basal Cell Carcinoma or	Basosquamo	us 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%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/90 (0%)	1/50 (2%)	0/50 (0%)		0/90 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	· · /
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	3/590 (0.51%)	Mean 0.55%	SD 1.29%

		Toxicology Data Management System							-						
contract/Lab: All Laboratorie	S			Tur	nor Incider	nce for Select	ed Control A	nimal Groups				Report Da	ate: 10/05/20	)22	
pecies: RATS						Route: ALL	ROUTES								
Strain: Harlan Sprague-Dawle	еу					Vehicle: ALL	VEHICLES								
ength of Study: CHRONIC															
					Male						F	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%)	
		1/49	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
		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%)	0/50	(0%)			
Overall Incidence	Total	4/589 (0.6	,	Mean 0		SD 0.949		Total	4/590 (0.	,		0.73%	SD 1.	85%	
Skin: Basal or Sq. Cell Carcinor Adenoma, Papilloma, Sq I	ma, Carcinon Papilloma, Ke	na, Basosq. Tui eratoacanthom 1/50	mor (M or I a, Trichoer (2%)	B), Basal Ce bithelioma 1/50	ell Adenon (2%)	n <b>a,</b> 4/50	(8%)		0/50	(0%)	0/50	(0%)	1/50	(2%)	
	Total	9/49 8/90 3/50 44/589 (7.4 4/50 3/49 2/90	,	4/50 5/50 4/50 Mean 7 3/50 3/50 2/50		4/50 1/50 SD 4.694 3/50 0/50 3/50		Total	0/50 0/90 0/50 5/590 (0. 0/50 0/50 2/90			(0%) (6%) (0%) 0.91% (0%) (0%) (0%)	1/50 0/50 SD 1. 0/50 0/50 1/50	(2%) (0%) 87% 	
Skin:		8/90 3/50 44/589 (7.4 4/50 3/49 2/90 4/50	(9%) (6%) (7%) (8%) (6%) (2%) (8%)	5/50 4/50 Mean 7 3/50 3/50	(10%) (8%) (.39% (	1/50 SD 4.69 3/50 0/50 3/50	(2%) % (6%) (0%) (6%)		0/90 0/50 5/590 (0. 0/50 0/50 2/90 1/50	(0%) (0%) 85%) (0%) (0%) (2%) (2%)	3/50 0/50 Mean 0/50 0/50 0/50 0/50 0/50	(6%) (0%) 0.91% (0%) (0%) (0%) (0%)	0/50 SD 1. 0/50 0/50 1/50	(0%) 87% (0%) (0%) (2%)	
Overall Incidence #Skin: Fibroma		8/90 3/50 44/589 (7.4 4/50 3/49 2/90	(9%) (6%) (7%) (8%) (6%) (2%)	5/50 4/50 Mean 7 3/50 3/50 2/50	(10%) (8%) (.39% (6%) (6%) (6%) (4%)	1/50 SD 4.69 3/50 0/50	(2%) % (6%) (0%)		0/90 0/50 5/590 (0. 0/50 0/50 2/90	(0%) (0%) 85%) (0%) (0%) (2%)	3/50 0/50 Mean 0/50 0/50 0/50	(6%) (0%) (0%) (0%) (0%) (0%)	0/50 SD 1. 0/50 0/50	(0%) 87% (0%) (0%)	
∕Skin:	Total	8/90 3/50 44/589 (7.4 4/50 3/49 2/90 4/50 29/589 (4.5	(9%) (6%) (7%) (8%) (6%) (2%) (2%) (8%) )2%) coma, Mali (12%)	5/50 4/50 Mean 7 3/50 3/50 2/50 2/50 Mean 5	(10%) (8%) (39% (6%) (6%) (6%) (4%) (4%) (4%) 5.12%	1/50 SD 4.69 3/50 0/50 3/50 SD 2.49	(2%) % (6%) (0%) (6%) 6 (6%)	Total	0/90 0/50 5/590 (0. 0/50 0/50 2/90 1/50 4/590 (0.	(0%) (0%) 85%) (0%) (0%) (2%) (2%) 68%) 	3/50 0/50 Mean 0/50 0/50 0/50 0/50 0/50	(6%) (0%) (0%) (0%) (0%) (0%) (0%) (0%) (0	0/50 SD 1. 0/50 0/50	(0%) 87% (0%) (0%) (2%) 97% (2%)	
#Skin: Fibroma Overall Incidence #Skin: Fibroma, Fibrosarcoma, S	Total	8/90 3/50 44/589 (7.4 4/50 3/49 2/90 4/50 29/589 (4.9 coma, Myxosar 6/50	(9%) (6%) (7%) (8%) (6%) (2%) (8%) )2%) coma, Mali	5/50 4/50 Mean 7 3/50 3/50 2/50 2/50 Mean 5 9 gnant Fibro 3/50	(10%) (8%) (39% (6%) (6%) (4%) (4%) (4%) 5.12% ous Histioo (6%)	1/50 SD 4.69 3/50 0/50 3/50 SD 2.49 cytoma, or 3/50	(2%) % (6%) (0%) (6%) %	Total	0/90 0/50 5/590 (0. 0/50 0/50 2/90 1/50 4/590 (0.	(0%) (0%) 85%) (0%) (0%) (0%) (2%) (2%) 68%)	3/50 0/50 Mean 0/50 0/50 0/50 Mean 1/50	(6%) (0%) 0.91% (0%) (0%) (0%) (0%) 0.57%	0/50 SD 1. 0/50 0/50 1/50 SD 0. 1/50	(0%) 87% (0%) (0%) (2%) 97%	
Skin: Fibroma Overall Incidence Skin: Fibroma, Fibrosarcoma, S	Total	8/90 3/50 44/589 (7.4 4/50 3/49 2/90 4/50 29/589 (4.9 coma, Myxosar 6/50 4/49	(9%) (6%) (7%) (8%) (6%) (2%) (2%) (8%) 22%) coma, Mali (12%) (8%)	5/50 4/50 Mean 7 3/50 3/50 2/50 2/50 Mean 5 9 9 9 9 9 9 1 9 1 9 1 9 1 9 1 9 1 9 1	(10%) (8%) (39% (6%) (6%) (4%) (4%) (4%) (4%) (4%) (4%) (4%) (6%) (6%)	1/50 SD 4.69 3/50 0/50 3/50 SD 2.49 Sytoma, or 3/50 1/50	(2%) % (6%) (0%) (6%) % (6%) (2%)	Total	0/90 0/50 5/590 (0. 0/50 2/90 1/50 4/590 (0. 0/50 1/50	(0%) (0%) 85%) (0%) (0%) (2%) (2%) 68%) 	3/50 0/50 Mean 0/50 0/50 0/50 Mean 1/50 0/50	(6%) (0%) (0%) (0%) (0%) (0%) (0%) (0%) (2%) (0%)	0/50 SD 1. 0/50 0/50 1/50 SD 0. 1/50 0/50	(0%) 87% (0%) (0%) (2%) 97% (2%) (0%)	

Version: Oct2022 Contract/Lab: All Laborato Species: RATS Strain: Harlan Sprague-Da Length of Study: CHRON	awley	Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES										Page: 35 Report Da	t <b>e:</b> 10/05/20	)22	
			Male								Female				
#Skin:															
Fibroma, Fibrosarcoma	a, Sarcoma, My	xoma, Myxosarc	oma, or N	/lalignant Fi	brous Hist	tiocytoma									
		6/50	(12%)	3/50	(6%)	3/50	(6%)		0/50	(0%)	1/50	(2%)	1/50	(2%)	
		4/49	(8%)	3/50	(6%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		5/90	(6%)	3/50	(6%)	3/50	(6%)		5/90	(6%)	0/50	(0%)	2/50	(4%)	
		4/50	(8%)	3/50	(6%)				2/50	(4%)	1/50	(2%)			
Overall Incidence	Total	38/589 (6.4	5%)	Mean 6	5.52%	SD 2.41	%	Total	13/590 (	2.2%)	Mean	1.96%	SD 1.	.91%	
#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%)	0/50	(0%)		0/50	(0%)	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%)	0/50	(0%)				1/50	(2%)	1/50	(2%)			
Overall Incidence	Total	4/589 (0.68	,	Mean C		SD 0.94		Total	4/590 (0	,		0.73%	SD 1.	.01%	
#Skin:															
Fibrosarcoma, Sarcom	a, Myxosarcom	· •		-											
		2/50	(4%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	1/50	(2%)	
		1/49	(2%)	0/50	(0%)	1/50	(2%)		1/50	(2%)	0/50	(0%)	0/50	(0%)	
		3/90	(3%)	1/50	(2%)	0/50	(0%)		3/90	(3%)	0/50	(0%)	1/50	(2%)	
		0/50	(0%)	1/50	(2%)				1/50	(2%)	1/50	(2%)			
Overall Incidence	Total	9/589 (1.53	8%)	Mean	1.4%	SD 1.48	%	Total	9/590 (1	.53%)	Mean	1.39%	SD 1.	.17%	
#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%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)	
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)	
		0/50	(0%)	0/50	(0%)		· · /		0/50	(0%)	0/50	(0%)		. /	
			(,		(-,-,					()		(			

SD 0.6%

Total

0/590 (0%)

Mean 0%

SD 0%

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

Total

1/589 (0.17%)

Mean 0.18%

#: Denominator is number of animals necropsied

**Overall Incidence** 

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

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			Male				Female	
Skin: Hemangiopericytoma								
		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	1/50 (2%)
	<b>T</b> ( )	0/50 (0%)	0/50 (0%)	00.000	<b>T</b>	0/50 (0%)	0/50 (0%)	00.000/
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.18%	SD 0.6%
Skin: Keratoacanthoma								
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		8/49 (16%)	2/50 (4%)	3/50 (6%)		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%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Verall Incidence	Total	30/589 (5.09%)	Mean 5.08%	SD 4.02%	Total	0/590 (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%)
		0/49 (0%)	2/50 (4%)	1/50 (2%)		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%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	10/589 (1.7%)	Mean 1.66%	SD 2.16%	Total	3/590 (0.51%)	Mean 0.55%	SD 0.93%
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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.18%	SD 0.6%	Total	0/590 (0%)	Mean 0%	SD 0%

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

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

					Male						F	emale		
/Skin:														
Malignant Fibrous His	tiocytoma													
		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%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		1/90	(1%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	1/589 (0.17		Mean 0	.18%	SD 0.6%	D	Total	2/590 (0.	34%)	Mean	0.28%	SD 0.	.66%
Skin:														
Neurofibrosarcoma or	· Schwannoma (n	nalignant or NC	S)											
		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%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	2/589 (0.34		Mean 0		SD 1.21%		Total	2/590 (0.	34%)	Mean	0.36%	SD 0.	.81%
Skin:														
Neurofibrosarcoma, N	leurofibroma, or	Schwannoma (	benign, ma	alignant or I	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%)	0/50	(0%)
		0/90	(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)		· · ·		0/50	(0%)	0/50	(0%)		· · /
verall Incidence	Total	2/589 (0.34		Mean 0		SD 1.21%		Total	2/590 (0.	,		0.36%	SD 0.	
Skin:														
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%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	1/50	(2%)
		0/90	(0/0)							···/		···/		
		0/90 0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		

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

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

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					Male						F	emale		
≭Skin: Pilomatrixoma														
		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%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
verall Incidence	Total	3/589 (0.51%)		Mean 0	.56%	SD 1.85%		Total	0/590 (	0%)	Mea	in 0%	SD	0%
Skin: Sarcoma														
		1/50 (	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/49 (	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/90	(2%)	0/50	(0%)	0/50	(0%)		2/90	(2%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	4/589 (0.68%)	,	Mean 0		SD 0.97%		Total	3/590 (0.			0.38%	SD 0.	
Skin: Schwannoma Malignant														
		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%)	0/50	(0%)
			(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)				0/50	(0%)	0/50	(0%)		
Verall Incidence	Total	2/589 (0.34%)	,	Mean 0		SD 1.21%		Total	2/590 (0.	,		0.36%	SD 0.	
Skin: Squamous Cell Carcinoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
			(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
			(0%)	1/50	(2%)		( <b>/</b>		0/50	(0%)	0/50	(0%)		()
Overall Incidence	Total	2/589 (0.34%)	. ,	Mean 0	· · ·	SD 0.81%	4	Total	1/590 (0.	( )		0.18%	SD 0	6%

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

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC				Tur	nor Incider	logy Data Ma nce for Selecto Route: ALL Vehicle: ALL	ed Control A	Animal Groups				Page: 39 Report Da	i <b>te:</b> 10/05/20	22
					Male						I	Female		
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	Carcinoma, Ba	sosquamo	ous Tumor (r	nalignant	or NOS),								
		0/50 0/49 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 1/50 1/50	(0%) (0%) (2%) (2%)	1/50 0/50 0/50	(2%) (0%) (0%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 2/50 0/50	(0%) (0%) (4%) (0%)	1/50 1/50 0/50	(2%) (2%) (0%)
Overall Incidence	Total	3/589 (0.51	1%)	Mean 0.	55%	SD 0.93%		Total	4/590 (0.	68 <sup>°</sup> %)	Mean	0.73%	SD 1.	
#Skin: Squamous Cell Papilloma														
		0/50 0/49 2/90 1/50	(0%) (0%) (2%) (2%)	0/50 2/50 2/50 0/50	(0%) (4%) (4%) (0%)	0/50 1/50 0/50	(0%) (2%) (0%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)
Overall Incidence	Total	8/589 (1.36	,	Mean 1.		SD 1.63%		Total	0/590 (	,		an 0%	SD (	)% 
#Skin: Squamous Cell Papilloma o	r Papilloma													
		0/50 0/49 2/90 1/50	(0%) (0%) (2%) (2%)	0/50 2/50 2/50 0/50	(0%) (4%) (4%) (0%)	0/50 1/50 0/50	(0%) (2%) (0%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50	(0%) (0%) (0%)
Overall Incidence	Total	8/589 (1.36	5%)	Mean 1.	29%	SD 1.63%	6	Total	0/590 (	0%)	Mea	an 0%	SD (	0%
#Skin: Squamous Cell Papilloma, F	Papilloma, S	quamous Cell	Carcinom	a or Keratoa	canthom	a								
	-	1/50 8/49 7/90 3/50	(2%) (16%) (8%) (6%)	1/50 4/50 4/50 4/50	(2%) (8%) (8%) (8%)	3/50 4/50 1/50	(6%) (8%) (2%)		0/50 0/50 0/90 0/50	(0%) (0%) (0%) (0%)	0/50 0/50 0/50 0/50	(0%) (0%) (0%) (0%)	1/50 0/50 0/50	(2%) (0%) (0%)
Overall Incidence	Total	40/589 (6.7	,	Mean 6.		SD 4.1%		Total	1/590 (0.	,		0.18%	SD 0	.6%

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC			Tumo	or Incider	logy Data Ma nce for Select Route: ALL Vehicle: ALL	ROUTES	Animal Groups				Page: 40 Report Da	<b>te:</b> 10/05/20	)22
			r	Male						F	emale		
#Skin:													
Squamous Cell Papilloma,	Papilloma,			(22)	a (= a	(		o /= o	(22()	o /= o	(00)	a (= a	(22)
		1/50 (2%)		(2%)	2/50	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		8/49 (16%)	,	(8%)	4/50	(8%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		7/90 (8%)		(8%)	1/50	(2%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
o	<b>T</b> ( )	3/50 (6%)		(6%)			<b>T</b> ( )	0/50	(0%)	0/50	(0%)	0.5	<b>~</b> ~/
Overall Incidence	Total	38/589 (6.45%)	Mean 6.3		SD 4.15		Total	0/590 (			an 0%	SD	
#Skin: Trichoepithelioma													
		0/50 (0%)	•	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/49 (0%)	,	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/90 (0%)	•	(0%)	0/50	(0%)		0/90	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (0%)	•	(0%)				0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	1/589 (0.17%)	Mean 0.1		SD 0.6%		Total	0/590 (	,		an 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%)	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%)	0/50	(0%)		
Overall Incidence	Total	2/589 (0.34%)	Mean 0.2		SD 0.66		Total	0/590 (	0%)	Mea	an 0%	SD	0%
≴Skin: Sebaceous Gland: Carcinoma or 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%)	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%)	0/50	(0%)		
• ··· ··	<b>-</b>	0/500 (0.040()			00 000		<b>T</b> ( )	0/500 /	00()		001	00	<b>~</b> ~′

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

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			Male				Female	
Spleen: Hemangiosarcoma								
•		0/50 (0%)	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%)
		3/90 (3%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
warall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 4 040/	Total	0/49 (0%)	0/49 (0%)	
Verall Incidence	Total	3/589 (0.51%)	Mean 0.3%	SD 1.01%	Total	2/587 (0.34%)	Mean 0.29%	SD 0.67%
Stomach, Forestomach: Sarcoma								
		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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
	<b>T</b> ( )	0/50 (0%)	0/50 (0%)	00.00/	<b>T</b> ( )	0/50 (0%)	0/49 (0%)	00.00404
verall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%
Stomach, Forestomach: Squamous Cell Carcinoma		na 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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%	Total	0/589 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Papilloma								
		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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
verall Incidence	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%	Total	0/589 (0%)	Mean 0%	SD 0%

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

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

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			Male					Female	
Testis: Adenoma									
		1/50 (2%)	7/50 (14%)	3/49	(6%)				
		2/49 (4%)	1/50 (2%)	0/50	(0%)				
		2/90 (2%)	0/50 (0%)	1/50	(2%)				
		0/50 (0%)	0/50 (0%)						
verall Incidence	Total	17/588 (2.89%)	Mean 2.95%	SD 4.14%					
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%)	0/48	(0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/88 (0%)	0/48 (0%)	0/48	(0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)
		0/49 (0%)	0/48 (0%)				0/50 (0%)	0/43 (0%)	
Verall Incidence	Total	0/564 (0%)	Mean 0%	SD 0%		Total	1/569 (0.18%)	Mean 0.1%	SD 0.35%
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%)	0/48	(0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/88 (0%)	0/48 (0%)	0/48	(0%)		1/87 (1%)	0/50 (0%)	0/47 (0%)
		0/49 (0%)	0/48 (0%)				0/50 (0%)	0/43 (0%)	
Verall Incidence	Total	0/564 (0%)	Mean 0%	SD 0%		Total	1/569 (0.18%)	Mean 0.1%	SD 0.35%
Thymus:									
Thymoma: Benign, Maligr	nant, 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%)	0/48	(0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/88 (0%)	0/48 (0%)	0/48	(0%)		2/87 (2%)	0/50 (0%)	0/47 (0%)
		0/49 (0%)	0/48 (0%)				0/50 (0%)	0/43 (0%)	
Overall Incidence	Total	0/564 (0%)	Mean 0%	SD 0%		Total	2/569 (0.35%)	Mean 0.21%	SD 0.69%

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

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

### Page: 43 Report Date: 10/05/2022

			Male				Female	
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%)	2/50 (4%)		12/50 (24%)	5/50 (10%)	2/50 (4%)
		8/89 (9%)	8/50 (16%)	4/50 (8%)		6/90 (7%)	16/50 (32%)	5/50 (10%)
		9/50 (18%)	8/50 (16%)			10/50 (20%)	6/50 (12%)	
verall Incidence	Total	88/588 (14.97%)	Mean 15.39%	SD 6.43%	Total	91/589 (15.45%)	Mean 16.09%	SD 8.5%
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%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		2/89 (2%)	0/50 (0%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
verall Incidence	Total	9/588 (1.53%)	Mean 1.48%	SD 1.31%	Total	9/589 (1.53%)	Mean 1.64%	SD 1.75%
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%)	3/50 (6%)		13/50 (26%)	6/50 (12%)	2/50 (4%)
		10/89 (11%)	8/50 (16%)	4/50 (8%)		6/90 (7%)	16/50 (32%)	7/50 (14%)
		9/50 (18%)	8/50 (16%)			12/50 (24%)	7/50 (14%)	
Verall Incidence	Total	93/588 (15.82%)	Mean 16.14%	SD 6.22%	Total	100/589 (16.98%)	Mean 17.73%	SD 8.89%
Thyroid Gland: Follicular Cel 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%)	0/50 (0%)
		0/89 (0%)	2/50 (4%)	0/50 (0%)		0/90 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/45 (0%)			1/50 (2%)	0/45 (0%)	
Overall Incidence	Total	3/583 (0.51%)	Mean 0.55%	SD 1.3%	Total	1/584 (0.17%)	Mean 0.18%	SD 0.6%

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

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

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			Male				Female	
*Thyroid Gland: Follicular Cel Carcinoma	II:							
		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%)
		0/89 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/45 (0%)			0/50 (0%)	0/45 (0%)	
Overall Incidence	Total	0/583 (0%)	Mean 0%	SD 0%	Total	1/584 (0.17%)	Mean 0.1%	SD 0.34%
Thyroid Gland: Follicular Cel 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%)	0/50 (0%)
		0/89 (0%)	2/50 (4%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/45 (0%)			1/50 (2%)	0/45 (0%)	
Overall Incidence	Total	3/583 (0.51%)	Mean 0.55%	SD 1.3%	Total	2/584 (0.34%)	Mean 0.28%	SD 0.66%
≭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%)
		1/90 (1%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/589 (0.17%)	Mean 0.1%	SD 0.34%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%
≭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%)
		0/90 (0%)	0/50 (0%)	0/50 (0%)		1/90 (1%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/589 (0%)	Mean 0%	SD 0%	Total	1/590 (0.17%)	Mean 0.1%	SD 0.34%

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

Male    #Tongue: Squamous Cell Carcinoma or Papilloma Squamous    0/50  0%)  0/50  0%)    0/49  0%)  0/50  0%)    0/90  0%)  0/50  0%)    0/50  0%)  0/50  0%)    Overall Incidence  Total  0/589  0%)  Mean 0%    #Tooth: Odontoma  0/50  0%)  0/50  0%)    0/90  0%)  0/50  0%)  0/50  0%)    0/90  0%)  0/50  0%)  0/50  0%)    0/50  0%)  0/50  0%)  0/50  0%)    0/50  0%)  0/50  0%)  0/50  0%)    Overall Incidence  Total  1/589  0.17%)  Mean 0.18%    'Urinary Bladder: Leiomyosarcoma    0/50  0%)  0/50  0%)  0/50  0%)    0/50  0%)  0/50  0%)  0/50  0%)    0/50  0%)  0/50	by Data Management System the for Selected Control Animal G Route: ALL ROUTES /ehicle: ALL VEHICLES	pups	Page: 45 Report Date: 10/05/2022
Squamous Cell Carcinoma or Papilloma Squamous  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  #Uterus:  #Uterus:  #Uterus  #Uterus <th></th> <th></th> <th>Female</th>			Female
0/50  (0%)  0/50  (0%)    0/49  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    #Tooth:  0  0/50  (0%)  Mean 0%    #Tooth:  0/50  (0%)  0/50  (0%)    0/49  (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%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50			
0/49  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    #Tooth:  0/50  (0%)  0/50  (0%)    Ødontoma  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/90  (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%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)	0/50 (00/)		
0/90  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  Mean  0%    #Tooth:  0  0/50  (0%)  Mean  0%    0/49  (0%)  0/50  (0%)  0/50  (0%)    0/49  (0%)  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)  0/50  (0%)    0/50  (0%)  0	0/50 (0%)	0/50 (0%) 0/5	
0/50  (0%)  0/50  (0%)    Overall Incidence  Total  0/589  (0%)  Mean  0%    #Tooth:  0  0/50  (0%)  0/50  (0%)    Odontoma  0/50  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 1/90 (1%) 0/5	
Overall Incidence  Total  0/589 (0%)  Mean 0%    #Tooth: Odontoma  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (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%)    Verall Incidence  Total  0/588 (0%)  Mean 0%    #Uterus:  Total  0/588 (0%)  Mean 0%	0/30 (0%)	0/50 (0%) 0/5	
#Tooth: Odontoma 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	SD 0% To	. ,	Mean 0.1% SD 0.34%
Odontoma  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)    Overall Incidence  Total  1/589 (0.17%)  Mean 0.18%    *Urinary Bladder: Leiomyosarcoma  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/89 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)    Overall Incidence  Total  0/588 (0%)  Mean 0%			
0/49  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/90  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    *Urinary Bladder:			
0/90 (0%)  0/50 (0%)    0/50 (0%)  0/50 (0%)    0/50 (0%)  0/50 (0%)    Overall Incidence  Total  1/589 (0.17%)  Mean 0.18%    *Urinary Bladder:	0/50 (0%)	0/50 (0%) 0/5	50 (0%) 0/50 (0%)
0/50  (0%)  0/50  (0%)    Overall Incidence  Total  1/589  (0.17%)  Mean 0.18%    *Urinary Bladder:	1/50 (2%)	0/50 (0%) 0/5	
Overall Incidence  Total  1/589 (0.17%)  Mean 0.18%    *Urinary Bladder: Leiomyosarcoma  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/89 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)    Overall Incidence  Total  0/588 (0%)  Mean 0%	0/50 (0%)	0/90 (0%) 0/5	
*Urinary Bladder: Leiomyosarcoma 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/89 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% #Uterus:		0/50 (0%) 0/5	50 (0%)
*Urinary Bladder: Leiomyosarcoma	SD 0.6% To	l 0/590 (0%) l	Mean 0% SD 0%
0/49 (0%) 0/50 (0%) 0/89 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/588 (0%) Mean 0%			
0/89  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    0/50  (0%)  0/50  (0%)    Overall Incidence  Total  0/588  (0%)  Mean  0%    #Uterus:  #Uterus:  Image: Comparison of the second secon	0/50 (0%)	0/50 (0%) 0/5	
0/50 (0%) 0/50 (0%) Overall Incidence Total 0/588 (0%) Mean 0% #Uterus:	0/50 (0%)	0/50 (0%) 0/4	
Overall Incidence Total 0/588 (0%) Mean 0%	0/50 (0%)	1/88 (1%) 0/4	
#Uterus:		0/50 (0%) 0/4	
#Uterus:	SD 0% To	( )	Mean 0.1% SD 0.34%
		2/50 (4%) 2/5 5/5 2/5	50 (Ì0%́) 1/50 (2%́)
		3/50 (6%) 5/4	
Overall Incidence	To	. ,	lean 5.8% SD 2.77%

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC	Toxicology Data Management Syste Tumor Incidence for Selected Control Anima Route: ALL ROUTES Vehicle: ALL VEHICLES		3		Page: 46 Report Da	t <b>e:</b> 10/05/20	022
	Male				Female		
#Uterus:							
Adenocarcinoma or Adenoma			2/50 (4%)	2/50 5/50 4/50	(4%) (10%) (8%)	3/50 1/50 3/50	(6%) (2%) (6%)
			3/50 (6%)	5/49	(10%)	5/50	(078)
Overall Incidence		Total	28/449 (6.24%)		n 6.24%	SD 2.	.76%
#Uterus: Adenoma							
			0/50 (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
			0/50 (0%)	2/50 0/49	(4%) (0%)	0/50	(0%)
Overall Incidence		Total	2/449 (0.45%)		n 0.44%	SD 1.	.33%
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or	- Sa Cell Panilloma						
			4/50 (8%)	2/50 5/50	(4%) (10%)	3/50 2/50	(6%) (4%)
			0/50 (00/)	4/50	(8%)	5/50	(10%)
Overall Incidence		Total	3/50 (6%) 35/449 (7.8%)	7/49 Mear	(14%) n 7.81%	SD 3	3.3%
#Uterus: Deciduoma Benign							
			0/50 (0%)	0/50 0/50	(0%) (0%)	1/50 0/50	(2%) (0%)
				0/50	(0%)	0/50	(0%)
Overall Incidence		Total	0/50 (0%) 1/449 (0.22%)	0/49 Mear	(0%) n 0.22%	SD 0.	67%
			( )		1 U.ZZ 70	JU U.	.07 /0

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC	Toxicology Data Management S Tumor Incidence for Selected Control A Route: ALL ROUTES Vehicle: ALL VEHICLES	-	i	Page: 47 Report Da	e: 10/05/2022
	Male			Female	
#Uterus:					
Granular Cell Tumor Benign			0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)
			0/50 (0%)	1/49 (2%)	
Overall Incidence		Total	2/449 (0.45%)	Mean 0.45%	SD 0.89%
#Uterus: Hemangioma					
			0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
			1/50 (2%)	0/49 (0%)	0/30 (070)
Overall Incidence		Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%
#Uterus:					
Polyp Stromal			9/50 (18%)	5/50 (10%) 8/50 (16%)	8/50 (16%) 7/50 (14%)
			E/E0 (400/)	2/50 (4%)	5/50 (10%)
Overall Incidence		Total	5/50 (10%) 53/449 (11.8%)	4/49 (8%) Mean 11.8%	SD 4.5%
			· · · · · · · · · · · · · · · · · · ·		
#Uterus: Sarcoma					
			0/50 (0%)	1/50 (2%)	0/50 (0%)
				0/50 (0%)	0/50 (0%)
			0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/50 (0%) 1/449 (0.22%)	0/49 (0%) Mean 0.22%	SD 0.67%
		IUlai	1/449 (U.2270)		JU.U.7%

/ersion: Oct2022 Contract/Lab: All Laboratories Species: RATS	Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES	5	Page: 48 Report Dat	te: 10/05/2022
Strain: Harlan Sprague-Dawley	Vehicle: ALL VEHICLES			
ength of Study: CHRONIC				
	Male		Female	
Uterus: Sarcoma Stromal				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (00/)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 1/449 (0.22%)	0/49 (0%) Mean 0.22%	SD 0.67%
		1/449 (0.2270)		
Uterus: Sarcoma Stromal or Polyp Stromal				
		9/50 (18%)	5/50 (10%)	8/50 (16%)
			8/50 (16%)	7/50 (14%)
		5/50 (10%)	2/50 (4%) 4/49 (8%)	6/50 (12%)
verall Incidence	Total	54/449 (12.03%)	Mean 12.02%	SD 4.45%
Jterus: 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%)	1/49 (2%)	0/50 (0%)
verall Incidence	Total	2/449 (0.45%)	Mean 0.45%	SD 0.89%
		· · ·		
Uterus:				
Sq Cell Carcinoma or Papilloma Squamous		0/50 (40/)		
		2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
			0/50 (0%)	2/50 (4%)
		0/50 (0%)	2/49 (4%)	
verall Incidence	Total	7/449 (1.56%)	Mean 1.56%	SD 1.96%

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC	Toxicology Data Management System Tumor Incidence for Selected Control Animal Group Route: ALL ROUTES Vehicle: ALL VEHICLES	5	Page: 49 Report Date: 10/05/2022						
	Male	1/50 (2%) 0/50 (0%) 0/50 0/50 (0%) 1/50 0/50 (0%) 2/50							
#Uterus:									
Squamous Cell Carcinoma		0/	/50 (0%)	1/50 (2%)					
			( )	2/50 (4%)					
Overall Incidence	Total	6/449 (1.34%)	Mean 1.34%	SD 1.75%					
#Uterus: Squamous Cell Papilloma									
		0/	/50 (0%) /50 (0%) /50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)					
			/49 (0%)	0/30 (078)					
Overall Incidence	Total	1/449 (0.22%)	Mean 0.22%	SD 0.67%					
#Vagina: Granular Cell Tumor Benign									
-			/50 (0%)	0/50 (0%)					
		( )	/50 (0%)	1/50 (2%)					
			/50 (0%) /47 (0%)	0/50 (0%)					
Overall Incidence	Total		/47 (0%) Mean 0.18%	SD 0.6%					
#Vagina: Polyp									
<i></i>		0/50 (0%) 0/	/50 (0%)	0/50 (0%)					
		0/50 (0%) 0/	/50 (0%)	0/50 (0%)					
		( )	/50 (0%)	1/50 (2%)					
o			/47 (0%)	<b>OD</b> 0.00/					
Overall Incidence	Total	( /	Mean 0.18%	SD 0.6%					

Version: Oct2022 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawle Length of Study: CHRONIC			Toxicol Tumor Incider	Page: 50 Report Date: 10/05/2022							
			Male			Female					
#Vagina: Sarcoma											
						0/50 (0%) 0/50 (0%) 0/90 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence					Total	1/50 (2%) 1/587 (0.17%)	0/47 (0%) Mean 0.18%	SD 0.6%			
#Vagina: Schwannoma Malignant											
						0/50 (0%) 0/50 (0%) 1/90 (1%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%) 0/50 (0%)			
Overall Incidence					Total	0/50 (0%) 4/587 (0.68%)	0/47 (0%) Mean 0.65%	SD 0.93%			
≭Zymbal's Gland: Adenoma											
		1/50 (2%) 0/49 (0%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	2/589 (0.34%)	Mean 0.36%	SD 0.81% Total		0/590 (0%)	Mean 0%	SD 0%			
#Zymbal's Gland: Carcinoma											
		1/50 (2%) 1/49 (2%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 2/50 (4%)	1/50 (2%) 1/50 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/90 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	8/589 (1.36%)	Mean 1.46%	SD 1.3%	Total	0/590 (0%)	Mean 0%	SD 0%			

Version: Oct2022 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: 10/05/2022				
		Male									Female				
#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%)	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%)	3/50	(6%)				0/50	(0%)	0/50	(0%)			
Overall Incidence	Total	10/589 (1.7%)		Mean 1.82%		SD 1.89%		Total	0/590 (0%)		Mean 0%		SD 0%		