

NTP Historical Controls Report

All Routes and Vehicles

Harlan Sprague-Dawley RATS

November 2019

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	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	050303803	01/30/12	729	50(2)	12(621)	610.8	Sodium Tungstate Dihydrate
					Female		
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	050303803	01/31/12	730	50(5)	30(667)	393.3	Sodium Tungstate Dihydrate

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

Page: 4 Report Date: 02/17/2020

			Male				Female	
All Organs: Benign Tumors								
		27/50 (54%)	28/50 (56%)	35/49 (71%)		37/50 (74%)	41/50 (82%)	40/50 (80%)
		38/50 (76%)	27/50 (54%)	30/50 (60%)		41/50 (82%)	40/50 (80%)	39/50 (78%)
			32/50 (64%)	49/90 (54%)		39/50 (78%)		82/90 (91%)
		29/50 (58%)				39/50 (78%)		
verall Incidence	Total	295/489 (60.33%)	Mean 60.87%	SD 8.05%	Total	398/490 (81.22%)	Mean 80.35%	SD 4.72%
All Organs: Malignant Tumors								
		13/50 (26%)	15/50 (30%)	14/49 (29%)		16/50 (32%)	14/50 (28%)	13/50 (26%)
		11/50 (22%)	12/50 (24%)	12/50 (24%)		15/50 (30%)	19/50 (38%)	11/50 (22%)
			9/50 (18%)	24/90 (27%)		14/50 (28%)		37/90 (41%)
		14/50 (28%)				17/50 (34%)		
verall Incidence	Total	124/489 (25.36%)	Mean 25.25%	SD 3.71%	Total	156/490 (31.84%)	Mean 31.01%	SD 5.98%
All Organs: Malignant and Benign 1								
		32/50 (64%)	36/50 (72%)	41/49 (84%)		41/50 (82%)	44/50 (88%)	44/50 (88%)
		42/50 (84%)	33/50 (66%)	37/50 (74%)		47/50 (94%)	46/50 (92%)	41/50 (82%)
			37/50 (74%)	57/90 (63%)		47/50 (94%)		89/90 (99%)
		36/50 (72%)				47/50 (94%)		
verall Incidence	Total	351/489 (71.78%)	Mean 72.56%	SD 7.59%	Total	446/490 (91.02%)	Mean 90.32%	SD 5.77%
All Organs: Hemangioma								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

*: 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		
#All Organs: Hemangiosarcoma														
		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%)	1/50	(2%)	0/50	(0%)
				0/50	(0%)	3/90	(3%)		0/50	(0%)			3/90	(3%)
		1/50	(2%)						0/50	(0%)				
Verall Incidence	Total	5/489 (1.029	,	Mean 0		SD 1.289		Total	5/490 (1.	,		0.81%	SD 1.	28%
All Organs: Hemangiosarcoma or Hem														
-	•	1/50	(2%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
				0/50	(0%)	3/90	(3%)		0/50	(0%)			3/90	(3%)
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	7/489 (1.439	,	Mean 1		SD 1.279		Total	6/490 (1.	,		1.04%	SD 1.	
#All Organs: Histiocytic Sarcoma														
		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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/489 (0%	,	Mean	- / -	SD 0%		Total	1/490 (0	,		0.22%	SD 0.	67%
#All Organs: Leukemia: Granulocytic														
		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%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/489 (0.2%	6)	Mean 0	.22%	SD 0.679	%	Total	1/490 (0	.2%)	Mean	0.22%	SD 0.	67%

*: 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		
#All Organs:														
Leukemia: Lymphocytie	c, Monocytic, Mo	ononuclear, or	Undifferer	ntiated										
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	3/50	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
				3/50	(6%)	0/90	(0%)		1/50	(2%)			0/90	(0%)
		1/50	(2%)						0/50	(0%)				
verall Incidence	Total	7/489 (1.43	,	Mean 1	.56%	SD 2.6%	0	Total	2/490 (0.	41%)	Mean	0.44%	SD 0.	88%
All Organs:														
Malignant Lymphoma:	Histiocytic, I vm	phocytic Mixe	d NOS or	Undifferen	tiated Cel	Type								
		2/50	(4%)	0/50	(0%)	1/49	(2%)		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%)
		0,00	(0,0)	1/50	(2%)	2/90	(2%)		1/50	(2%)	0,00	(0,0)	5/90	(6%)
		1/50	(2%)	1/00	(270)	2/00	(270)		2/50	(4%)			0/00	(070)
Overall Incidence	Total	7/489 (1.43	()	Mean 1	36%	SD 1.439	<i>V</i> ~	Total	10/490 (2	· · /	Mean	1.73%	SD	2%
			,						10/400 (2					
All Organs:														
Malignant Schwannom	a													
		3/50	(6%)	6/50	(12%)	3/49	(6%)		1/50	(2%)	3/50	(6%)	2/50	(4%)
		1/50	(2%)	2/50	(4%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	2/50	(4%)
				1/50	(2%)	3/90	(3%)		0/50	(0%)			4/90	(4%)
		1/50	(2%)						2/50	(4%)				
Verall Incidence	Total	20/489 (4.0	9%)	Mean 4	.16%	SD 3.55	%	Total	16/490 (3	.27%)	Mean	3.16%	SD 2.	06%
							•••••			•••••			•••••	
#All Organs:	Mallanant NOO													
Mesothelioma: Benign,	malignant, NOS		(40()	4/50	(00())	4/40	(00()		0/50	(00()	0/50	(00()	0/50	(00()
		2/50	(4%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
				1/50	(2%)	2/90	(2%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	10/489 (2.0	4%)	Mean 2	2.03%	SD 1%		Total	0/490 (0%)	Mea	an 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: 7 Report Date: 02/17/2020

			Male				Female	
All Organs: Mesothelioma: Malignant								
		2/50 (4%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	2/90 (2%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	10/489 (2.04%)	Mean 2.03%	SD 1%	Total	0/490 (0%)	Mean 0%	SD 0%
All Organs:								
Osteosarcoma								
		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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)
		0/50 (0%)				1/50 (2%)		
verall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
All Organs:								
Osteosarcoma or Osteom	na							
		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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)
		0/50 (0%)				1/50 (2%)		
verall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
Adrenal Cortex: Adenoma								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	0/50 (0%)	3/50 (6%)		3/50 (6%)	0/50 (0%)	0/50 (0%)
		0,00 (0,0)	0/50 (0%)	1/90 (1%)		2/50 (4%)	0,00 (0,0)	1/90 (1%)
		0/50 (0%)	0,00 (0,0)	1/00 (1/0)		0/50 (0%)		(170)
verall Incidence	Total	8/489 (1.64%)	Mean 1.68%	SD 2.55%	Total	6/490 (1.22%)	Mean 1.23%	SD 2.22%
	TUtal	0/403 (1.0470)	WEal1 1.0070	SD 2.33/0	TULAI	0,430 (1.22/0)	WEall 1.23/0	JD 2.22/0

*: 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	
Adrenal Cortex: Carcinoma								
		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%) 1/90 (1%)
		0/50 (0%)	0/30 (078)	0/90 (078)		0/50 (0%)		1/90 (178)
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
Adrenal Medulla: Ganglioneuroma								
-		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%)	0/49 (0%)
			0/50 (0%)	0/88 (0%)		0/50 (0%)		0/86 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/487 (0.21%)	Mean 0.22%	SD 0.67%	Total	1/485 (0.21%)	Mean 0.22%	SD 0.67%
Adrenal Medulla: Pheochromocytoma Ben	ign							
		4/50 (8%)	5/50 (10%)	7/49 (14%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		9/50 (18%)	5/50 (10%)	12/50 (24%)		3/50 (6%)	0/50 (0%)	0/49 (0%)
			8/50 (16%)	10/88 (11%)		1/50 (2%)		1/86 (1%)
		10/50 (20%)				1/50 (2%)		
Overall Incidence	Total	70/487 (14.37%)	Mean 14.63%	SD 5.33%	Total	7/485 (1.44%)	Mean 1.46%	SD 1.94%
Adrenal Medulla: Pheochromocytoma Con	nplex							
-	•	0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/88 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/86 (0%)
			0/00 (0%)	1/00 (170)		0/00 (0%)		0/00 (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

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Malig	nant							
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		3/50 (6%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	1/88 (1%)		0/50 (0%)		0/86 (0%)
		2/50 (4%)				1/50 (2%)		
Overall Incidence	Total	12/487 (2.46%)	Mean 2.58%	SD 2.05%	Total	3/485 (0.62%)	Mean 0.67%	SD 1.41%
Adrenal Medulla:								
Pheochromocytoma: Benig	gn, Complex	د, Malignant, NOS						
-		5/50 (10%)	6/50 (12%)	8/49 (16%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		12/50 (24%)	8/50 (16%)	14/50 (28%)		5/50 (10%)	0/50 (0%)	0/49 (0%)
			8/50 (16%)	11/88 (13%)		1/50 (2%)		1/86 (1%)
		12/50 (24%)				2/50 (4%)		
Overall Incidence	Total	84/487 (17.25%)	Mean 17.65%	SD 6.24%	Total	10/485 (2.06%)	Mean 2.13%	SD 3.25%
#Bone: Osteosarcoma								
		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%)	0/90 (0%)		1/50 (2%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
#Bone:								
Osteosarcoma or Osteoma	-		0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Osteosarcoma or Osteoma		0/50 (0%)						
Osteosarcoma or Osteoma		0/50 (0%) 0/50 (0%)	()	()		0/50 (0%)	0/50 (0%)	()
Osteosarcoma or Osteoma		()	0/50 (0%)	0/50 (0%)		()	()	0/50 (0%)
Osteosarcoma or Osteoma		()	()	()		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

Page: 10 Report Date: 02/17/2020

			Male				Female	
*Brain: Glioma Malignant								
		4/50 (8%)	0/50 (0%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)		2/50 (4%)		0/50 (0%)		1/50 (2%)
			1/50 (2%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	11/439 (2.51%)	Mean 2.76%	SD 2.82%	Total	2/440 (0.45%)	Mean 0.5%	SD 0.93%
Brain: Granular Cell Tumor Ben	ign							
	-	3/50 (6%)	0/50 (0%)	0/49 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)		0/50 (0%)		1/50 (2%)		0/50 (0%)
			2/50 (4%)	1/90 (1%)		0/50 (0%)		1/90 (1%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	8/439 (1.82%)	Mean 1.89%	SD 2.41%	Total	5/440 (1.14%)	Mean 1.14%	SD 1.46%
'Brain: Granular Cell Tumor Mal								
		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%)		0/90 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/439 (0.23%)	Mean 0.25%	SD 0.71%	Total	0/440 (0%)	Mean 0%	SD 0%
'Brain: Meningioma Benign								
		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
		1/439 (0.23%)		SD 0.72%				

*: 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		
Brain: Meningioma Malignant														
		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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
			(0%)						0/50	(0%)				
Overall Incidence	Total	0/439 (0%)		Mean		SD 0%		Total	1/440 (0.	,		0.25%	SD 0.	71%
Brain:														
Meningioma: Benign, Mal	gnant, NOS													
			(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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
			(0%)						0/50	(0%)				
Overall Incidence	Total	1/439 (0.23%	,	Mean 0		SD 0.72%		Total	1/440 (0.	,		0.25%	SD 0.	71%
Brain: Oligodendroglioma, Glion	na, or Astroc	ytoma												
		4/50	(8%)	0/50	(0%)	2/49	(4%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)			2/50	(4%)		0/50	(0%)			1/50	(2%)
				1/50	(2%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		2/50	(4%)						0/50	(0%)				
Overall Incidence	Total	11/439 (2.51%		Mean 2		SD 2.82%		Total	2/440 (0.	,		0.5%	SD 0.	93%
Brain:														
Schwannoma Malignant														
-		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%)
				1/50	(2%)	0/90	(0%)		0/50	(0%)			0/90	(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

Page: 12 Report Date: 02/17/2020

				Male						F	emale		
Clitoral/Preputial Gland: Adenoma													
		0/49 (04	%) 0/50	(0%)	1/49	(2%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		0/49 (04	%) 0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/88	(0%)			(0%)			0/87	(0%)
		0/50 (09	,						(0%)				
verall Incidence	Total	1/485 (0.21%)	Mean	0.23%	SD 0.689	%	Total	0/483 (0%	6)	Mea	n 0%	SD	0%
Clitoral/Preputial Gland: Carcinoma													
		1/49 (29	%) 0/50		0/49	(0%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		1/49 (29	%) 0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/88	(0%)		1/50	(2%)			0/87	(0%)
		0/50 (04	%)					0/50	(0%)				
Verall Incidence	Total	2/485 (0.41%)		0.45%	SD 0.9%	6	Total	1/483 (0.21	%)	Mean	0.22%	SD 0.	67%
Clitoral/Preputial Gland: Carcinoma or Adenoma													
		1/49 (29	%) 0/50	(0%)	1/49	(2%)		0/49	(0%)	0/50	(0%)	0/49	(0%)
		1/49 (29	%) 0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/88	(0%)		1/50	(2%)			0/87	(0%)
		0/50 (04	%)					0/50	(0%)				
Verall Incidence	Total	3/485 (0.62%)	Mean	0.68%	SD 1.029	%	Total	1/483 (0.21	%)	Mean	0.22%	SD 0.	67%
Clitoral/Preputial Gland: Squamous Cell Carcinoma													
		0/49 (04	,	· · ·	1/49	(2%)			(0%)	0/50	(0%)	0/49	(0%)
		0/49 (04	%) 0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	0/88	(0%)		0/50	(0%)			0/87	(0%)
		0/50 (04	%)					0/50	(0%)				
Overall Incidence	Total	1/485 (0.21%)	Mean	0.23%	SD 0.689	%	Total	0/483 (0%	6)	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

					Male						F	emale		
Clitoral/Preputial Gland: Squamous Cell Papilloma							·							,
		0/49	(0%)	1/50	(2%)	0/49	(0%)		1/49	(2%)	0/50	(0%)	0/49	(0%)
		0/49	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(00/)	0/50	(0%)	0/88	(0%)		0/50	(0%)			0/87	(0%)
warall Incidence	Total	0/50	(0%)	Maan 0	220/)/	Total	0/50	(0%)	Maan	0.000/	CD 0	600/
verall Incidence	Total	1/485 (0.21		Mean 0	.22%	SD 0.679	/o	Total	1/483 (0.	ZI%)	wean	0.23%	SD 0.	00%
Epididymis: Sarcoma														
		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%)											
Overall Incidence	Total	1/488 (0.2	,	Mean 0		SD 0.679								
Eye: Leiomyoma														
		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%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/489 (0.29		Mean 0		SD 0.679		Total	0/490 (,		ın 0%	SD (- / -
Heart: Schwannoma Malignant														
-		3/50	(6%)	2/50	(4%)	2/49	(4%)		1/50	(2%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)	1/50	(2%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						2/50	(4%)				
Overall Incidence	Total	9/489 (1.84	%)	Mean 2	.01%	SD 2.259	%	Total	3/488 (0.	61%)	Mean	0.67%	SD 1.	41%

*: 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: 14 Report Date: 02/17/2020

			Male				Female	
Intestine Large: Colon/Re Granular Cell Tumor Ben								
	-	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%)		0/50 (0%) 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%)		
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
#Intestine Large: Colon/Re Leiomyoma								
-		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%)
		0/50 (0%)	0/50 (0%)	0/90 (0%)		0/50 (0%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	2/50 (4%)	0/49 (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%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		1/50 (2%)	1/30 (2%)	2/90 (270)		1/50 (2%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	8/489 (1.64%)	Mean 1.58%	SD 1.34%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
fIntestine Small: Jejunum: Leiomyosarcoma								
,		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%)
		0/50 (0%)	0/50 (0%)	0/90 (0%)		0/50 (0%) 0/50 (0%)		1/90 (1%)
		0/50 (0%)				0/30 (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		
Intestine Small: Site Un Carcinoma	specified:													
		1/50	(2%)	2/50	(4%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)	0/50 1/50	(0%) (2%)	0/50 2/90	(0%) (2%)		0/50 1/50	(0%) (2%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		1/50	(2%)						0/50	(0%)				()
verall Incidence	Total	8/489 (1.64	l%)	Mean 1	.58%	SD 1.349	%	Total	1/490 (0	· · /	Mean	0.22%	SD 0.	.67%
Intestine Small: Site Un Carcinoma or Adenom	•													
		1/50	(2%)	2/50	(4%)	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%)
				1/50	(2%)	2/90	(2%)		1/50	(2%)			0/90	(0%)
		1/50	(2%)						0/50	(0%)				
verall Incidence	Total	8/489 (1.64	,	Mean 1		SD 1.349		Total	1/490 (0	,		0.22%	SD 0.	.67%
ntestine Small: Site Un Leiomyosarcoma														
		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%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			1/90	(1%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	1/489 (0.2	,	Mean (SD 0.679		Total	1/490 (0	,		0.12%	SD 0.	
slets, Pancreatic: Adenoma														
		3/49	(6%)	2/50	(4%)	4/49	(8%)		1/50	(2%)	3/49	(6%)	1/50	(2%)
		3/50	(6%)	2/50	(4%)	8/50	(16%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
				5/50	(10%)	5/90	(6%)		1/50	(2%)			5/90	(6%)
		2/50	(4%)						1/50	(2%)				
Overall Incidence	Total	34/488 (6.9	7%)	Mean 7	0.09%	SD 3.91	%	Total	13/489 (2	.66%)	Mean	2.41%	SD 2.	13%

*: 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		
Islets, Pancreatic: Carcinoma														
		0/49	(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%)		1/50	(2%)	0/50	(0%)	1/50	(2%)
				0/50	(0%)	8/90	(9%)		0/50	(0%)			2/90	(2%)
			(2%)						1/50	(2%)				
verall Incidence	Total	9/488 (1.84%		Mean 1	.21%	SD 2.95		Total	5/489 (1.	02%)	Mean	0.91%	SD 1.	09%
slets, Pancreatic: Carcinoma or Adenoma														
		3/49	(6%)	2/50	(4%)	4/49	(8%)		1/50	(2%)	3/49	(6%)	1/50	(2%)
		3/50	(6%)	2/50	(4%)	8/50	(16%)		1/50	(2%)	0/50	(0%)	2/50	(4%)
				5/50	(10%)	13/90	(14%)		1/50	(2%)			7/90	(8%)
			(6%)						2/50	(4%)				
verall Incidence	Total	43/488 (8.81%		Mean 8		SD 4.36		Total	18/489 (3	,		3.32%	SD 2.	41%
Kidney: Pelvis and Transiti Papilloma														
			(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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
			(0%)						0/50	(0%)				
verall Incidence	Total	1/489 (0.2%)	,	Mean 0		SD 0.67		Total	0/490 (,		in 0%	SD (
Kidney: Renal Tubule: Adenoma														
			(0%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
				1/50	(2%)	3/90	(3%)		0/50	(0%)			1/90	(1%)
			(4%)						0/50	(0%)				
verall Incidence	Total	9/489 (1.84%	1	Mean 1	710/	SD 1.46	2/2	Total	2/490 (0.	110()	Mean	0.35%	SD 0.	72%

*: 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: 17 Report Date: 02/17/2020

			Male				Female	
Kidney: Renal Tubule: Carcinoma								
		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%)		1/90 (1%)
Overall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (40/)	1/50 (2%)	3/90 (3%)		0/50 (0%)		2/90 (2%)
Overall Incidence	Total	2/50 (4%) 9/489 (1.84%)	Mean 1.71%	SD 1.46%	Total	0/50 (0%) 3/490 (0.61%)	Mean 0.47%	SD 0.93%
		()		3D 1.40%	TOLAI	5/490 (0.01%)		50 0.93%
Kidney: Renal Tubule: Lipoma								
		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 (00/)	0/50 (0%)	1/90 (1%)		0/50 (0%)		0/90 (0%)
Verall Incidence	Total	0/50 (0%) 1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	0/50 (0%) 0/490 (0%)	Mean 0%	SD 0%
		()				()		
Kidney: Renal Tubule: Liposarcoma								
-		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (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: 18 Report Date: 02/17/2020

			Male				Female	
Kidney: Renal Tubule: Nephroblastoma								
		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
(idney: Renal Tubule: Oncocytoma Benign								
		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%)	1/90 (1%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/489 (0.2%)	Mean 0.12%	SD 0.37%	Total	0/490 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Polyp Adenomatous								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
Lacrimal Gland: Carcinoma								
		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%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)	0/00 (0/0)	0/00 (0/0)		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

					Male						F	emale		
Liver: Cholangiocarcinoma														
		0/50 0/50	(0%) (0%)	0/50 0/50 1/50	(0%) (0%) (2%)	0/49 0/50 0/90	(0%) (0%) (0%)		0/50 0/50 0/50	(0%) (0%) (0%)	0/49 0/50	(0%) (0%)	0/50 0/50 0/90	(0%) (0%) (0%)
		0/50	(0%)	1/50	(2%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
overall Incidence	Total	1/489 (0.2%	,	Mean 0	.22%	SD 0.679	%	Total	0/489 (0%)	Mea	in 0%	SD	0%
Liver: Cholangioma														
-		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)		1/50 0/50	(2%) (0%)	1/49 0/50	(2%) (0%)	0/50 0/50	(0%) (0%)
		0/30	(070)	0/50	(0%) (0%)	0/90	(0%)		1/50	(0%)	0/50	(0 %)	0/90	(0%)
		1/50	(2%)						0/50	(0%)				
Verall Incidence	Total	1/489 (0.2%	,	Mean 0		SD 0.679		Total	3/489 (0.	,		0.67%	SD 1.	01%
Liver: Hemangioma														
		1/50	(2%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50 0/50	(0%) (0%)	0/50 0/90	(0%) (0%)		0/50 0/50	(0%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		0/50	(0%)	0/50	(0%)	0/90	(0%)		0/50	(0%) (0%)			0/90	(0%)
verall Incidence	Total	1/489 (0.2%))	Mean 0		SD 0.679		Total	0/489 (0%)		in 0%	SD	- / -
Liver: Hepatocellular Adenoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	1/49	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	2/50	(4%)
			(00()	0/50	(0%)	0/90	(0%)		2/50	(4%)			7/90	(8%)
	Total	1/50	(2%)	Meer 0	4.40/		<i></i>	Tatal	1/50	(2%)	Marr	0.650/	CD 0	E00/
Overall Incidence	Total	2/489 (0.41%	,	Mean 0	.44%	SD 0.889	7o	Total	15/489 (3	.07%)	iviean	2.65%	SD 2.	59%

*: 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		
Liver: Hepatocellular Carcino	oma													
		0/50	(0%)	1/50	(2%)	1/49	(2%)		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%)		1/50	(2%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	2/489 (0.419	,	Mean 0		SD 0.899		Total	1/489 (0	,		0.22%	SD 0.	67%
.iver:														
Hepatocellular Carcino	oma or Hepatobl	astoma												
•		0/50	(0%)	1/50	(2%)	1/49	(2%)		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%)		1/50	(2%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	2/489 (0.419	,	Mean 0		SD 0.899		Total	1/489 (0	,		0.22%	SD 0.	67%
Liver: Hepatocellular Carcino														
		0/50	(0%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	1/49	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	2/50	(4%)
		0,00	(0,0)	0/50	(0%)	0/90	(0%)		3/50	(6%)	2,00	(170)	7/90	(8%)
		1/50	(2%)	0,00	(0,0)	0,00	(0,0)		1/50	(2%)			.,	(0,0)
Verall Incidence	Total	4/489 (0.829	%)	Mean 0		SD 1.069		Total	16/489 (3	.27%)		2.87%	SD 2	.8%
Liver:														
Hepatocellular Carcino	ma. Hepatocelli	ular Adenoma, o	r Hepatok	lastoma										
	, riopatobolit	0/50	(0%)	1/50	(2%)	1/49	(2%)		0/50	(0%)	1/49	(2%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	2/50	(4%)	2/50	(4%)
		0,00	(0,0)	0/50	(0%)	0/90	(0%)		3/50	(6%)	_,	(. , .,	7/90	(8%)
		1/50	(2%)	0,00	(0,0)	0,00	(0,0)		1/50	(2%)			.,	(0,0)
			(-·-/							()				

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2019 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: 02/17/2020

					Male						F	emale		
Lung:														
Alveolar/Bronchiolar A	Adenoma													
		0/50	(0%)	0/50	(0%)	1/49	(2%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	1/50	(2%)	0/50	(0%)
				0/50	(0%)	1/90	(1%)		0/50	(0%)			0/90	(0%)
		1/50	(2%)						0/50	(0%)				
verall Incidence	Total	3/488 (0.61	%)	Mean 0	.57%	SD 0.9%)	Total	1/488 (0	.2%)	Mean	0.22%	SD 0.	67%
Lung: Alveolar/Bronchiolar (arcinoma													
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50	(2%)	0/49	(0%)	0/50	(0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		.,	(= /0)	0/50	(0%)	0/90	(0%)		0/50	(0%)	0,00	(0,0)	0/90	(0%)
		1/50	(2%)	0/00	(070)	0/00	(070)		0/50	(0%)			0/00	(070)
Overall Incidence	Total	2/488 (0.41	. ,	Mean 0	44%	SD 0.889	6	Total	0/488 (· · /	Mea	n 0%	SD (0%
			,						·····	· · · · · · · · · · · · · · · · · · ·				
Lung:														
Alveolar/Bronchiolar (Carcinoma or Alv													
		0/50	(0%)	0/50	(0%)	1/49	(2%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		1/50			(0%)							· · ·		
		1/50	(2%)	0/49	· · ·	0/50	(0%)		0/49	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)	0/49 0/50	(0%)	0/50 1/90	(0%) (1%)		0/49 0/50	(0%) (0%)	1/50	(2%)		(0%) (0%)
		2/50	(2%) (4%)		· · ·		()			· · ·	1/50	(2%)	0/50	. ,
verall Incidence	Total		(4%)		(0%)		(1%)	Total	0/50	(0%) (0%)		(2%) 0.22%	0/50	(0%)
	Total	2/50	(4%)	0/50	(0%)	1/90	(1%)	Total	0/50 0/50	(0%) (0%)		()	0/50 0/90	(0%)
Lung:	Total	2/50	(4%)	0/50	(0%)	1/90	(1%)	Total	0/50 0/50	(0%) (0%)		()	0/50 0/90	(0%)
	Total	2/50 5/488 (1.02	(4%) 2%)	0/50 Mean 1	(0%) .02%	1/90 SD 1.429	(1%) %	Total	0/50 0/50 1/488 (0	(0%) (0%) .2%)	Mean	0.22%	0/50 0/90 SD 0.	(0%) 67%
Lung:	Total	2/50 5/488 (1.02	(4%) 2%) 	0/50 Mean 1 0/50	(0%) .02% 	1/90 SD 1.429 0/49	(1%) % (0%)	Total	0/50 0/50 1/488 (0 0/50	(0%) (0%) .2%) (0%)	Mean 0/49	0.22%	0/50 0/90 SD 0. 0/50	(0%) 67%
Lung:	Total	2/50 5/488 (1.02	(4%) 2%)	0/50 Mean 1 0/50 0/49	(0%) .02% 	1/90 SD 1.429 0/49 0/50	(1%) 6 (0%) (0%)	Total	0/50 0/50 1/488 (0 0/50 0/49	(0%) (0%) .2%) (0%) (0%)	Mean	0.22%	0/50 0/90 SD 0. 0/50 0/50	(0%) 67%
Lung:	Total	2/50 5/488 (1.02 0/50 0/50	(4%) 2%) (0%) (0%)	0/50 Mean 1 0/50	(0%) .02% 	1/90 SD 1.429 0/49	(1%) % (0%)	Total	0/50 0/50 1/488 (0 0/50 0/49 0/50	(0%) (0%) .2%) (0%) (0%) (0%)	Mean 0/49	0.22%	0/50 0/90 SD 0. 0/50	(0%) 67%
Dverall Incidence Lung: Sarcoma Dverall Incidence	Total	2/50 5/488 (1.02	(4%) 2%) (0%) (0%) (0%)	0/50 Mean 1 0/50 0/49	(0%) .02% (0%) (0%) (0%)	1/90 SD 1.429 0/49 0/50	(1%) 6 (0%) (0%)	Total	0/50 0/50 1/488 (0 0/50 0/49	(0%) (0%) .2%) (0%) (0%) (0%) (0%)	Mean 0/49 1/50	0.22%	0/50 0/90 SD 0. 0/50 0/50	(0%) 67% (0%) (0%) (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: 22 Report Date: 02/17/2020

			Male				Female	
*Lung: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (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%)	1/50 (2%)	0/90 (0%)		0/50 (0%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	1/488 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/488 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
		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%) 0/90 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)	0/30 (078)	0/90 (078)		0/50 (0%)		0/90 (078)
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma								
		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 (00/)	0/50 (0%)	0/90 (0%)		0/50 (0%) 0/50 (0%)		0/90 (0%)
Verall Incidence	Total	0/50 (0%) 0/489 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/490 (0.2%)	Mean 0.22%	SD 0.67%
		· · /				· · · ·		
Mammary Gland: Adenoma								
		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%)	3/50 (6%)	4/50 (8%)
		0/50 (00/)	0/50 (0%)	0/90 (0%)		1/50 (2%)		8/90 (9%)
Warall Incidence	Total	0/50 (0%)	Maan 00/	SD 00/	Tatal	3/50 (6%)	Moon 2 650/	CD 2 500/
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	20/490 (4.08%)	Mean 3.65%	SD 3.59%

*: 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		
Mammary Gland: Carcinoma														
		0/50	(0%)	1/50	(2%)	0/49	(0%)		8/50 (16%)	1/50	(2%)	4/50	(8%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		7/50 (14%)	3/50	(6%)	5/50	(10%)
				0/50	(0%)	0/90	(0%)			(6%)			10/90	(11%)
		0/50	(0%)							(4%)				
verall Incidence	Total	3/489 (0.61	,	Mean 0		SD 1.419		Total	43/490 (8.7	,		8.57%	SD 4	
Mammary Gland: Carcinoma or Adenoma														
		0/50	(0%)	1/50	(2%)	0/49	(0%)		8/50 (16%)	2/50	(4%)	4/50	(8%)
		2/50	(4%)	0/50	(0%)	0/50	(0%)		7/50 (14%)	6/50	(12%)	9/50	(18%)
				0/50	(0%)	0/90	(0%)			(8%)			16/90	(18%)
		0/50	(0%)						5/50 (10%)				
verall Incidence	Total	3/489 (0.61	,	Mean 0		SD 1.419		Total	61/490 (12.4	,		11.98%	SD 4	
Mammary Gland: Fibroadenoma														
		0/50	(0%)	2/50	(4%)	1/49	(2%)		25/50 (50%)	28/50	(56%)	33/50	(66%)
		2/50	(4%)	1/50	(2%)	2/50	(4%)		32/50 (64%)	29/50	(58%)	20/50	(40%)
				2/50	(4%)	2/90	(2%)		,	42%)			63/90	(70%)
		0/50	(0%)						30/50 (60%)				
verall Incidence	Total	12/489 (2.4	,	Mean 2		SD 1.669		Total	281/490 (57.	,		56.22%	SD 10	
Mammary Gland: Fibroma, Fibroadenoma or														
,		0/50	(0%)	2/50	(4%)	1/49	(2%)		25/50 (50%)	29/50	(58%)	33/50	(66%)
		2/50	(4%)	1/50	(2%)	2/50	(4%)		```	64%)	30/50	(60%)	23/50	(46%)
			. ,	2/50	(4%)	2/90	(2%)		22/50 (44%)		. ,	64/90	(71%)
		0/50	(0%)		· · /		. ,		32/50 (64%)				. ,
Overall Incidence	Total	12/489 (2.4	5%)	Mean 2	47%	SD 1.669	6	Total	290/490 (59.	18%)	Mean	58.12%	SD 9	.46%

*: 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	
#Mammary Gland: Fibroma, Fibroadenom	a. Carcinoma. o	r Adenoma						
,		0/50 (0%)	3/50 (6%)	1/49 (2%)		29/50 (58%)	30/50 (60%)	35/50 (70%)
		3/50 (6%)	1/50 (2%)	2/50 (4%)		36/50 (72%)	32/50 (64%)	27/50 (54%)
			2/50 (4%)	2/90 (2%)		25/50 (50%)	· · · · ·	66/90 (73%)
		0/50 (0%)	(),			34/50 (68%)		, , , , , , , , , , , , , , , , , , ,
Overall Incidence	Total	14/489 (2.86%)	Mean 2.92%	SD 2.25%	Total	314/490 (64.08%)	Mean 63.26%	SD 8.26%
#Mammary Gland: Myoepithelioma								
		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
*Nose: Carcinoma								
		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%)	0/49 (0%)	0/50 (0%)
			0/50 (0%)	0/89 (0%)		1/50 (2%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/488 (0%)	Mean 0%	SD 0%	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%
Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Pha							
		0/50 (0%)	0/50 (0%)	1/49 (2%)		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%)		2/90 (2%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	2/489 (0.41%)	Mean 0.45%	SD 0.89%	Total	2/490 (0.41%)	Mean 0.25%	SD 0.74%

*: 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		
Oral Cavity (Oral Mucosa, 1 Squamous Cell Carcinoma														
·	· •	0/50	(0%)	0/50	(0%)	1/49	(2%)		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%)			2/90	(2%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	2/489 (0.4		Mean 0	.45%	SD 0.89%	6	Total	2/490 (0	.41%)	Mean	0.25%	SD 0.	.74%
Oral Mucosa: Squamous Cell Carcinoma														
-		0/50	(0%)	0/50	(0%)	1/49	(2%)		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%)			1/90	(1%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	2/489 (0.4	1%)	Mean 0	.45%	SD 0.89%	6	Total	1/490 (0	0.2%)	Mean	0.12%	SD 0.	.37%
Ovary: Cystadenoma														
									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%)				
Overall Incidence								Total	1/490 (0	,		0.12%	SD 0.	.37%
Ovary: Granulosa Cell Tumor Ber														
	-								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%)				
Overall Incidence								Total	7/490 (1	()	Maaa	1.46%	SD 1.	0.40/

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2019 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 Da	te: 02/17/2020
	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
		0/50 (0%) 1/5 0/50 (0%) 0/5 0/50 (0%) 1/50 (2%)	()	0/50 (0%) 0/50 (0%) 2/90 (2%)
Overall Incidence	Total	· · · ·	ean 0.69%	SD 1.04%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		1/50 (2%) 2/5 0/50 (0%) 0/5 1/50 (2%) 1/50 (2%)	()	0/50 (0%) 3/50 (6%) 3/90 (3%)
Overall Incidence	Total	11/490 (2.24%) M	ean 2.15%	SD 2.05%
*Ovary: Granulosa-Theca Tumor Benign				
		0/50 (0%) 0/5 0/50 (0%) 1/5 0/50 (0%) 0/50 (0%)	()	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	. ,	ean 0.22%	SD 0.67%
*Ovary: Granulosa-Theca Tumor Malignant				
		0/50 (0%) 0/5 0/50 (0%) 0/5 0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total		ean 0.22%	SD 0.67%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2019 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: 02/17/2020					
	Male		Female					
*Ovary: Luteoma		1/50 (2%) 0/5 0/50 (0%) 0/5		0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/490 (0.2%) M	lean 0.22%	0/90 (0%) SD 0.67%				
			50 (0%)					
Overall Incidence	Total		lean 0.22%	SD 0.67%				
'Ovary: Sertoli Cell Tumor Benign		0/50 (0%) 0/5 0/50 (0%) 0/5 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/90 (1%)				
Overall Incidence	Total	1/490 (0.2%) M	lean 0.12%	SD 0.37%				
*Ovary: Thecoma Benign		0/50 (0%) 0/5 0/50 (0%) 0/5 0/50 (0%) 0/50 (0%)	()	0/50 (0%) 1/50 (2%) 0/90 (0%)				
Overall Incidence	Total	1/490 (0.2%) M	lean 0.22%	SD 0.67%				

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2019 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC			Tumor Incider	ogy Data Management nce for Selected Control A Route: ALL ROUTES Vehicle: ALL VEHICLES	nimal Groups		Page: 28 Report Da	te: 02/17/2020
			Male				Female	
*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%)
Overall Incidence					Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
*Pancreas: Adenoma								
		1/49 (2%) 5/50 (10%)	10/50 (20%) 5/50 (10%) 3/50 (6%)	4/49 (8%) 0/50 (0%) 18/90 (20%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	14/50 (28%) 60/488 (12.3%)	Mean 11.58%	SD 9.25%	Total	0/50 (0%) 0/489 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
		0/49 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	2/49 (4%) 0/50 (0%) 1/90 (1%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	4/488 (0.82%)	Mean 0.8%	SD 1.42%	Total	0/489 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		1/49 (2%) 5/50 (10%) 14/50 (28%)	10/50 (20%) 5/50 (10%) 3/50 (6%)	6/49 (12%) 0/50 (0%) 18/90 (20%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	62/488 (12.7%)	Mean 12.03%	SD 9.16%	Total	0/489 (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: 29 Report Date: 02/17/2020

					Male						F	emale		
Parathyroid Gland: Adenoma														
		0/43	(0%)	0/42	(0%)	0/48	(0%)		0/42	(0%)	0/42	(0%)	0/45	(0%)
		0/49	(0%)	0/43	(0%)	0/48	(0%)		1/41	(2%)	0/47	(0%)	0/45	(0%)
				0/41	(0%)	1/83	(1%)		0/47	(0%)			0/87	(0%)
		0/43	(0%)						0/46	(0%)				
verall Incidence	Total	1/440 (0.23		Mean 0		SD 0.4%		Total	1/442 (0.	,		0.27%	SD 0.	.81%
Peripheral Nerve: Paraganglioma														
		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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/489 (0.29	,	Mean 0		SD 0.689		Total	0/490 (,		n 0%	SD	
Peripheral Nerve: Schwannoma Malignant														
		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%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	1/489 (0.29	,	Mean 0		SD 0.689		Total	0/490 (,		n 0%	SD	0%
Peripheral Nerve: Schwannoma: Benign, Mal														
Contraintential Donight, mai	ignail, itoo	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%)	0/90	(0%)		0/50	(0%)		()	0/90	(0%)
		0/50	(0%)	0,00	(0,0)	0,00	(0,0)		0/50	(0%)			0,00	(0,0)
Overall Incidence	Total	1/489 (0.29	· · ·	Mean 0	220/	SD 0.689	<i>.</i>	Total	0/490 (· · /	Maa	n 0%	SD	00/

*: 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		
Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 3/50 (6%) 4/50 (8%) 15/48 (31%) 13/49 (27%) 15/49 (31%) 12/50 (24%)														
		3/50	(6%)	4/50	(8%)	15/48	(31%)		13/49	(27%)	15/49	(31%)	12/50	(24%)
		14/50 (2	28%)	5/50	(10%)	11/50	(22%)		19/50	(38%)	18/50	(36%)	18/50	(36%)
				5/50	(10%)	17/89	(19%)		22/50	(44%)			43/90	(48%)
		8/50 (*	16%)						16/50	(32%)				
Overall Incidence	Total	82/487 (16.849	,	Mean 16		SD 9.049		Total	176/488 (3	,		34.99%	SD 7	
Pituitary Gland: Pars Dis Carcinoma														
		0/50	(0%)	0/50	(0%)	0/48	(0%)		0/49	(0%)	1/49	(2%)	1/50	(2%)
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/89	(0%)		0/50	(0%)			1/90	(1%)
		1/50	(2%)						1/50	(2%)				
Overall Incidence	Total	1/487 (0.21%	,	Mean 0		SD 0.679		Total	4/488 (0	,		0.79%	SD 0	
Pituitary Gland: Pars Dis Carcinoma or Adenoma	stalis or Unspec													
		3/50	(6%)	4/50	(8%)	15/48	(31%)		13/49	(27%)	16/49	(33%)	13/50	(26%)
		14/50 (2	28%)	5/50	(10%)	11/50	(22%)		19/50	(38%)	18/50	(36%)	18/50	(36%)
		14/50 (.	20/0)	5/50	(10,0)	11/00	(22/0)							
		14/30 (.	2070)	5/50	(10%)		(19%)		22/50	(44%)	10,00		44/90	(49%)
		,	18%)		· · ·		· · ·			(44%) (34%)			44/90	(49%)
	Total	9/50 (1 83/487 (17.049	, 18%) %)	5/50 Mean 16	(10%) 6.93%	17/89 SD 9.049	(19%) %	Total	22/50 17/50 180/488 (3	(34%) 6.89%)	Mean	35.79%	44/90 SD 7	()
Overall Incidence 'Pituitary Gland: Pars Int Adenoma		9/50 (1 83/487 (17.049	, 18%) %)	5/50 Mean 16	(10%) 6.93%	17/89 SD 9.049	(19%) %		22/50 17/50 180/488 (3	(34%) 6.89%)	Mean	35.79%		()
Pituitary Gland: Pars Int		9/50 (* 83/487 (17.049	, 18%) %)	5/50 Mean 16	(10%) 5.93% (0%)	17/89 SD 9.049	(19%) % 		22/50 17/50 180/488 (3	(34%) 6.89%)	Mean	35.79%		(0%)
Pituitary Gland: Pars Int		9/50 (* 83/487 (17.049 1/50	18%) %)	5/50 Mean 16	(10%) 5.93%	17/89 SD 9.049	(19%) %		22/50 17/50 180/488 (3	(34%) 66.89%) 	Mean		SD 7 0/50 0/50	(0%) (0%)
Pituitary Gland: Pars Int		9/50 (* 83/487 (17.045 1/50 2/50	18%) %) (2%) (4%)	5/50 Mean 16 	(10%) 5.93% (0%)	17/89 SD 9.049 0/48	(19%) % 		22/50 17/50 180/488 (3 0/49 0/50 0/50	(34%) 66.89%) (0%) (0%) (0%)	Mean 0/49	(0%)	SD 7	(0%)
Pituitary Gland: Pars Int		9/50 (* 83/487 (17.045 1/50 2/50	(2%)	5/50 Mean 16 0/50 0/50	(10%) 5.93% (0%) (0%)	17/89 SD 9.049 0/48 0/50	(19%) % (0%) (0%)		22/50 17/50 180/488 (3 0/49 0/50	(34%) 66.89%) 	Mean 0/49	(0%)	SD 7 0/50 0/50	(0%) (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: 31 Report Date: 02/17/2020

					Male					Female	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:										
		1/50 ((2%)	0/50	(0%)	0/48	(0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		2/50 ((4%)	0/50	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
				0/50	(0%)	0/89	(0%)		0/50 (0%)		0/90 (0%)
		1/50 ((2%)						0/50 (0%)		
Overall Incidence	Total	4/487 (0.82%))	Mean 0.	89%	SD 1.459	%	Total	0/488 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Nervo Schwannoma Malignant											
		0/50 ((0%)	0/50	(0%)	0/48	(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%)	0/89	(0%)		0/50 (0%)		0/90 (0%)
		1/50 ((2%)						0/50 (0%)		
Overall Incidence	Total	1/487 (0.21%))	Mean 0.	22%	SD 0.679	%	Total	0/488 (0%)	Mean 0%	SD 0%
Prostate: Adenoma											
		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%)								
Overall Incidence	Total	7/489 (1.43%))	Mean 1.	36%	SD 2.019	%				
Prostate: Carcinoma or Adenoma											
		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%)								
Overall Incidence	Total	7/489 (1.43%)	`	Mean 1.	260/	SD 2.019	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	
Salivary Glands: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%)		0/49 (0%) 0/49 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/90 (0%)
		0/50 (0%)	0/49 (0/0)	0/30 (078)		0/49 (078) 0/50 (0%)		0/90 (078)
verall Incidence	Total	3/488 (0.61%)	Mean 0.67%	SD 1.41%	Total	0/485 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/49 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		4/50 (00()	0/50 (0%)	0/90 (0%)				
warell in siden as	Tatal	1/50 (2%)	Maan 0.000/					
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%				
Skeletal Muscle: Hemangioma								
		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%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
verall Incidence	Total	0/50 (0%) 0/489 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/490 (0.2%)	Mean 0.22%	SD 0.67%
		()				, ,		
Skeletal Muscle: Liposarcoma								
		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 /00/	0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
Duranall In airdan an	Tatal	0/50 (0%)	Maga, 00/	CD 00/	Tatal	0/50 (0%)	Maan 0.000/	CD 0.070/
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

*: 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		
/Skeletal Muscle: Sarcoma														
		0/50	(0%)	1/50	(2%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50 0/50	(0%) (0%)	0/50 0/90	(0%) (0%)		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50 0/90	(0%) (0%)
		0/50	(0%)		()		、 ,		0/50	(0%)				· · /
overall Incidence	Total	1/489 (0.2	,	Mean 0	.22%	SD 0.679	6	Total	1/490 (0	.2%)	Mean	0.22%	SD 0.	67%
Skin: Basal Cell Adenoma														
		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%)
				1/50	(2%)	1/90	(1%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
overall Incidence	Total	3/489 (0.61	,	Mean 0	.57%	SD 0.9%	, D	Total	0/490 (0%)	Mea	in 0%	SD	0%
Skin: Basal Cell Adenoma or														
	•	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%)
				1/50	(2%)	1/90	(1%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)		. ,		. ,		0/50	(0%)				. ,
Verall Incidence	Total	3/489 (0.61	,	Mean 0		SD 0.9%		Total	0/490 (,		ın 0%	SD	- / -
∕Skin:														
Basal Cell Adenoma, Ba	asosquamous T	•		•	()		()			()		(··		()
		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%)	0/50	(0%)	0/50	(0%)
				1/50	(2%)	1/90	(1%)		0/50	(0%)			0/90	(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

					Male						F	emale		
Skin: Basal Cell Carcinoma														
		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%)	1/50	(2%)
			()	0/50	(0%)	0/90	(0%)		0/50	(0%)		()	0/90	(0%)
		0/50	(0%)		· · /		、		0/50	(0%)				()
verall Incidence	Total	1/489 (0.29	,	Mean 0		SD 0.679		Total	1/490 (0	,		0.22%	SD 0	
ikin:														
Basal Cell Carcinoma d	or Basosquamou	us Tumor (malig	gnant or N	IOS)										
	-	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%)	1/50	(2%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
		0/00												
	Total	1/489 (0.2	%)	Mean 0		SD 0.679		Total	1/490 (0	,		0.22%	SD 0	
	Basal Cell Aden	1/489 (0.2	%)						•	,				
Skin: Basal Cell Carcinoma,	Basal Cell Aden	1/489 (0.2 oma, Basosqua 0/50	%) amous Tur (0%)	m or (benign 1/50	, malignai (2%)	nt or 1/49	(2%)		`.	(0%)	0/50	(0%)	0/50	(0%)
Skin: Basal Cell Carcinoma,	Basal Cell Aden	1/489 (0.2 oma, Basosqua	%) amous Tui	m or (benign 1/50 1/50	, maligna (2%) (2%)	nt or 1/49 0/50	(2%) (0%)		0/50 0/50	(0%) (0%)			0/50 1/50	(0%) (2%)
Skin: Basal Cell Carcinoma,	Basal Cell Aden	1/489 (0.2 oma, Basosqua 0/50 0/50	%) amous Tur (0%) (0%)	m or (benign 1/50	, malignai (2%)	nt or 1/49	(2%)		0/50 0/50 0/50	(0%) (0%) (0%)	0/50	(0%)	0/50	(0%)
Skin: Basal Cell Carcinoma,	Basal Cell Aden	1/489 (0.2 oma, Basosqua 0/50	%) amous Tur (0%)	m or (benign 1/50 1/50	, maligna (2%) (2%)	nt or 1/49 0/50	(2%) (0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50 1/50	(0%) (2%)
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli overall Incidence	Basal Cell Aden ioma	1/489 (0.2 oma, Basosqua 0/50 0/50 0/50 5/489 (1.02	%) amous Tur (0%) (0%) (0%) 2%)	mor (benign 1/50 1/50 1/50 Mean 1	, malignai (2%) (2%) (2%)	nt or 1/49 0/50 1/90 SD 1.019	(2%) (0%) (1%) %	Total	0/50 0/50 0/50 0/50 1/490 (0	(0%) (0%) (0%) (0%) .2%)	0/50 0/50 Mean	(0%) (0%) 0.22%	0/50 1/50 0/90 SD 0	(0%) (2%) (0%) 67%
	Basal Cell Aden lioma Total inoma, Carcinom	1/489 (0.2 oma, Basosqua 0/50 0/50 0/50 5/489 (1.02	%) amous Tur (0%) (0%) (0%) 2%) 2%) nor (M or I	mor (benign 1/50 1/50 1/50 Mean 1 B), Basal Ce	, malignar (2%) (2%) (2%) .02%	nt or 1/49 0/50 1/90 SD 1.019	(2%) (0%) (1%) %	Total	0/50 0/50 0/50 0/50 1/490 (0	(0%) (0%) (0%) (0%) .2%)	0/50 0/50 Mean	(0%) (0%) 0.22%	0/50 1/50 0/90 SD 0	(0%) (2%) (0%) 67%
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci	Basal Cell Aden lioma Total inoma, Carcinom	1/489 (0.2 oma, Basosqua 0/50 0/50 0/50 5/489 (1.02	%) amous Tur (0%) (0%) (0%) 2%) 2%) nor (M or I	mor (benign 1/50 1/50 1/50 Mean 1 B), Basal Ce	, malignar (2%) (2%) (2%) .02%	nt or 1/49 0/50 1/90 SD 1.019	(2%) (0%) (1%) %	Total	0/50 0/50 0/50 0/50 1/490 (0	(0%) (0%) (0%) (0%) .2%)	0/50 0/50 Mean	(0%) (0%) 0.22%	0/50 1/50 0/90 SD 0	(0%) (2%) (0%) 67%
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci	Basal Cell Aden lioma Total inoma, Carcinom	1/489 (0.2 oma, Basosqua 0/50 0/50 5/489 (1.02 ba, Basosq. Tun eratoacanthoma	%) amous Tur (0%) (0%) (0%) 2%) 2%) nor (M or I a, Trichoeg	mor (benign 1/50 1/50 1/50 Mean 1 B), Basal Ce bithelioma	, malignar (2%) (2%) (2%) .02% Il Adenon	nt or 1/49 0/50 1/90 SD 1.019	(2%) (0%) (1%) %	Total	0/50 0/50 0/50 0/50 1/490 (0	(0%) (0%) (0%) (0%) .2%)	0/50 0/50 Mean	(0%) (0%) 0.22%	0/50 1/50 0/90 SD 0	(0%) (2%) (0%) 67%
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci	Basal Cell Aden lioma Total inoma, Carcinom	1/489 (0.2 oma, Basosqua 0/50 0/50 5/489 (1.02 ba, Basosq. Tun eratoacanthoma 1/50	%) amous Tur (0%) (0%) (0%) 2%) 2%) nor (M or I a, Trichoeg (2%)	mor (benign 1/50 1/50 1/50 Mean 1 B), Basal Ce Dithelioma 4/50	, malignar (2%) (2%) (2%) .02% Il Adenon (8%) (12%)	nt or 1/49 0/50 1/90 SD 1.019 na, 9/49 4/50	(2%) (0%) (1%) % (18%) (8%)	Total	0/50 0/50 0/50 0/50 1/490 (0 0/50	(0%) (0%) (0%) (0%) .2%) (0%) (0%)	0/50 0/50 Mean 1/50	(0%) (0%) 0.22% (2%)	0/50 1/50 0/90 SD 0	(0%) (2%) (0%) 67% (0%) (2%)
Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence Skin: Basal or Sq. Cell Carci	Basal Cell Aden lioma Total inoma, Carcinom	1/489 (0.2 oma, Basosqua 0/50 0/50 5/489 (1.02 ba, Basosq. Tun eratoacanthoma 1/50	%) amous Tur (0%) (0%) (0%) 2%) 2%) nor (M or I a, Trichoeg (2%)	mor (benign 1/50 1/50 1/50 Mean 1 B), Basal Ce Dithelioma 4/50 6/50	, malignar (2%) (2%) (2%) .02% Il Adenon (8%)	nt or 1/49 0/50 1/90 SD 1.019 na, 9/49	(2%) (0%) (1%) % (18%)	Total	0/50 0/50 0/50 0/50 1/490 (0 0/50 0/50	(0%) (0%) (0%) (0%) .2%)	0/50 0/50 Mean 1/50	(0%) (0%) 0.22% (2%)	0/50 1/50 0/90 SD 0 0/50 1/50	(0%) (2%) (0%) 67% (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: Fibroma														
		3/50	(6%)	3/50	(6%)	3/49	(6%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		3/50	(6%)	5/50 1/50	(10%) (2%)	0/50 2/90	(0%) (2%)		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50 2/90	(0%) (2%)
		3/50	(6%)						1/50	(2%)				
verall Incidence	Total	23/489 (4.7	%)	Mean 4		SD 3%		Total	4/490 (0.8	32%)	Mean	0.69%	SD 1.	04%
Skin:														
Fibroma, Fibrosarcom Hemangiopericytoma	ia, Sarcoma, My	coma, Myxosarc	oma, Mali	ignant Fibro	ous Histioc	ytoma, or								
		3/50	(6%)	3/50	(6%)	4/49	(8%)		1/50	(2%)	1/50	(2%)	1/50	(2%)
		3/50	(6%)	7/50	(14%)	1/50	(2%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
			()	2/50	(4%)	5/90	(6%)		1/50	(2%)			5/90	(6%)
		3/50	(6%)						3/50	(6%)				
Overall Incidence	Total	31/489 (6.34	,	Mean 6		SD 3.3%		Total	14/490 (2.	86%)	Mean	2.62%	SD 2.	16%
/Skin: Fibroma, Fibrosarcom														
FIDIOIIIa, FIDIOSalcolli	ia, Sarconia, My	3/50	(6%)	3/50	(6%)	4/49	(8%)		1/50	(2%)	1/50	(2%)	1/50	(2%)
		3/50	(6%)	7/50	(14%)	1/50	(2%)		0/50	(0%)	2/50	(4%)	0/50	(0%)
		0,00	(070)	2/50	(4%)	5/90	(6%)		1/50	(2%)	2,00	(170)	5/90	(6%)
		3/50	(6%)		(/		(<i>)</i>		2/50	(4%)				()
	Total	31/489 (6.34	· · /	Mean 6	.41%	SD 3.3%	D	Total	13/490 (2.	· · ·	Mean	2.4%	SD 1.	85%
Overall Incidence	Total									•••••	•••••			
Overall Incidence KSkin: Fibrosarcoma														
∕Skin:		0/50	(0%)	0/50	(0%)	1/49	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
∕Skin:									0/50 0/50	(0%) (0%)	1/50 1/50	(2%) (2%)	0/50 0/50	(0%) (0%)
∕Skin:		0/50	(0%)	0/50	(0%)	1/49	(2%)			()		()		· · /
∕Skin:		0/50	(0%)	0/50 1/50	(0%) (2%)	1/49 0/50	(2%) (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

			Male				Female	
#Skin:								
Fibrosarcoma, Sarcoma,	Myxosarcoma	a, or Malignant Fibrous	Histiocytoma					
		0/50 (0%)	0/50 (0%)	1/49 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
			1/50 (2%)	3/90 (3%)		1/50 (2%)		3/90 (3%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	8/489 (1.64%)	Mean 1.49%	SD 1.56%	Total	9/490 (1.84%)	Mean 1.7%	SD 1.06%
¢Skin: Hemangioma								
		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%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
≴Skin: Hemangiopericytoma								
		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
≠Skin: Hemangiosarcoma								
J		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%)	0/90 (0%)		0/50 (0%)	· · ·	0/90 (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

					Male						F	emale		
#Skin: Keratoacanthoma														
		1/50	(2%)	2/50	(4%)	8/49	(16%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50	(4%)	4/50 5/50	(8%) (10%)	3/50 5/90	(6%) (6%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50 0/90	(0%) (0%)
		1/50	(2%)		()		()		0/50	(0%)				()
verall Incidence	Total	31/489 (6.34	,	Mean 6	6.43%	SD 4.54	%	Total	0/490 (0%)	Mea	in 0%	SD	0%
Skin: Lipoma														
•		3/50	(6%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		2/50	(4%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	2/90	(2%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
overall Incidence	Total	8/489 (1.64	%)	Mean 1	.58%	SD 2.19	%	Total	1/490 (0	0.2%)	Mean	0.22%	SD 0.	.67%
Skin: Liposarcoma														
		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%)
				0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	1/489 (0.29	,	Mean 0		SD 0.67		Total	0/490 (,		in 0%	SD	- / -
Skin: Malignant Fibrous Histi														
inalignant i broad inda	looytonia	0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			()	0/50	(0%)	0/90	(0%)		0/50	(0%)		()	1/90	(1%)
		0/50	(0%)		()		()		0/50	(0%)				(,
Overall Incidence	Total	2/489 (0.41	()	Mean 0	110/	SD 0.88	0/.	Total	2/490 (0.	· · ·	Moon	0.35%	SD 0.	72%

*: 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	
Skin:								
Neurofibrosarcoma or	Schwannoma (n	nalignant or NOS)						
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		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%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)	Mean 0.67%	SD 1%
Skin:								
	eurofibroma. or	Schwannoma (benign, ma	alignant or NOS)					
	,	0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		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%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		(1))
Verall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)	Mean 0.67%	SD 1%
Skin:								
Osteosarcoma								
Osteosarconia		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%)
		0,00 (0,0)	0/50 (0%)	0/90 (0%)		0/50 (0%)	0/00 (0/0)	0/90 (0%)
		0/50 (0%)	0/00 (070)	0/00 (0/0)		1/50 (2%)		0/00 (0/0)
Verall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
	10tai	0/489 (078)		30 0 /0	10tai	1/490 (0.276)		30 0.07 /0
Skin:								
Pilomatrixoma								
		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%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
		0/00 (0/0)				0/00 (0/0)		

*: 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	
Skin: Sarcoma								
		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%)
			0/50 (0%)	2/90 (2%)		1/50 (2%)		2/90 (2%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/489 (0.41%)	Mean 0.25%	SD 0.74%	Total	4/490 (0.82%)	Mean 0.69%	SD 1.04%
Skin: Schwannoma Malignant								
		0/50 (0%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		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%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 1.33%	Total	3/490 (0.61%)	Mean 0.67%	SD 1%
Skin: Squamous Cell Carcinoma								
-		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%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	2/489 (0.41%)	Mean 0.44%	SD 0.88%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%
Skin:								
Squamous Cell Carcinoma, or Carcinoma	Basal Cell	Carcinoma, Basosquai	nous Tumor (malignan	t or NOS),				
		0/50 (0%)	1/50 (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%)	0/50 (0%)	1/50 (2%)
			0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Verall Incidence	Total	3/489 (0.61%)	Mean 0.67%	SD 1.41%	Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%

*: 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: Squamous Cell Papillor	na												
		0/50 (0%	%) 0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50 (4%	%) 1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	2/90	(2%)		0/50	(0%)			0/90	(0%)
		0/50 (0%	6)					0/50	(0%)				
Overall Incidence	Total	6/489 (1.23%)	Mean	1.14%	SD 1.479	%	Total	0/490 (0)%)	Mea	n 0%	SD	0%
tSkin:													
Squamous Cell Papillor	na or Papilloma	à											
	•	0/50 (0%	%) 0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		2/50 (4%	%) 1/50	(2%)	1/50	(2%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
			0/50	(0%)	2/90	(2%)		0/50	(0%)			0/90	(0%)
		0/50 (0%	%)					0/50	(0%)				
Overall Incidence	Total	6/489 (1.23%)	Mean		SD 1.479		Total	0/490 (0)%)	Mea	n 0%	SD	0%
#Skin:													
Squamous Cell Papillor	na. Papilloma. S	Squamous Cell Carc	inoma or Kerate	oacanthom	a								
	.,	1/50 (2%		(6%)	8/49	(16%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
		4/50 (8%	%) 5/50	(10%)	4/50	`(8%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		,	, 5/50	(10%)	7/90	(8%)		0/50	(0%)		()	0/90	(0%)
				· · ·				0/50	(0%)				
		1/50 (2%	%)										• - • /
Overall Incidence	Total	1/50 (29 38/489 (7.77%)	‰) Mean T	7.79%	SD 4.379	%	Total	1/490 (0.	2%)	Mean	0.22%	SD 0.	67%
		38/489 (7.77%)	Mean						,		0.22%	SD 0.	67%
#Skin:		38/489 (7.77%)	Mean T						,		0.22%	SD 0.	67%
		38/489 (7.77%) or Keratoacanthoma	Mean T					``````````````````````````````````````	····				
#Skin:		38/489 (7.77%) or Keratoacanthoma 1/50 (29	Mean 7 N N %) 2/50	(4%)	8/49	(16%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
/Skin:		38/489 (7.77%) or Keratoacanthoma	Mean 7 N %) 2/50 %) 5/50	(4%) (10%)	8/49 4/50	(16%) (8%)		0/50 0/50	(0%) (0%)			0/50 0/50	(0%) (0%)
Overall Incidence #Skin: Squamous Cell Papillor		38/489 (7.77%) or Keratoacanthoma 1/50 (29	Mean M %) 2/50 %) 5/50 5/50	(4%)	8/49	(16%)		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

			Male				Female	
≮Skin: Trichoepithelioma								
·		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%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/90 (0%)		0/50 (0%) 0/50 (0%)		0/90 (0%)
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
∕Skin: Sebaceous Gland: Adenoma								
		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%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)		.,		0/50 (0%)		0,00 (0,0)
Overall Incidence	Total	2/489 (0.41%)	Mean 0.35%	SD 0.72%	Total	0/490 (0%)	Mean 0%	SD 0%
/Skin: Sebaceous Gland: Carcinoma or Adenoma								
		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%) 1/90 (1%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)				0/50 (0%)		
Verall Incidence	Total	2/489 (0.41%)	Mean 0.35%	SD 0.72%	Total	0/490 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant								
		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%)	0/50 (0%)	0/50 (0%) 0/90 (0%)
		0/50 (0%)	0/30 (0/8)	0/00 (0/0)		0/50 (0%)		0/00 (0/0)
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.22%	SD 0.67%

*: 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		
Spleen: Hemangiosarcoma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/49 0/50	(0%) (0%)		0/50 0/50	(0%) (0%)	1/49 0/50	(2%) (0%)	0/50 0/50	(0%) (0%)
		0/50	(0%)	0/50	(0%)	3/90	(3%)		0/50 0/50	(0%) (0%)			1/90	(1%)
Overall Incidence	Total	3/489 (0.61	1%)	Mean 0	.37%	SD 1.119	%	Total	2/489 (0.	· · ·	Mean	0.35%	SD 0.	73%
Stomach, Forestomach: Sarcoma														
		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 0/50	(0%) (0%)			1/90	(1%)
Overall Incidence	Total	0/489 (0%	6)	Mean	0%	SD 0%		Total	1/490 (0	()	Mean	0.12%	SD 0.	37%
Stomach, Forestomach: Squamous Cell Carcinoma														
		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%)	1/50	(2%)	0/50	(0%)
		0/50	(09/)	0/50	(0%)	0/90	(0%)		0/50	(0%)			0/90	(0%)
Overall Incidence	Total	0/50 1/489 (0.2	,	Mean 0		SD 0.679		Total	0/50 1/490 (0	,		0.22%	SD 0.	
Stomach, Forestomach:														
Squamous Cell Carcinoma o	or Papillom	a Squamous 0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(0%)	0/49	(0%)		0/50	(0%)	1/50	(0%)	0/50	(0%)
		0,00	(0,0)	0/50	(0%)	1/90	(1%)		0/50	(0%)		(_,0)	0/90	(0%)
		0/50	(0%)		· · /		. /		0/50	(0%)				. ,
Overall Incidence	Total	2/489 (0.41	(%)	Mean 0	.35%	SD 0.729	%	Total	1/490 (0	.2%)	Mean	0.22%	SD 0.	67%

*: 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	Female		
≮Stomach, Forestomach: Squamous Cell Papilloma							·							·
		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	(00()	0/50	(0%)	1/90	(1%)		0/50	(0%)			0/90	(0%)
	Tetal	0/50	(0%)	Maara 0	400/		N/	Tatal	0/50	(0%)	Мал		00	00/
verall Incidence	Total	1/489 (0.29		Mean 0	.12%	SD 0.379	/o	Total	0/490 (0%)	INIE2	an 0%	SD	U%
Testis: Adenoma														
		7/50	(14%)	3/49	(6%)	2/49	(4%)							
		1/50	(2%)	3/49	(6%)	0/50	(0%)							
				0/50	(0%)	2/90	(2%)							
		1/50	(2%)											
Verall Incidence	Total	19/487 (3.9	,	Mean 4		SD 4.369								
Thymus: Thymoma Benign														
		0/48	(0%)	0/47	(0%)	0/48	(0%)		0/49	(0%)	0/46	(0%)	0/49	(0%)
		0/46	(0%)	1/46	(2%)	0/48	(0%)		0/49	(0%)	0/47	(0%)	0/50	(0%)
			(·)	0/48	(0%)	0/88	(0%)		0/49	(0%)			1/87	(1%)
		0/48	(0%)		-	AB A	.,		0/47	(0%)			AA -	
overall Incidence	Total	1/467 (0.21	,	Mean 0		SD 0.729		Total	1/473 (0	,		0.13%	SD 0.	
Thymus: Thymoma Malignant														
		0/48	(0%)	0/47	(0%)	0/48	(0%)		0/49	(0%)	0/46	(0%)	0/49	(0%)
		0/46	(0%)	0/46	(0%)	0/48	(0%)		0/49	(0%)	0/47	(0%)	0/50	(0%)
				0/48	(0%)	0/88	(0%)		0/49	(0%)			1/87	(1%)
		0/48	(0%)						0/47	(0%)				
Overall Incidence	Total	0/467 (0%	6)	Mean	0%	SD 0%		Total	1/473 (0	.21%)	Mean	0.13%	SD 0.	38%

*: 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	
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/48 (0%)	0/47 (0%)	0/48 (0%)		0/49 (0%)	0/46 (0%)	0/49 (0%)
		0/46 (0%)	1/46 (2%)	0/48 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
			0/48 (0%)	0/88 (0%)		0/49 (0%)		2/87 (2%)
		0/48 (0%)				0/47 (0%)		
verall Incidence	Total	1/467 (0.21%)	Mean 0.24%	SD 0.72%	Total	2/473 (0.42%)	Mean 0.26%	SD 0.77%
Thyroid Gland: C-Cell: Adenoma								
		13/50 (26%)	10/50 (20%)	8/49 (16%)		12/50 (24%)	8/49 (16%)	12/50 (24%)
		7/50 (14%)	13/50 (26%)	2/50 (4%)		5/50 (10%)	11/49 (22%)	2/50 (4%)
			11/49 (22%)	8/89 (9%)		9/50 (18%)		6/90 (7%)
		4/50 (8%)				5/50 (10%)		
Overall Incidence	Total	76/487 (15.61%)	Mean 16.2%	SD 8.05%	Total	70/488 (14.34%)	Mean 15.05%	SD 7.65%
Thyroid Gland: C-Cell: Carcinoma								
		2/50 (4%)	1/50 (2%)	1/49 (2%)		2/50 (4%)	0/49 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
			0/49 (0%)	2/89 (2%)		1/50 (2%)		0/90 (0%)
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	8/487 (1.64%)	Mean 1.59%	SD 1.35%	Total	7/488 (1.43%)	Mean 1.56%	SD 1.67%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		14/50 (28%)	10/50 (20%)	8/49 (16%)		14/50 (28%)	8/49 (16%)	13/50 (26%)
		8/50 (16%)	13/50 (26%)	3/50 (6%)		6/50 (12%)	11/49 (22%)	2/50 (4%)
		. ,	11/49 (22%)	10/89 (11%)		9/50 (18%)	. ,	6/90 (7%)
		4/50 (8%)		· · · · ·		7/50 (14%)		
Overall Incidence	Total	81/487 (16.63%)	Mean 17.11%	SD 7.72%	Total	76/488 (15.57%)	Mean 16.38%	SD 8.21%

*: 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		
Thyroid Gland: Follicular Ce Adenoma	ell:													
		0/50	(0%)	0/50	(0%)	1/49	(2%)		0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)	0/50 0/49	(0%) (0%)	0/50 0/89	(0%) (0%)		0/50 0/50	(0%) (0%)	0/49	(0%)	0/50 0/90	(0%) (0%)
		0/50	(0%)		· · ·		· · ·		0/50	(0%)				、 ,
verall Incidence	Total	1/487 (0.21	,	Mean 0	.23%	SD 0.689	6	Total	0/488 (0%)	Mea	in 0%	SD	0%
Thyroid Gland: Follicular Ce Carcinoma														
		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%)	0/49	(0%)	0/50	(0%)
				0/49	(0%)	0/89	(0%)		0/50	(0%)			1/90	(1%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	0/487 (0%	,	Mean		SD 0%		Total	1/488 (0	,		0.12%	SD 0.	.37%
Thyroid Gland: Follicular Ce Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	1/49	(2%)		0/50	(0%)	0/49	(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%)	0/89	(0%)		0/50	(0%)			1/90	(1%)
		0/50	(0%)						0/50	(0%)				
verall Incidence	Total	1/487 (0.21	,	Mean 0		SD 0.689		Total	1/488 (0	,		0.12%	SD 0.	
Tissue NOS: Schwannoma Malignant														
		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%)	1/90	(1%)		0/50	(0%)			1/90	(1%)
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/489 (0.2	%)	Mean 0	12%	SD 0.379	6	Total	1/490 (0	2%)	Mean	0.12%	SD 0.	37%

*: 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	
#Tongue: Squamous Cell Carcinoi	ma							
-		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 (00/)	0/50 (0%)	0/90 (0%)		0/50 (0%)		1/90 (1%)
	Tatal	0/50 (0%)	Maan 00/	CD 00/	Tatal	0/50 (0%)	Maar 0 400/	
Overall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
≠Tongue: Squamous Cell Carcinoi	ma or Papilloma	a Squamous						
•	•	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%)	0/90 (0%)		0/50 (0%)		1/90 (1%)
		0/50 (0%)				0/50 (0%)		
Verall Incidence	Total	0/489 (0%)	Mean 0%	SD 0%	Total	1/490 (0.2%)	Mean 0.12%	SD 0.37%
Tooth: Odontoma								
		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%)
		- / / /	0/50 (0%)	0/90 (0%)		0/50 (0%)		0/90 (0%)
		0/50 (0%)		0.5. 0.050/		0/50 (0%)		65 <i>au</i> /
Overall Incidence	Total	1/489 (0.2%)	Mean 0.22%	SD 0.67%	Total	0/490 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
-		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%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
			0/49 (0%)	0/89 (0%)		0/50 (0%)		1/88 (1%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/487 (0%)	Mean 0%	SD 0%	Total	1/486 (0.21%)	Mean 0.13%	SD 0.38%

*: Denominator is number of animals with tissues examined microscopically

Version: Nov2019 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawley	Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups Route: ALL ROUTES Vehicle: ALL VEHICLES		Page: 47 Report Date	e: 02/17/2020
Length of Study: CHRONIC				
	Male		Female	
#Uterus: Adenocarcinoma				
		2/50 (4%) 5/50 (10%) 1/50 (2%) 3/50 (6%)	3/50 (6%) 5/50 (10%)	1/50 (2%)
Overall Incidence	Total	20/350 (5.71%)	Mean 5.71%	SD 3.35%
#Uterus: Adenocarcinoma or Adenoma				
		2/50 (4%) 5/50 (10%) 2/50 (4%) 3/50 (6%)	3/50 (6%) 5/50 (10%)	1/50 (2%)
Overall Incidence	Total	21/350 (6%)	Mean 6%	SD 3.06%
#Uterus: Adenoma				
		0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Uterus: Deciduoma Benign				
		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

Version: Nov2019 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	s	Page: 48 Report Da	te: 02/17/2020
	Male		Female	
#Uterus: Granular Cell Tumor Benign				
-		0/50 (0%) 1/5 0/50 (0%) 0/5 0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	. ,	ean 0.29%	SD 0.76%
#Uterus: Polyp Stromal				
		5/50 (10%) 8/5 8/50 (16%) 10/5 16/50 (32%) 5/50 (10%)		5/50 (10%)
Overall Incidence	Total	57/350 (16.29%) Me	an 16.29%	SD 7.95%
#Uterus: Sarcoma				
		1/50 (2%) 0/5 0/50 (0%) 0/5 0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Total	. ,	ean 0.29%	SD 0.76%
#Uterus: Sarcoma Stromal				
		0/50 (0%) 0/5 0/50 (0%) 2/5 1/50 (2%) 1/50 (2%)		1/50 (2%)
Overall Incidence	Total	. ,	ean 1.43%	SD 1.51%

Version: Nov2019 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: 02/17/2020		
	Male	Female				
#Uterus:						
Sarcoma Stromal or Polyp Stromal			5/50 (10%) 8/50 (16%) 16/50 (32%) 6/50 (12%)	8/50 12/50	(16%) (24%)	6/50 (12%)
Overall Incidence	То	tal	61/350 (17.43%)	Mean	17.43%	SD 7.89%
#Uterus: Schwannoma Malignant						
			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 0/50	(2%) (0%)	0/50 (0%)
Overall Incidence	То		1/350 (0.29%)		0.29%	SD 0.76%
Uterus: Squamous Cell Carcinoma						
			0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)	0/50 0/50	(0%) (0%)	0/50 (0%)
Overall Incidence	То	tal	2/350 (0.57%)	Mean	0.57%	SD 1.51%
Vagina:						
Granular Cell Tumor Benign			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 0/50	(0%) (0%)	0/50 (0%) 1/50 (2%) 0/90 (0%)
Overall Incidence	То	tal	1/490 (0.2%)	Mean	0.22%	SD 0.67%

Version: Nov2019 Contract/Lab: All Laboratories Species: RATS Strain: Harlan Sprague-Dawle Length of Study: CHRONIC				logy Data Management : nce for Selected Control A Route: ALL ROUTES Vehicle: ALL VEHICLES	nimal Groups		Page: 50 Report Da	te: 02/17/2020
			Male				Female	
#Vagina: Polyp								
						0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence					Total	2/490 (0.41%)	Mean 0.44%	SD 0.88%
#Vagina: Schwannoma Malignant								
						0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 1/90 (1%)
Overall Incidence					Total	4/490 (0.82%)	Mean 0.79%	SD 0.98%
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	1/49 (2%) 1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	0/490 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	1/49 (2%) 1/50 (2%) 0/90 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/90 (0%)
Overall Incidence	Total	4/489 (0.82%)	Mean 0.89%	SD 1.06%	Total	0/490 (0%)	Mean 0%	SD 0%