

NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

October 2022

REPORT DESCRIPTION

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

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" 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
Female F1
F1
F1 F2

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.

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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: INHALATION Vehicle: AIR

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Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
					Male					
Battelle Northwest	051047203	01/17/11	729	50(5)	25(661)	609.4	p-Chloro-a,a,a-trifluorotoluene			
	Female									
Battelle Northwest	051047203	01/17/11	731	50(5)	22(626)	377.3	p-Chloro-a,a,a-trifluorotoluene			

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%	Total	39/50 (78%) 39/50 (78%)	Mean 78%	SD 0%
#All Organs: Malignant Tumors								
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%
#All Organs: Malignant and Benign T	umors	37/50 (74%)				41/50 (82%)		
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%
#All Organs: Hemangioma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

O22 Toxi

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: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
-		0/50 (0	0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
Overall Incidence	Total	1/50 (2 1/50 (2%)	2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incidence	Total	1/50 (2%)	iviean 2%	SD 0%	TOTAL	0/50 (0%)	wean 0%	3D 0%
			*0/ \			0/50 (0%)		
Overall Incidence	Total	3/50 (6 3/50 (6%)	%) Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs:		3/50 (6%)	,		Total Total	` '	Mean 0% Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: H	istiocytic, Lymp	3/50 (6%) chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6% IOS, or Undifferentiated Co)%) Mean 0%	ell Type		0/50 (0%) 0/50 (0%) 0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs: Malignant Schwannoma	istiocytic, Lymp	3/50 (6%) Chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6% OS, or Undifferentiated Comment Mean 0% Mean 0%	ell Type SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hi Overall Incidence #All Organs:	istiocytic, Lymp	3/50 (6%) chocytic, Mixed, N 0/50 (0 0/50 (0%)	Mean 6% IOS, or Undifferentiated Co)%) Mean 0%	ell Type		0/50 (0%) 0/50 (0%) 0/50 (0%)		
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs: Malignant Schwannoma	istiocytic, Lymp Total Total	3/50 (6%) chocytic, Mixed, N 0/50 (0 0/50 (0%) 0/50 (0%)	Mean 6% OS, or Undifferentiated Comment Mean 0% Mean 0%	ell Type SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 2/50 (4%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

Page: 7

			Male				Female	
#All Organs: Mesothelioma: Malignant	t							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteon	na	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

Page: 8

			Male				Female						
*Adrenal Medulla: Pheochromocytoma Benign													
		12/50 (24%)				0/49 (0%)							
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
*Adrenal Medulla: Pheochromocytoma Co													
	-	0/50 (0%)				0/49 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
*Adrenal Medulla: Pheochromocytoma Ma	alignant	2/50 (4%)				0/49 (0%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
*Adrenal Medulla: Pheochromocytoma: B						0/49 (0%)							
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
#Bone: Osteosarcoma	•••••												
		0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Bone: Osteosarcoma or Osteo	oma	0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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				Male				Female	
*Brain: Glioma Malignant									
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Brain: Granular Cell Tumor Benigi	า								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Malign	ant	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Malig	nant, NOS	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50	(U ⁷ 0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female					
*Brain: Oligodendroglioma Malignant												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glioma												
	.,	2/50 (4%)				1/50 (2%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Brain: Schwannoma Malignant		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Clitoral/Preputial Gland: Adenoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Carcinoma or Adenoma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	Mean 0% Mean 0% Mean 2%	SD 0% SD 0% SD 0%	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 0%	SD 0%		0/50 (0%)		
0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 0%	SD 0%		0/50 (0%)		
0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
0/50 (0%) 1/50 (2%) 1/50 (2%)			Total	` '	Mean 0%	SD 0%
1/50 (2%)	Mean 2%	SD 0%				
1/50 (2%)	Mean 2%	SD 0%				
				0/50 (00)		
1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
0/50 (00)				0/50 (00)		
` ,	Moon 0%	SD 0%	Total	` '	Moon 0%	SD 0%
	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 2% 0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%)	1/50 (2%) Mean 2% SD 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% 0/50 (0%)	1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male			Female			
.	0/50	(0%)		05.00/	-	0/50 (0%)		OD 00/	
l otal	0/50 (0%)		Mean 0%	SD 0%	l otal	0/50 (0%)	Mean 0%	SD 0%	
		(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
ım:	1/50	(2%)				0/50 (0%)			
Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50	(0%)				0/50 (0%)			
	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	1/50	(2%)				0/50 (0%)			
Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
ified:	0/50	(00()				0/50 (00/)			
Total		(0%)	Moan 0%	SD 0%	Total	, ,	Moan 0%	SD 0%	
	Total	Total 0/50 (0%) um: n 0/50 Total 0/50 (0%) um: 1/50 Total 1/50 (2%) Total 0/50 (0%) Total 1/50 (2%) Total 1/50 Total 1/50 (2%)	Total 0/50 (0%) um: n 0/50 (0%) Total 0/50 (0%) um: 1/50 (2%) Total 1/50 (2%) Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Total 1/50 (2%) 1/50 (2%) Total 1/50 (2%)	Total 0/50 (0%) Mean 0% um: n	Total 0/50 (0%) Mean 0% SD 0% um: n	Total 0/50 (0%) Mean 0% SD 0% Total um: n 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total um: 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 0% SD 0% Total 1/50 (2%) Total 0/50 (0%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 1/50 (2%) Total 1/50 (2%) Total 1/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) um: 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Um: 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% um: n 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% um: 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Mean 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Site Unspe Carcinoma or Adenoma	cified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspectionyosarcoma	cified:							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		8/50 (16%)				1/50 (2%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Carcinoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		•••••				•••••		
		8/50 (16%)				2/50 (4%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Kidney: Pelvis and Transition		m:						
		0/50 (0%)		05.00/		0/50 (0%)		00.007
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (00/)				0/50 (00)		
Overell Incidence	Total	0/50 (0%)	Moon OO/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Oncocytoma Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incidence				5D 0%	ı olal	0/50 (0%)		3D 0%
*Liver: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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				Male				Female	
*Liver: Hepatocellular Carcinon	na								
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinon	na or Henatohla								
Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
	10tai	0/50 (0%)			3D 0%	10lai	0/50 (0%)		3D 0%
*Liver: Hepatocellular Carcinon Overall Incidence		0/50	(0%)	Maan 00/	SD 00/	Total	2/50 (4%)	Magn. 40/	SD 0%
Overali incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinon Overall Incidence	na, Hepatocellul Total		Hepatobla (0%)	stoma Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Ad	lenoma								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	rcinoma	0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0 /0)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups **Route: INHALATION**

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Report Date: 10/05/2022

Vehicle: AIR

Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Male **Female** *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Mammary Gland: Adenolipoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma 0/50 (0%)4/50 (8%) **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 4/50 (8%) Mean 8% SD 0% #Mammary Gland: Carcinoma 0/50 (0%)5/50 (10%) **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 5/50 (10%) Mean 10% SD 0% **#Mammary Gland:** Carcinoma or Adenoma 0/50 (0%)9/50 (18%) **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 9/50 (18%) Mean 18% SD 0% #Mammary Gland: Fibroadenoma 2/50 (4%)20/50 (40%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% 20/50 (40%) Mean 40% SD 0% Total

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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				Male				Female	
#Mammary Gland: Fibroma									
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mea	ո 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	a or Adenoma								
		2/50 (4%)				23/50 (46%)		
Overall Incidence	Total	2/50 (4%)	Mea	ո 4%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%
Fibroma, Fibroadenom Overall Incidence	Total	2/50 (4%)		ո 4%	SD 0%	Total	27/50 (54%) 27/50 (54%)	Mean 54%	SD 0%
		2/50 (4%)	Mea	า 4%	SD 0%	Total	, ,	Mean 54%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin							0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0%) Mea	າ 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		quamous, or Pap	illoma				0/50 (0%)		
#Oral Cavity (Oral Mucos		quamous, or Pap	illoma 0%)	า 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	oma, Papilloma S	quamous, or Pap 0/50 (0 0/50 (0%)	illoma 0%)	า 0%	SD 0%	Total	` '	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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	Male			Female	
*Ovary: Cystadenoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign					
Overall Incidence	-	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor Malignant					
Overall Incidence	-	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			•••••	•••••	
Overall Incidence		Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign			•••••	•••••	
Overall Incidence	-	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Male **Female** *Ovary: Luteoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: **Schwannoma Malignant** 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% *Ovary: Sertoli Cell Tumor Benign 0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% *Ovary: Thecoma Benign 1/50 (2%)**Overall Incidence** SD 0% Total 1/50 (2%) Mean 2% *Pancreas: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Pancreas: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% Total 0/50 (0%) SD 0% Total Mean 0% SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/48 (0%)				0/45 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma		0/50 /00/				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
·····		` '						
#Peripheral Nerve: Schwannoma Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mal								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma		fied Site:						
		11/50 (22%)				18/50 (36%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Dista Carcinoma	lis or Unspeci	ified Site:						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma	lis or Unspeci	ified Site:						
Overall Incidence	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Interr Adenoma	nedia:	0/50 (00)				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Nervo			•••••					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

n: 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: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		2/52 (224)						
	-	0/50 (0%)		OD 00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
_		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma								
		0/50 (0%)		OD 40/		1/50 (2%)		00.004
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	·	0/50 (0%)	Mann 00/	SD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Ba	sosquamous Ti	umor Benign, or Trich 0/50 (0%)	oepithelioma			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (malignant o	r NOS)			1/50 (2%)		
		0/30 (0/6)				1/30 (270)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: INHALATION Vehicle: AIR

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Report Date: 10/05/2022

SD 0%

SD 0%

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Male **Female** #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)1/50 (2%)SD 0% SD 0% Overall Incidence Total 0/50 (0%) Mean 0% Total 1/50 (2%) Mean 2% Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma (8%)1/50 (2%)Mean 8% Mean 2% **Overall Incidence** Total 4/50 (8%) SD 0% Total 1/50 (2%) SD 0% #Skin: **Fibroma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, Malignant Fibrous Histiocytoma, or Hemangiopericytoma 1/50 (2%)0/50 (0%)Overall Incidence 1/50 (2%) SD 0% 0/50 (0%) SD 0% Total Mean 2% Total Mean 0%

SD 0%

SD 0%

0/50

0/50

0/50 (0%)

0/50 (0%)

Total

Total

(0%)

(0%)

Mean 0%

Mean 0%

Total

Total

Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 1/50

1/50 (2%)

0/50

0/50 (0%)

(2%)

(0%)

Mean 2%

Mean 0%

Overall Incidence

Fibrosarcoma

Overall Incidence

#Skin:

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Overall Incidence

Hemangioma

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Liposarcoma

Overall Incidence

Keratoacanthoma

Hemangiopericytoma

.....

#Skin:

#Skin:

#Skin:

#Skin:

#Skin: Lipoma

#Skin:

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups Route: INHALATION

Vehicle: AIR

SD 0%

SD 0%

SD 0%

Total

Total

Total

Male **Female** Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 0/50 (0%)Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)

0/50 (0%)

0/50

0/50

0/50 (0%)

0/50 (0%)

(0%)

(0%)

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Mean 0%

Mean 0%

Mean 0%

SD 0%

SD 0%

SD 0%

Report Date: 10/05/2022

*: Denominator is number of animals with tissues examined microscopically

Total

Total

Total

Total

Total

Total

1/50

1/50 (2%)

1/50

1/50 (2%)

0/50

0/50 (0%)

3/50

3/50 (6%)

1/50

1/50 (2%)

0/50

0/50 (0%)

(2%)

(2%)

(0%)

(6%)

(2%)

(0%)

Mean 6%

Mean 2%

Mean 0%

#: Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Malignant Fibrous Hist	iocytoma							
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma or	Schwannoma (m	-				0(50 (00))		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Cl-in.								
#Skin: Neurofibrosarcoma, No	eurofibroma, or S	chwannoma (benign, ma	lignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Pilomatrixoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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				Male				Female	
#Skin: Schwannoma Malignant									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	Carcinoma, Base	osquamou (0%)	us Tumor (malignan	t or NOS),		1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Squamous Cell Papilloma			(00()				- /		
		1/50	('2%)				0/50 (0%)		
	Total	1/50 1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #Skin: Squamous Cell Papilloma c		1/50 (2%)			SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma c		1/50 (2%)	(2%)		SD 0%	Total Total	` '	Mean 0% Mean 0%	SD 0%
#Skin:	or Papilloma Total	1/50 (2%) 1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%		0/50 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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			Male		Female					
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 4/50 (8%) 0/50 (0%)										
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Trichoepithelioma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Adenoma		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Sebaceous Gland: Carcinoma or Adenoma		1/50 (2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Stomach, Forestomach: Sarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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				Male			Female			
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%) 0/50 (0%)										
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Forestomach: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Testis: Adenoma		0/50	(0%)							
Overall Incidence	Total	0/50 (0%)	(=,=)	Mean 0%	SD 0%					
*Thymus: Thymoma Benign Overall Incidence	Total	0/48 0/48 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/48	(0%)				0/50 (0%)			
Overall Incidence	Total	0/48 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/48	(0%)				0/50 (0%)			
Overall Incidence	Total	0/48 (0%)	(370)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male						Female			
*Thyroid Gland: C-Cell: Adenoma										
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		3/50	(6%)				2/50 (4%)			
Overall Incidence	Total	3/50 (6%)	,	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Thyroid Gland: Follicular Cell Adenoma	:	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell Carcinoma	l:									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(-/0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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	Male						Female			
#Tissue NOS: Schwannoma Malignant										
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma							0/50 (00/)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma of Overall Incidence	or Papilloma Total	-	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Leiomyosarcoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenocarcinoma							4/50 (00/)			
Overall Incidence						Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

Page: 33

	Male			Female				
#Uterus: Adenocarcinoma or Adenoma								
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Uterus: Adenoma								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cel	l Papilloma		2/50 (4%)					
Overall Incidence		Total	2/50 (4%)	Mean 4%	SD 0%			
#Uterus: Deciduoma Benign			0/50 (0%)					
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Granular Cell Tumor Benign								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Hemangioma			0/50 (0%)					
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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	Male			Female				
#Uterus: Polyp Stromal								
Overall Incidence		Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%			
#Uterus: Sarcoma								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sarcoma Stromal or Polyp Stromal								
Overall Incidence		Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%			
#Uterus: Schwannoma Malignant								
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Uterus: Sq Cell Carcinoma or Papilloma Squamous								
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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	Male		Female				
#Uterus: Squamous Cell Carcinoma							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Uterus: Squamous Cell Papilloma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Granular Cell Tumor Benign			4/50 (00)				
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Polyp							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Sarcoma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Schwannoma Malignant							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: INHALATION Vehicle: AIR

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		Male					Female			
#Zymbal's Gland: Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Zymbal's Gland: Carcinoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Zymbal's Gland: Carcinoma or Adenoma		` '				, ,				
Overell Incidence	Total	1/50 (2%)	Maan 20/	SD 09/	Total	0/50 (0%)	Moon 09/	SD 00/		
#Zymbal's Gland:	Total		Mean 2%	SD 0%	Total		Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 37

Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	051018801	02/17/11	733	50(2)	32(675)	525.8	Di(2-ethylhexyl) Phthalate
					Female		
Battelle Columbus Laboratory	051018801	02/18/11	736	50(4)	33(691)	329.5	Di(2-ethylhexyl) Phthalate

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male			Female			
#All Organs: Benign Tumors									
-		27/50 (54%)				37/50 (74%)			
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total	37/50 (74%)	Mean 74%	SD 0%	
All Organs: Malignant Tumors									
Overall Incidence	Total	13/50 (26%) 13/50 (26%)	Mean 26%	SD 0%	Total	16/50 (32%) 16/50 (32%)	Mean 32%	SD 0%	
All Organs: Malignant and Benign Tu									
		32/50 (64%)				41/50 (82%)			
Overall Incidence	Total	32/50 (64%)	Mean 64%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%	
All Organs: Hemangioma		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
All Organs: Hemangiosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
All Organs: Hemangiosarcoma or He		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
		1/30 (2/6)				` ,			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 10/05/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Contract/Lab: All Laboratories

			Male			Female				
#All Organs: Histiocytic Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
								30 0/0		
#All Organs: Leukemia: Granulocytic										
		0/50 (0%)		05 00/		0/50 (0%)		05		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Leukemia: Lymphocytic, N	Monocytic, Mo	ononuclear, or Undifferen 0/50 (0%)	itiated			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Malignant Lymphoma: His	tiocytic, Lym	phocytic, Mixed, NOS, or 2/50 (4%)	Undifferentiated Ce	ell Type		1/50 (2%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs: Malignant Schwannoma		3/50 (6%)				1/50 (2%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#All Organs: Mesothelioma: Benign, Ma	alignant. NOS									
		2/50 (4%)				0/50 (0%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Male **Female** #All Organs: Mesothelioma: Malignant 2/50 (4%)0/50 (0%)SD 0% **Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Mean 0% #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #All Organs: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Adrenal Cortex: Adenoma 1/50 (2%)0/50 (0%)SD 0% **Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% *Adrenal Cortex: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Adrenal Medulla: Ganglioneuroma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 41 Report Date: 10/05/2022

			Male			Female			
*Adrenal Medulla: Pheochromocytoma Benig	n								
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Comp	lex								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Malig	nant	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma: Beni						1/50 (2%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Bone: Osteosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Bone: Osteosarcoma or Osteoma	1	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED Page: 42

				Male			Female			
*Brain: Glioma Malignant										
	.	4/50	(8%)		OD 00/		0/50 (0%)		OD 00/	
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benign										
_		3/50	(6%)				2/50 (4%)			
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Brain: Granular Cell Tumor Maligna		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Benign		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Malignant										
_			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Malign										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall incidence		` ,					0/50 (0%)			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Report Date: 10/05/2022

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Strain: Harlan Sprague-Dawley Length of Study: CHRONIC Route: ORAL Vehicle: FEED

			Male				Female			
*Brain: Oligodendroglioma Malign	ant									
Occupation of desires	T-1-1	0/50 (0%)	Mara 2007	00.00/	Tatal	0/50 (0%)	Maran 00/	00.00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Oligodendroglioma, Gliom	a. or Astrocy	vtoma								
	,	4/50 (8%)				0/50 (0%)				
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Brain: Schwannoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Adenoma		0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
Clitoral/Preputial Gland: Carcinoma										
		1/49 (2%)				0/49 (0%)				
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Carcinoma or Adenoma										
Overall Incidence	Total	1/49 (2%)	Mean 2.04%	CD 00/	Total	0/49 (0%)	Maan 00/	CD 00/		
	Total	1/49 (2.04%)		SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED Page: 44

Report Date: 10/05/2022

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

		Male				Female				
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/49 (0%)				0/49 (0%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/49 (0%)				1/49 (2%)				
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/49 (2.04%)	Mean 2.04%	SD 0%		
*Epididymis: Sarcoma		0/50 (0%)								
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%						
#Eye: Leiomyoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Heart: Schwannoma Malignant				•••••						
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Intestine Large: Cecum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 45

				Male				Female			
#Intestine Large: Cecum: Liposarcoma											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Re Granular Cell Tumor Be											
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Re Leiomyoma	ectum:	0/50	(00/)				0/50 (00/)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum Carcinoma Overall Incidence	: Total		(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum Leiomyosarcoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Uns Carcinoma	pecified:	1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)	(2 70)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 46

			Male				Female	
#Intestine Small: Site Unspe Carcinoma or Adenoma	ecified:							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		3/49 (6%)				1/50 (2%)		
Overall Incidence	Total	3/49 (6%)	Mean 6.12%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
		0.1270)						
*Islets, Pancreatic: Carcinoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		3/49 (6%)				1/50 (2%)		
Overall Incidence	Total	3/49 (6.12%)	Mean 6.12%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Pelvis and Transiti Papilloma	onal Epitheliu							
		0/50 (0%)		00.00/		0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED Page: 47 Report Date: 10/05/2022

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/05/2022

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Male **Female** *Kidney: Renal Tubule: **Oncocytoma Benign** 0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% *Kidney: Renal Tubule: **Polyp Adenomatous** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Lacrimal Gland:** Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Cholangioma 0/50 (0%)1/50 (2%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% *Liver: Hemangioma 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Hepatocellular Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/05/2022

SD 0%

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC Male **Female** *Liver: **Hepatocellular Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Lung: Alveolar/Bronchiolar Adenoma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

SD 0%

0/50

0/50 (0%)

Total

(0%)

Mean 0%

Total

0/50

0/50 (0%)

(0%)

Mean 0%

Alveolar/Bronchiolar Carcinoma

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

			Male			Female				
*Lung: Alveolar/Bronchiolar Carc	inoma or Alve		na							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Adenolipoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Mammary Gland: Carcinoma		0/50 (0%)				8/50 (16%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	8/50 (16%)	Mean 16%	SD 0%		
#Mammary Gland: Carcinoma or Adenoma		0/50 (00/)				0/50 (400)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%		
#Mammary Gland: Fibroadenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

n: Oct2022

Contract/Lab: All Laboratories

Species: RATS **Strain:** Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 10/05/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Mammary Gland: Fibroma		0/50 (00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
		0/50 (0%)				25/50 (50%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	25/50 (50%)	Mean 50%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma Overall Incidence	Total	Adenoma 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino		vnx, Tooth, Gingiva): 0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (00()				0/50 (00()		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 52

	Male			Female	
*Ovary: Cystadenoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor Malignant			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant			0/50 (0%)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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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: ORAL Vehicle: FEED **Page:** 53

			Male				Female	
*Ovary: Luteoma								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign	•••••					(201)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign						0/50 /00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	1/49 (2%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Male **Female** *Pancreas: Carcinoma or Adenoma 1/49 (2%)0/50 (0%)**Overall Incidence** Total 1/49 (2.04%) Mean 2.04% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Parathyroid Gland: Adenoma 0/43 (0%)0/42 (0%)**Overall Incidence** Total 0/43 (0%) Mean 0% SD 0% Total 0/42 (0%) Mean 0% SD 0% **#Peripheral Nerve:** Paraganglioma 0/50 (0%)0/50 (0%)Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Peripheral Nerve: Schwannoma Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Peripheral Nerve:** Schwannoma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

SD 0%

13/49

Total

13/49 (26.53%)

(27%)

Mean 26.53%

SD 0%

Total

3/50

3/50 (6%)

(6%)

Mean 6%

Adenoma

Overall Incidence

*Pituitary Gland: Pars Distalis or Unspecified Site:

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 55

				Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma												
		0/50	(0%)				0/49 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Distali Carcinoma or Adenoma												
		3/50	(6%)				13/49 (27%)					
Overall Incidence	Total	3/50 (6%)		Mean 6%	SD 0%	Total	13/49 (26.53%)	Mean 26.53%	SD 0%			
*Pituitary Gland: Pars Interm Adenoma	edia:		· · · · · · · · · · · · · · · · · · ·									
		1/50	(2%)	••	05 00/		0/49 (0%)		05.00/			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:											
		1/50	(2%)				0/49 (0%)					
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Nervos Schwannoma Malignant												
_		0/50	(0%)				0/49 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma												
	-	1/50	(2%)		OD 00/							
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%							

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/05/2022

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Male **Female** *Prostate: Carcinoma or Adenoma 1/50 (2%)1/50 (2%) SD 0% **Overall Incidence** Total Mean 2% *Salivary Glands: **Schwannoma Malignant** 0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Hemangiosarcoma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangioma 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Liposarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED nimal Groups Report Date: 10/05/2022

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Female			
(0%)			
O%) Mea	an 0% SD 0%		
(0%)			
O%) Mea	an 0% SD 0%		
(0%) 0%) Mea	an 0% SD 0%		
(0%)	00/ CD 00/		
O%) Mea	an 0% SD 0%		
(221)			
(0%)	OD 00/		
J%) Mea	an 0% SD 0%		
(0%)			
` '	an 0% SD 0%		
	(0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

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Report Date: 10/05/2022

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Contract/Lab: All Laboratories

#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%) 0/50 (0%)												
0/50 (0%)												
0/50 (0%)	Mean 0% SD 0%											
0/50 (09/)												
0/50 (0%)	Mean 0% SD 0%											
0/50 (0%)												
0/50 (0%)	Mean 0% SD 0%											
1/50 (2%)	M 00/											
1/50 (2%)	Mean 2% SD 0%											
1/50 (29/)												
1/50 (2%)	Mean 2% SD 0%											
0/50 (0%)	Mean 0% SD 0%											
	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%)											

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED Report Date: 10/05/2022

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			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma,	_	stiocytoma			4/50 (20/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		` '				, ,		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 60

			Male				Female					
#Skin: Malignant Fibrous Histiocytoma												
-		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin:		aliament or NOS)		•••••								
Neurofibrosarcoma or	Schwannoma (m	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Neurofibrosarcoma, No Overall Incidence	eurofibroma, or S Total	schwannoma (benign, ma 0/50 (0%) 0/50 (0%)	llignant or NOS) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Pilomatrixoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sarcoma												
		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 61

				Male				Female			
#Skin: Schwannoma Malignant											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Carcinoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell C	Carcinoma, Base	osquamou (0%)	us Tumor (malignan	t or NOS),		0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Squamous Cell Papilloma			(00/)				- /				
oquamous com rapmoma		0/50					0/50 (0%)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
Overall Incidence #Skin: Squamous Cell Papilloma o		0/50 (0%)	•••••		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Overall Incidence #Skin: Squamous Cell Papilloma o		0/50 (0%)	` ,		SD 0%	Total Total	` '	Mean 0% Mean 0%	SD 0%		
Overall Incidence #Skin:	or Papilloma Total	0/50 (0%) 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%		0/50 (0%)				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL

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Report Date: 10/05/2022

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: FEED

			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma, o					0/50 (00)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma				•••••				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 63

		Male		Female			
a or Papilloma	ı Squamous						
	0/50 (0%)				0/50 (0%)		
Total	` ,	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
l							
	,				()		
	` ,				` ,		SD 0%
	7/50 (14%)						
Total	7/50 (14%)	Mean 14%	SD 0%				
					0/49 (0%)		
Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
	0/48 (0%)				0/49 (0%)		
Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
nant, NOS							
Total	` ,	Moon 0%	SD 0%	Total	(,	Moon 0%	SD 0%
- · · · ·	Total Total Total Total Total Total Total	Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 7/50 (14%) Total 7/50 (14%) 0/48 (0%) Total 0/48 (0%) Total 0/48 (0%) annt, NOS 0/48 (0%) Total 0/48 (0%)	O/50 (0%) Total O/50 (0%) Mean 0% O/50 (0%) Total O/50 (0%) Mean 0% 7/50 (14%) Total 7/50 (14%) Mean 14% O/48 (0%) Total O/48 (0%) Mean 0% O/48 (0%) Mean 0% Mean 0% O/48 (0%) Mean 0% Mean 0% O/48 (0%) Mean 0% Mean 0%	7/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 7/50 (14%) Total 7/50 (14%) Mean 14% SD 0% 7/50 (14%) Mean 0% SD 0% 7/50 (14%) Mean 0% SD 0% 0/48 (0%) Total 0/48 (0%) Mean 0% SD 0% 0/48 (0%) Total 0/48 (0%) Mean 0% SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total O/50 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/49 (0%) Total O/48 (0%) Mean 0% SD 0% Total O/49 (0%) Total O/48 (0%) Mean 0% SD 0% Total O/49 (0%) Total O/48 (0%) Mean 0% SD 0% Total O/49 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: ORAL Vehicle: FEED

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Male Female *Thyroid Gland: C-Cell: Adenoma 13/50 (26%)12/50 (24%)**Overall Incidence** Total 13/50 (26%) Mean 26% SD 0% Total 12/50 (24%) Mean 24% SD 0% *Thyroid Gland: C-Cell: Carcinoma 2/50 (4%)2/50 (4%)**Overall Incidence** Total 2/50 (4%) Mean 4% SD 0% Total 2/50 (4%) Mean 4% SD 0% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 14/50 (28%)14/50 (28%)**Overall Incidence** Total 14/50 (28%) Mean 28% SD 0% Total 14/50 (28%) Mean 28% SD 0% *Thyroid Gland: Follicular Cell: Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) *Thyroid Gland: Follicular Cell: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/50 (0%) SD 0% Total SD 0% 0/50 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 65

				Male			Female			
#Tissue NOS: Schwannoma Malignant										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma										
Occupation of James	T-1-1	0/50	(0%)	Maran 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tongue: Squamous Cell Carcinoma of Coverall Incidence	or Papilloma	9 Squamous 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma Overall Incidence	Total	, ,	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Leiomyosarcoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Adenocarcinoma							0/50 (40/)			
Overall Incidence						Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 66

	Male			Female	
#Uterus: Adenocarcinoma or Adenoma			2/22 (194)		
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Adenoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell P	apilloma		2/50 (4%)		
Overall Incidence		Total	2/50 (4%)	Mean 4%	SD 0%
#Uterus: Deciduoma Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 67

	Male			Female	Female		
#Uterus: Polyp Stromal							
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%		
#Uterus: Sarcoma							
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Uterus: Sarcoma Stromal							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal or Polyp Stromal			5/50 (400)				
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%		
#Uterus: Schwannoma Malignant							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sq Cell Carcinoma or Papilloma Squamous							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 68

	Male			Female		
#Uterus: Squamous Cell Carcinoma						
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Squamous Cell Papilloma						
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Granular Cell Tumor Benign			0/50 (00)			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Polyp			0/50 (00/)			
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Sarcoma						
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Schwannoma Malignant						
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: ORAL Vehicle: FEED **Page:** 69

		Male				Female	
	2/22 (224)				(201)		
Total		Moon 0%	SD 0%	Total	` ,	Moon 0%	SD 0%
	` '				` ,		
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
			•••••				
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	Total	0/50 (0%) Total 0/50 (0%) 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%) Total 0/50 (0%) Mean 0% 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	O/50 (0%) Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) O/50 (0%) Mean 0% SD 0% Total O/50 (0%) O/50 (0%) Total O/50 (0%) O/50 (0%) O/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	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	052071203	12/12/11	729	50(2)	25(652)	589.0	Tris(Chloropropyl)phosphate
					Female		
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	052071203	12/13/11	731	50(4)	22(629)	380.1	Tris(Chloropropyl)phosphate

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#All Organs: Benign Tumors								
		28/50 (56%) 25/50 (50%)	35/49 (71%)	38/50 (76%)		41/50 (82%) 41/50 (82%)	40/50 (80%)	41/50 (82%)
Overall Incidence	Total	126/199 (63.32%)	Mean 63.36%	SD 12.35%	Total	163/200 (81.5%)	Mean 81.5%	SD 1%
#All Organs: Malignant Tumors								
		15/50 (30%) 9/50 (18%)	14/49 (29%)	11/50 (22%)		14/50 (28%) 10/50 (20%)	13/50 (26%)	15/50 (30%)
Overall Incidence	Total	49/199 (24.62%)	Mean 24.64%	SD 5.63%	Total	52/200 (26%)	Mean 26%	SD 4.32%
#All Organs: Malignant and Benign To	umors	36/50 (72%) 30/50 (60%)	41/49 (84%)	42/50 (84%)		44/50 (88%) 46/50 (92%)	44/50 (88%)	47/50 (94%)
Overall Incidence	Total	149/199 (74.87%)	Mean 74.92%	SD 11.4%	Total	181/200 (90.5%)	Mean 90.5%	SD 3%
#All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#All Organs: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female					
#All Organs: Hemangiosarcoma or Hemangioma												
-	_	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%				
#All Organs: Histiocytic 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%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%				
#All Organs: Leukemia: Granulocytic												
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
#All Organs: Leukemia: Lymphocyti	c, Monocytic, M	ononuclear, or Undiffere	ntiated									
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 2/50 (4%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%				
#All Organs: Malignant Lymphoma:		phocytic, Mixed, NOS, o										
		0/50 (0%) 2/50 (4%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.92%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#All Organs: Malignant Schwannoma								
		6/50 (12%) 0/50 (0%)	3/49 (6%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	10/199 (5.03%)	Mean 5.03%	SD 5.3%	Total	5/200 (2.5%)	Mean 2.5%	SD 3%
#All Organs: Mesothelioma: Benign, Maliç								
		1/50 (2%) 1/50 (2%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant		1/50 (2%)	1/49 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/49 (276)	1/30 (2/6)		0/50 (0%)	0/30 (0 %)	0/30 (0 /8)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 0.02%	Total	0/200 (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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

Page: 74

			Male				Female	
*Adrenal Cortex: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%
*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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Adrenal Medulla: Pheochromocytoma Benign								
		5/50 (10%) 6/50 (12%)	7/49 (14%)	9/50 (18%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	27/199 (13.57%)	Mean 13.57%	SD 3.43%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%
*Adrenal Medulla: Pheochromocytoma Comple	ex							
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Maligna	ant							
		0/50 (0%) 0/50 (0%)	1/49 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/200 (1%)	Mean 1%	SD 2%
*Adrenal Medulla: Pheochromocytoma: Benigr		, Malignant, NOS		40/50 (040/)		0/50 (00/)	0/50 (00/)	E/50 (400V)
		6/50 (12%) 6/50 (12%)	8/49 (16%)	12/50 (24%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	5/50 (10%)
Overall Incidence	Total	32/199 (16.08%)	Mean 16.08%	SD 5.66%	Total	5/200 (2.5%)	Mean 2.5%	SD 5%
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant						•••••		
		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Brain: Granular Cell Tumor Ber	nign							
		0/50 (0%) 1/50 (2%)	0/49 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%
*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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Brain: Meningioma: Benign, Ma	alignant, NOS							
		0/50 (0%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Brain: Oligodendroglioma Malign	nant							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma, Gliom								
		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Schwannoma Malignant		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/49 (0%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/193 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma				4/40 (00%)		0/50 (00%)	0/40 (00%)	0/40 /00/
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/193 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	1/49 (2%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%	Total	0/193 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	1/49 (2%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
		1/50 (2%)	1/49 (276)	0/49 (0 %)		0/46 (0%)	0/49 (0 %)	0/48 (0 /8)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/193 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/193 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Heart: Schwannoma Malignan	t							
		2/50 (4%) 0/50 (0%)	2/49 (4%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.52%	SD 1.94%	Total	0/198 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/R Granular Cell Tumor Be								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Leiomyoma	lectum:							
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma								
		2/50 (4%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma	ecified:							
		2/50 (4%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma	ecified:							
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Islets, Pancreatic: Adenoma								
		2/50 (4%) 4/50 (8%)	4/49 (8%)	3/50 (6%)		3/49 (6%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	13/199 (6.53%)	Mean 6.54%	SD 1.96%	Total	4/198 (2.02%)	Mean 2.03%	SD 2.89%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.5%	SD 1%
lslets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%) 4/50 (8%)	4/49 (8%)	3/50 (6%)		3/49 (6%) 0/49 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	13/199 (6.53%)	Mean 6.54%	SD 1.96%	Total	5/198 (2.53%)	Mean 2.53%	SD 2.57%
Kidney: Pelvis and Transitic Papilloma	onal Epitheli	um:						
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Adenoma								
		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma						0/50 (00/)	0/50 (00)	0/50 (00/)
		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
ū		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: 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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Kidney: 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Cholangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Liver: Hepatocellular Adenon	na							
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Liver: Hepatocellular Carcino	oma							
		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/199 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 2/199 (1.01%)	1/49 (2%) Mean 1.01%	0/50 (0%) SD 1.17%	Total	0/49 (0%) 0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocellular Carcino	uma or Henatoce	allular Adenoma						
ricpatocendiai carcino	ina or riepatoce	1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
*Liver: Hepatocellular Carcino	ma, Hepatocellı	ılar Adenoma, or Hepatol	blastoma					
-	•	1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Lung: Alveolar/Bronchiolar A	denoma							
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/198 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		0/50 (0%) 1/50 (2%)	0/49 (0%)	1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/198 (0%)	Mean 0%	SD 0%
		veolar/Bronchiolar Adeno 0/50 (0%) 1/50 (2%)	1/49 (2%)	1/50 (2%)	Total	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	0/198 (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%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	2/50 (4%)		1/50 (2%) 1/50 (2%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	13/200 (6.5%)	Mean 6.5%	SD 5.74%
#Mammary Gland: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	2/50 (4%)		2/50 (4%) 1/50 (2%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	14/200 (7%)	Mean 7%	SD 5.29%
#Mammary Gland: Fibroadenoma								
		2/50 (4%) 2/50 (4%)	1/49 (2%)	2/50 (4%)		28/50 (56%) 29/50 (58%)	33/50 (66%)	32/50 (64%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	Total	122/200 (61%)	Mean 61%	SD 4.76%
#Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or		•••••	•••••					
		2/50 (4%) 2/50 (4%)	1/49 (2%)	2/50 (4%)		29/50 (58%) 29/50 (58%)	33/50 (66%)	32/50 (64%)
Overall Incidence	Total	7/199 (3.52%)	Mean 3.51%	SD 0.98%	Total	123/200 (61.5%)	Mean 61.5%	SD 4.12%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Mammary Gland: Fibroma, Fibroadenom	na. Carcinoma. o	r Adenoma				,		
· ibroma, · ibroadonom	ia, caromema, c	3/50 (6%) 2/50 (4%)	1/49 (2%)	3/50 (6%)		30/50 (60%) 30/50 (60%)	35/50 (70%)	36/50 (72%)
Overall Incidence	Total	9/199 (4.52%)	Mean 4.51%	SD 1.9%	Total	131/200 (65.5%)	Mean 65.5%	SD 6.4%
Oral Cavity (Oral Mucos		ynx, Tooth, Gingiva):						
·		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Squamous Cell Carcin	oma, Papilloma :	Squamous, or Papilloma						
·	oma, Papilloma s Total	Squamous, or Papilloma 0/50 (0%) 0/50 (0%) 1/199 (0.5%)	1/49 (2%) Mean 0.51%	0/50 (0%) SD 1.02%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #Oral Mucosa:	Total	0/50 (0%) 0/50 (0%)	,	,	Total	0/50 (0%)	, ,	,
Overall Incidence #Oral Mucosa: Squamous Cell Carcin	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%) 0/50 (0%)	Mean 0.51%	SD 1.02%	Total Total	0/50 (0%) 0/200 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall Incidence #Oral Mucosa: Squamous Cell Carcin Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%) 0/50 (0%) 0/50 (0%)	Mean 0.51%	SD 1.02%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
Overall Incidence #Oral Mucosa: Squamous Cell Carcin Overall Incidence *Ovary:	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%) 0/50 (0%) 0/50 (0%)	Mean 0.51%	SD 1.02%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%)	Mean 0% 0/50 (0%)	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female	
*Ovary: Granulosa Cell Tumor Benign					
			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Granulosa Cell Tumor Malignant					
			1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					•••••
			2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	2/200 (1%)	Mean 1%	SD 2%
*Ovary: Granulosa-Theca Tumor Benign					
			0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary: Granulosa-Theca Tumor Malignant					
- -			0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Ovary: Luteoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Schwannoma Malignant								
						0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
'Ovary: Sertoli Cell Tumor Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Thecoma Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Adenoma								
		10/50 (20%) 9/50 (18%)	4/49 (8%)	5/50 (10%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	28/199 (14.07%)	Mean 14.04%	SD 5.83%	Total	0/198 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Pancreas: Carcinoma								
		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	0/198 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		10/50 (20%) 9/50 (18%)	6/49 (12%)	5/50 (10%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	30/199 (15.08%)	Mean 15.06%	SD 4.71%	Total	0/198 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/42 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/42 (0%) 0/44 (0%)	0/45 (0%)	1/41 (2%)
Overall Incidence	Total	0/188 (0%)	Mean 0%	SD 0%	Total	1/172 (0.58%)	Mean 0.61%	SD 1.22%
#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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Peripheral Nerve: Schwannoma: Benign,	Malignant, NOS	·						
•	•	0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
		4/50 (8%) 7/50 (14%)	15/48 (31%)	14/50 (28%)		15/49 (31%) 11/50 (22%)	12/50 (24%)	19/50 (38%)
Overall Incidence	Total	40/198 (20.2%)	Mean 20.31%	SD 11.11%	Total	57/199 (28.64%)	Mean 28.65%	SD 7.24%
*Pituitary Gland: Pars Dis Carcinoma Overall Incidence	stalis or Unspec	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/198 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/49 (2%) 0/50 (0%) 2/199 (1.01%)	1/50 (2%)	0/50 (0%) SD 1.17%
						2,100 (1.0170)		
Pituitary Gland: Pars Dis* Carcinoma or Adenoma			.=((0.10)				(2/22 (222)	(
		4/50 (8%) 7/50 (14%)	15/48 (31%)	14/50 (28%)		16/49 (33%) 11/50 (22%)	13/50 (26%)	19/50 (38%)
Overall Incidence	Total	40/198 (20.2%)	Mean 20.31%	SD 11.11%	Total	59/199 (29.65%)	Mean 29.66%	SD 7.08%
*Pituitary Gland: Pars Into Adenoma	ermedia:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	2/50 (4%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		` ,						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	2/50 (4%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/199 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nervos Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%				
*Salivary Glands: Schwannoma Malignant								
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Seminal Vesicle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or B	asosquamous	s Tumor 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%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Basal Cell Adenoma, Bas	Total	1/50 (2%) 0/50 (0%) 2/199 (1.01%)	1/49 (2%) Mean 1.01%	0/50 (0%) SD 1.17%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#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%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
	Basosquamoı			0.000			2/22 (22/)	
#Skin:	Basosquamoı	us Tumor (malignant or N 0/50 (0%) 0/50 (0%) 0/199 (0%)	0/49 (0%)	0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male			Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		noma, Basosquamous Tui	nor (benign, malignant or				
, .		1/50 (2%) 0/50 (0%)	1/49 (2%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01% SD 1.17	7% Total	0/200 (0%)	Mean 0%	SD 0%
		na, Basosq. Tumor (M or l eratoacanthoma, Trichoep 4/50 (8%) 3/50 (6%)		(8%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	20/199 (10.05%)	Mean 10.09% SD 5.69	% Total	` ,	Mean 0.5%	SD 1%
#Skin: Fibroma		3/50 (6%) 4/50 (8%)	3/49 (6%) 3/50	(6%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	13/199 (6.53%)	Mean 6.53% SD 0.98	3% Total	` ,	Mean 0.5%	SD 1%
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myz	xoma, Myxosarcoma, Mali 3/50 (6%) 4/50 (8%)	gnant Fibrous Histiocytoma, or 4/49 (8%) 3/50	(6%)	1/50 (2%) 2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04% SD 1.29	% Total	` '	Mean 2%	SD 1.63%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myz	xoma, Myxosarcoma, or N 3/50 (6%) 4/50 (8%)	lalignant Fibrous Histiocytoma 4/49 (8%) 3/50	(6%)	1/50 (2%) 2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04% SD 1.29	% Total	` '	Mean 2%	SD 1.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Skin: Fibrosarcoma, Sarcoma, I	Myxosarcoma,	•	•					
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin: Hemangioma				0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma					•••••			
		2/50 (4%) 2/50 (4%)	8/49 (16%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.08%	SD 6.16%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Lipoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Liposarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous His								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Neurofibrosarcoma or	Schwannoma (n	nalignant or NOS)						
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Skin:		Schwannoma (benign, ma						
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Osteosarcoma		0/50 (00/)	0/40 /00%	0/50 /00//		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 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%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.53%	SD 3.06%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant					•••••			
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	2/200 (1%)	Mean 1%	SD 1.15%
#Skin: Squamous Cell Carcinoma					•••••			
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female				
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma											
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Squamous Cell Papillo	oma	0/50 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	0/49 (078)	2/30 (4/8)		0/50 (0%)	0/30 (0 %)	0/30 (0 %)			
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma or Papilloma	ı									
		0/50 (0%) 1/50 (2%)	0/49 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma, Papilloma, S	Squamous Cell Carcinom 3/50 (6%) 3/50 (6%)	a or Keratoacanthoma 8/49 (16%)	a 4/50 (8%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	18/199 (9.05%)	Mean 9.08%	SD 4.92%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Skin: Squamous Cell Papillo	oma, Papilloma, o	or Keratoacanthoma									
•		2/50 (4%) 3/50 (6%)	8/49 (16%)	4/50 (8%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	17/199 (8.54%)	Mean 8.58%	SD 5.42%	Total	0/200 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Trichoepithelioma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female				
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma 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%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Stomach, Forestomach: Squamous Cell Papilloma				0(50 (00))		0(50 (00/)	0/50 (00/)	0/50 (00/)			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
*Testis: Adenoma		•••••		•••••			•••••				
		3/49 (6%) 0/50 (0%)	2/49 (4%)	1/50 (2%)							
Overall Incidence	Total	6/198 (3.03%)	Mean 3.05%	SD 2.64%							
*Thymus: Thymoma Benign											
		0/47 (0%) 0/49 (0%)	0/48 (0%)	0/46 (0%)		0/46 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)			
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%			
*Thymus: Thymoma Malignant											
-		0/47 (0%) 0/49 (0%)	0/48 (0%)	0/46 (0%)		0/46 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)			
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
*Thymus: Thymoma: Benign, Maligna	ant, NOS	047 (04)	0(40 (00))	0/40 (00/)		2(12 (22()	0/40 (00/)	2/12 (22/)
		0/47 (0%) 0/49 (0%)	0/48 (0%)	0/46 (0%)		0/46 (0%) 0/50 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/190 (0%)	Mean 0%	SD 0%	Total	0/194 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%) 9/50 (18%)	8/49 (16%)	7/50 (14%)		8/49 (16%) 10/50 (20%)	12/50 (24%)	5/50 (10%)
Overall Incidence	Total	34/199 (17.09%)	Mean 17.08%	SD 2.54%	Total	35/199 (17.59%)	Mean 17.58%	SD 5.95%
*Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/49 (0%) 2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	4/199 (2.01%)	Mean 2%	SD 1.63%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		10/50 (20%) 9/50 (18%)	8/49 (16%)	8/50 (16%)		8/49 (16%) 12/50 (24%)	13/50 (26%)	6/50 (12%)
Overall Incidence	Total	35/199 (17.59%)	Mean 17.58%	SD 1.83%	Total	39/199 (19.6%)	Mean 19.58%	SD 6.55%
*Thyroid Gland: Follicular Ce Adenoma	ell:					•••••		
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
Thyroid Gland: Follicular Cell: 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
#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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fTongue: Squamous Cell 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o				•••••				
•	•	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%	6)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%	6)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma						3/50 (6%)		5/50 (10%)
Overall Incidence					Total	3/50 (6%) 11/150 (7.33%)	Mean 7.33%	SD 2.31%
#Uterus: Adenocarcinoma or Ad	denoma							
						3/50 (6%) 3/50 (6%)		5/50 (10%)
Overall Incidence					Total	11/150 (7.33%)	Mean 7.33%	SD 2.31%
#Uterus: Adenoma								
						0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female	
fUterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma	, or Sq Cell Papilloma				
			3/50 (6%) 3/50 (6%)		5/50 (10%)
Overall Incidence		Total	11/150 (7.33%)	Mean 7.33%	SD 2.31%
Uterus:					
Deciduoma Benign			1/50 (2%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Uterus: Granular Cell Tumor Benign					
oranaa oon ramor bornga			1/50 (2%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Uterus: Hemangioma					
Č			0/50 (0%) 1/50 (2%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Uterus: Polyp Stromal					
. XI			8/50 (16%) 5/50 (10%)		8/50 (16%)
Overall Incidence		Total	21/150 (14%)	Mean 14%	SD 3.46%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male			Female	
#Uterus: Sarcoma					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
			8/50 (16%) 5/50 (10%)		8/50 (16%)
Overall Incidence		Total	21/150 (14%)	Mean 14%	SD 3.46%
#Uterus: Schwannoma Malignant					
			1/50 (2%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Uterus: Sq Cell Carcinoma or Papilloma Squamous			•••••		
-,			0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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	Male		Female	
#Uterus: Squamous Cell Carcinoma				
		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Tot		Mean 0%	SD 0%
Uterus:				
Squamous Cell Papilloma		0/50 (0%) 0/50 (0%)		0/50 (0%)
Overall Incidence	Tot		Mean 0%	SD 0%
tVagina: Granular Cell Tumor Benign				
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tot	al 0/200 (0%)	Mean 0%	SD 0%
Vagina: Polyp				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tot		Mean 0%	SD 0%
Vagina: Sarcoma				
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tot		Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Vagina: Schwannoma Malignant								
						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Zymbal's 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%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma						•••••		
		1/50 (2%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Batelle Columbus	050303803 051105403	01/30/12 07/05/15	729 732	50(2) 50(2)	12(621) 16(650)	610.8 657.1	Sodium Tungstate Dihydrate Sulfolane
					Female		
Battelle Columbus Laboratory Batelle Columbus	050303803 051105403	01/31/12 07/05/15	730 734	50(5) 50(4)	30(667) 21(670)	393.3 438.1	Sodium Tungstate Dihydrate Sulfolane

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female		
#All Organs: Benign Tumors									
		29/50 (58%)	29/50 (58%)			39/50 (78%)	43/50 (86%)		
Overall Incidence	Total	58/100 (58%)	Mean 58%	SD 0%	Total	82/100 (82%)	Mean 82%	SD 5.66%	
#All Organs: Malignant Tumors									
_		14/50 (28%)	8/50 (16%)			17/50 (34%)	15/50 (30%)		
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 8.49%	Total	32/100 (32%)	Mean 32%	SD 2.83%	
#All Organs: Malignant and Benign Tu	umors	36/50 (72%)	32/50 (64%)			47/50 (94%)	45/50 (90%)		
Overall Incidence	Total	68/100 (68%)	Mean 68%	SD 5.66%	Total	92/100 (92%)	Mean 92%	SD 2.83%	
#All Organs: Hemangioma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
All Organs: Hemangiosarcoma									
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma or He	emangioma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
-		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic	;							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	ı Olai			3D 0%	10tai	0/100 (0%)		SD 0%
#All Organs: Leukemia: Lymphocytic Overall Incidence	c, Monocytic, Mo Total	ononuclear, or Undifferen 1/50 (2%) 1/100 (1%)	tiated 0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs:		•••••						
Malignant Lymphoma: I	Histiocytic, Lym _l	phocytic, Mixed, NOS, or 1/50 (2%)	Undifferentiated Cel 0/50 (0%)	Туре		2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
Overall Incidence	Total	1/50 (2%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` '	` ,	SD 0%
Overall Incidence #All Organs: Malignant Schwannoma	Total	1/50 (2%) 1/100 (1%) 1/50 (2%)	0/50 (0%) Mean 1% 0/50 (0%)	SD 1.41%		4/100 (4%) 2/50 (4%)	Mean 4% 0/50 (0%)	
Overall Incidence #All Organs:	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total Total	4/100 (4%)	Mean 4%	SD 0% SD 2.83%
Overall Incidence #All Organs: Malignant Schwannoma	Total a Total	1/50 (2%) 1/100 (1%) 1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1% 0/50 (0%)	SD 1.41%		4/100 (4%) 2/50 (4%)	Mean 4% 0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Benig	ın							
		10/50 (20%)	10/50 (20%)			1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 0%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
*Adrenal Medulla: Pheochromocytoma Comp	lex							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malig	nant	2/50 (4%)	0/50 (0%)			1/50 (2%)	1/49 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
*Adrenal Medulla: Pheochromocytoma: Beni			10/50 (20%)			2/50 (4%)	2/49 (4%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 2.83%	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma								
	.	0/50 (0%)	0/50 (0%)	00.00/	T	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Brain: Glioma Malignant								
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Be	nign							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ma	lignant	4/50 /20/\	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Benign						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma: Benign, M	alignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Brain: Oligodendroglioma Malig	ınant	0/50 (09/)	4/50 (20/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glior	ma, or Astrocy	rtoma						
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma						0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenocarcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma or Adenocarcin		0/50 (00/)	0/50 /00/			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (00/)	0/50 (00/)			0/50 (001)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Epididymis: Sarcoma		(00)	(00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Eye: Leiomyoma		0/50 (00/)	0/50 (004)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/99 (2.02%)	0/49 (0%) Mean 2%	SD 2.83%
#Intestine Large: Cecum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Intestine Large: Cecum: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyoma	tum:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenocarcinoma								
Overell Incidence	Tatal	1/50 (2%)	1/50 (2%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Any Site: Adenocarcinoma								
• " "	T	1/50 (2%)	1/50 (2%)	05.00/	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Intestine Small: Any Site: Adenoma or Adenocarcin	oma							
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Any Site: Leiomyosarcoma						0/50 (0%)	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		2/50 (4%)	3/50 (6%)	00 4 4404		1/50 (2%)	0/48 (0%)	05
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma		4/50 (00)	0/50 (00/)			4/50 (00()	0/40 /00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%)	3/50 (6%)			2/50 (4%)	0/48 (0%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	2/98 (2.04%)	Mean 2%	SD 2.83%
*Kidney: Pelvis and Transiti Papilloma		ım:						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
• " ' '	T	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/49 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (40/)	4/50 (00/)			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
·····		` '						
*Kidney: Renal Tubule: Hemangioma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0(40 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma	•••••							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Kidney: Renal Tubule: Oncocytoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangioma		4/50 (00)	0/50 (00/)			0/50 (00/)	0/40 (000)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		4/50 (20()	0/50 (0%)			4/50 (00()	0/40 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
Liver: Hepatocellular Carcino	ma			,				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
_iver: Hepatocellular Carcino	ma or Henatobla	astoma				•••••		
Tiopatoconalai caronio	a o. Hopatobio	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcino	ma or Hepatocel	Ilular Adenoma 1/50 (2%)	0/50 (0%)			1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Liver:		ilar Adenoma, or Hepatob 1/50 (2%)				1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Lung: Alveolar/Bronchiolar A								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Ca	arcinoma							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
						0/99 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female				
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 2/50 (4%) 0/50 (0%) 0/50 (0%) 0/49 (0%)											
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/99 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Adenolipoma		2/20 (201)				(00)	2/22 (221)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Mammary Gland: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%			
#Mammary Gland: Adenocarcinoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%			
#Mammary Gland: Adenoma or Adenocarc	inoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	5/50 (10%) 7/100 (7%)	2/50 (4%) Mean 7%	SD 4.24%			
#Mammary Gland: Fibroadenoma		0/50 (00%)	2/50 /42/			20/50 (60%)	22/50 (640/)				
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	30/50 (60%) 62/100 (62%)	32/50 (64%) Mean 62%	SD 2.83%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Mammary Gland: Fibroma		0/50 (00/)	0/50 (0%)			0/50 (0%)	4/50 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenom	a or Adenoma							
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	32/50 (64%) 65/100 (65%)	33/50 (66%) Mean 65%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenom		oma, or Adenoma 0/50 (0%)	2/50 (4%)			34/50 (68%)	33/50 (66%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	67/100 (67%)	Mean 67%	SD 1.41%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	sa, Tongue, Phar							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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	Male		Female	
*Ovary: Cystadenoma		0/50 (00/)	0/40 /00/)	
Overall Incidence	Tota	0/50 (0%) al 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign		0/50 (0%)	0/48 (0%)	
Overall Incidence	Tota	` '	0/48 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Malignant		1/50 (2%)	0/48 (0%)	
Overall Incidence	Tota	, ,	0/48 (0%) Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		1/50 (2%)	0/48 (0%)	
Overall Incidence	Tota	` '	Mean 1%	SD 1.41%
*Ovary: Granulosa-Theca Tumor Benign				
Overall Incidence	Tota	0/50 (0%) al 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant		4/50 (00/)	0/49 /09/	
Overall Incidence	Tota	1/50 (2%) al 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Ovary: Luteoma						27-2 (221)	(201)	
Overall Incidence					Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benign								
Overall Incidence					Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Ovary: Thecoma Benign						0/50 (0%)	0/48 (0%)	
Overall Incidence					Total	0/98 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	14/50 (28%) 18/100 (18%)	4/50 (8%) Mean 18%	SD 14.14%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%
*Pancreas: Adenocarcinoma		4/50 (00)	0/50 /00/			0/50 /00/	0/40 (000)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Pancreas: Adenoma or Adenocarcino	oma							
		14/50 (28%)	4/50 (8%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	18/100 (18%)	Mean 18%	SD 14.14%	Total	0/98 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/43 (0%)	0/44 (0%)			0/46 (0%)	1/43 (2%)	
Overall Incidence	Total	0/87 (0%)	Mean 0%	SD 0%	Total	1/89 (1.12%)	Mean 1.16%	SD 1.64%
#Peripheral Nerve: Paraganglioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignant		0/50 (00()	0/50 /00/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Ma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distal Adenoma								
		8/50 (16%)	9/50 (18%)			16/50 (32%)	14/50 (28%)	
Overall Incidence	Total	17/100 (17%)	Mean 17%	SD 1.41%	Total	30/100 (30%)	Mean 30%	SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Pituitary Gland: Pars Distali Carcinoma	is or Unspec	ified Site:		,				
		1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Pituitary Gland: Pars Distali Carcinoma or Adenoma								
		9/50 (18%)	9/50 (18%)			17/50 (34%)	14/50 (28%)	
Overall Incidence	Total	18/100 (18%)	Mean 18%	SD 0%	Total	31/100 (31%)	Mean 31%	SD 4.24%
*Pituitary Gland: Pars Interm Adenoma	nedia:							
Occupation of James	T-1-1	1/50 (2%)	0/50 (0%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma	nedia:							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	` '				0/100 (0%)	wiean 0%	
*Pituitary Gland: Pars Nervo Schwannoma Malignant	sa:							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Prostate: Adenoma or Adenocarcine	oma							
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skeletal Muscle: Sarcoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	Tatal	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma of	r Basosquamous Total	5 Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:		umor Benign, or Trichoep				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma		0/50 (00/)	0/50 (09/)			0/50 (09/)	0/50 (09/)	
Basal Cell Carcinoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Basal Cell Carcinoma Overall Incidence #Skin:		, ,	Mean 0%	SD 0%	Total	, ,	` '	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tur	nor (benign, maligna	nt or				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carci	noma, Carcinom	a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi), Basal Cell Adenor ithelioma					
Overall Incidence	Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						` ,	······································	
#Skin: Fibroma		2/50 (60/)	2/50 (40/)			4/50 (20/)	0/50 (0%)	
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Fibroma, Fibrosarcom Hemangiopericytoma	a, Sarcoma, Myx	oma, Myxosarcoma, Maliç	•	cytoma, or				
O	T-1-1	3/50 (6%)	3/50 (6%)	OD 00/	T-1-1	3/50 (6%)	1/50 (2%)	00.000/
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 2.83%
#Skin: Fibroma, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or Ma	•	tiocytoma		0/50 (40/)	4/50 (00/)	
Overall Incidence	Total	3/50 (6%) 6/100 (6%)	3/50 (6%) Mean 6%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
Overall incluence	ı olal	٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠٠	iviean o%	טט ע%	ı otal	3/100 (3%)	IVIEAN 3%	SU 1.41%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (09/)			1/50 (20/)	1/50 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
		0/100 (0%)				` ,	IVICALI Z/0	0/0 ط

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma	, or Malignant Fibrous His	stiocytoma 1/50 (2%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangiopericytoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Keratoacanthoma		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 /05()	0/50 /00:			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

Report Date: 10/05/2022

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			Male				Female	
#Skin: Malignant Fibrous Hist	tiocytoma							
_	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or	Schwannoma (m	nalignant or NOS)						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, No	eurofibroma, or \$	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Pilomatrixoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	1/50 /20/			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	ı Ulai	1/100 (1/0)	IVICALL 1 /0	JD 1.41/0	ı Ulai	0/100 (0/0)	IVICAII U/0	3D 0/0

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (or NOS),			2/22	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
······	10tai			30 1.4176				
#Skin: Squamous Cell Papilloma		2/22 (221)	2(22)			2/20 (201)	2(72)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	0/100 (0%)	iviean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma o	or Papilloma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, I	Papilloma, S	quamous Cell Carcinoma	or Keratoacanthom	а		0/50 (0%)	0/50 (0%)	
	Total	5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall Incidence								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma, o		3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 4/100 (4%)	Mean 4%	SD 2.83%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (00)	0/50 (05.1)			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma			(05.3)			(0.3)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 135

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcine		a Squamous						
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papillo								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		4/50 (00/)	0/50 (00/)					
Overall Incidence	Total	1/50 (2%)	0/50 (0%) Mean 1%	SD 1.41%				
Overali incidence		1/100 (1%)	iviean 1%	3D 1.41%				
*Thymus: Thymoma Benign								
	-	0/48 (0%)	0/48 (0%)	OD 00/	T	0/47 (0%)	0/43 (0%)	00.00/
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/48 (0%)	0/48 (0%)			0/47 (0%)	0/43 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Ma	lignant, NOS							
		0/48 (0%)	0/48 (0%)			0/47 (0%)	0/43 (0%)	
Overall Incidence	Total	0/96 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL

Vehicle: WATER

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Report Date: 10/05/2022

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	4/50 (8%) 12/100 (12%)	8/50 (16%)	CD F 660/	Total	5/50 (10%) 11/100 (11%)	6/50 (12%) Mean 11%	CD 4 440/
	Total	12/100 (12%)	Mean 12%	SD 5.66%	Total		iviean 11%	SD 1.41%
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		4/50 (8%)	8/50 (16%)			7/50 (14%)	7/50 (14%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 5.66%	Total	14/100 (14%)	Mean 14%	SD 0%
Thyroid Gland: Follicular Cell Adenoma								
		0/50 (0%)	0/45 (0%)			0/50 (0%)	0/45 (0%)	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma	l:							
		0/50 (0%)	0/45 (0%)			0/50 (0%)	0/45 (0%)	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell Carcinoma or Adenoma			0/45 (000)			0/50 (00)	0.45 (00)	
	-	0/50 (0%)	0/45 (0%)	00.00/	T	0/50 (0%)	0/45 (0%)	00.00/
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Tissue NOS: Schwannoma Malignant								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma of Overall Incidence	or Papilloma	a Squamous 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
#Uterus: Adenocarcinoma								
Overall Incidence					Total	3/50 (6%) 8/99 (8.08%)	5/49 (10%) Mean 8.1%	SD 2.97%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

Page: 138

	Male			Female	
#Uterus: Adenocarcinoma or Adenoma			0/50 (00%)	E/40 /400/C	
Overall Incidence		Total	3/50 (6%) 8/99 (8.08%)	5/49 (10%) Mean 8.1%	SD 2.97%
#Uterus: Adenoma					
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Pa	pilloma		5/50 (10%)	7/49 (14%)	
Overall Incidence		Total	12/99 (12.12%)	Mean 12.14%	SD 3.03%
#Uterus: Deciduoma Benign			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
#Uterus: Hemangioma			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Toxicology Data Management System

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Report Date: 10/05/2022

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: WATER

Male **Female #Uterus: Polyp Stromal** 5/50 (10%) 4/49 (8%)**Overall Incidence** Total 9/99 (9.09%) Mean 9.08% SD 1.3% #Uterus: Sarcoma 0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 1/50 (2%)0/49 (0%)**Overall Incidence** Total 1/99 (1.01%) Mean 1% SD 1.41% #Uterus: Sarcoma Stromal or Polyp Stromal 6/50 (12%) 4/49 (8%)**Overall Incidence** Total 10/99 (10.1%) Mean 10.08% SD 2.71% #Uterus: Schwannoma Malignant 0/50 (0%)1/49 (2%)**Overall Incidence** Total 1/99 (1.01%) Mean 1.02% SD 1.44% **#Uterus:** Sq Cell Carcinoma or Papilloma Squamous

2/50

4/99 (4.04%)

Total

(4%)

2/49

(4%)

SD 0.06%

Mean 4.04%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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	Male			Female	
#Uterus: Squamous Cell Carcinoma					
Overall Incidence		Total	2/50 (4%) 4/99 (4.04%)	2/49 (4%) Mean 4.04%	SD 0.06%
#Uterus: Squamous Cell Papilloma					
Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
#Vagina: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
#Vagina: Polyp			4/50 (00)	0/47 (00/)	
Overall Incidence		Total	1/50 (2%) 1/97 (1.03%)	0/47 (0%) Mean 1%	SD 1.41%
#Vagina: Sarcoma					•••••
Overall Incidence		Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%
#Vagina: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/97 (0%)	0/47 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Zymbal's Gland: Adenoma		2(20)	(70)			27-2 (201)	(00)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE
Vehicle: METHYLCELLULOSE

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Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	050005803 052032305	07/03/12 05/07/12	730 729	50(2) 50(2)	15(656) 29(669)	628.4 597.1	Black Cohosh Resveratrol
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	050005803 052032305	07/02/12 05/08/12	729 730	50(5) 50(5)	28(679) 34(690)	426.6 394.3	Black Cohosh Resveratrol

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#All Organs: Benign Tumors								
Overall Incidence	Total	30/50 (60%) 63/100 (63%)	33/50 (66%) Mean 63%	SD 4.24%	Total	44/50 (88%) 87/100 (87%)	43/50 (86%) Mean 87%	SD 1.41%
All Organs: Malignant Tumors		40/50 (000/)	40/50 (000)			7/50 (4.40)	10/50 (000)	
Overall Incidence	Total	10/50 (20%) 23/100 (23%)	13/50 (26%) Mean 23%	SD 4.24%	Total	7/50 (14%) 17/100 (17%)	10/50 (20%) Mean 17%	SD 4.24%
All Organs: Malignant and Benign Tur	mors	33/50 (66%)	39/50 (78%)			46/50 (92%)	45/50 (90%)	
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	91/100 (91%)	Mean 91%	SD 1.41%
All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
All Organs: Hemangiosarcoma						•••••		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	05.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma or Hen	nangioma							
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T -1-1	0/50 (0%)	1/50 (2%)	00 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
All Organs: Leukemia: Granulocytic						0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
fAII Organs: Leukemia: Lymphocytic, N		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
All Organs:								
Malignant Lymphoma: His		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Malignant Lymphoma: His	ti ocytic, Lym Total			I Type SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Malignant Lymphoma: Hist		0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%		Total	1/100 (1%) ´	Mean 1%	SD 1.41%
Malignant Lymphoma: Hist Overall Incidence All Organs: Malignant Schwannoma	Total	0/50 (0%) 1/100 (1%) 0/50 (0%)	1/50 (2%) Mean 1% 0/50 (0%)	SD 1.41%		1/100 (1%) ´ 1/50 (2%)	Mean 1%	
Malignant Lymphoma: Hist Dverall Incidence FAII Organs: Malignant Schwannoma		0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%		Total Total	1/100 (1%) ´	Mean 1%	SD 1.41% SD 0%
Malignant Lymphoma: Hist Overall Incidence #All Organs:	Total Total	0/50 (0%) 1/100 (1%) 0/50 (0%) 0/100 (0%)	1/50 (2%) Mean 1% 0/50 (0%) Mean 0%	SD 1.41%		1/100 (1%) 1/50 (2%) 2/100 (2%)	Mean 1% 1/50 (2%) Mean 2%	
Malignant Lymphoma: History Overall Incidence All Organs: Malignant Schwannoma Overall Incidence All Organs:	Total Total	0/50 (0%) 1/100 (1%) 0/50 (0%) 0/100 (0%)	1/50 (2%) Mean 1% 0/50 (0%)	SD 1.41%		1/100 (1%) ´ 1/50 (2%)	Mean 1%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SE				Female			
#All Organs: Mesothelioma: Malignant												
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%		, ,		SD 0%				
#All Organs: Osteosarcoma												
		0/50 (0%)	1/50 (2%)			` ,	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	` '	` '	SD 0%				
Adrenal Cortex: Adenoma		0/50 (0%)	0/50 (0%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		5/100 (5%)	Mean 5%	SD 1.41%				
Adrenal Cortex:												
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
Adrenal Medulla: Ganglioneuroma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Be	enign							
		14/50 (28%)	4/50 (8%)			3/50 (6%)	3/50 (6%)	
Overall Incidence	Total	18/100 (18%)	Mean 18%	SD 14.14%	Total	6/100 (6%)	Mean 6%	SD 0%
*Adrenal Medulla: Pheochromocytoma Co	omplex	2(22)	0.50			-()	(704)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma	alignant	0/50 (00()	4/50 (00()			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: B	enign, Complex	, Malignant, NOS 14/50 (28%)	5/50 (10%)			3/50 (6%)	3/50 (6%)	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 12.73%	Total	6/100 (6%)	Mean 6%	SD 0%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteo	oma	0/50 (0%)	1/50 (29/)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
Brain: Glioma Malignant				,				
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benig	ın							
		3/50 (6%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mali	gnant, NOS							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male		Female				
*Brain: Oligodendroglioma Malign	ant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma, Gliom									
,		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%	
						(,			
*Clitoral/Preputial Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female		
*Clitoral/Preputial Gland: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 2/97 (2.06%)	1/48 (2%) Mean 2.06%	SD 0.03%	
·····		, ,				, ,			
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Epididymis: Sarcoma		0/50 (00/)	0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
#Eye: Leiomyoma							2.72		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Heart: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	
#Intestine Large: Cecum: Leiomyosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Large: Cecum: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Re Granular Cell Tumor Ben								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Red Leiomyoma	ctum:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma		-4						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	10lal	1/100 (1%)	iviedii 170	3D 1.41%	10tai	0/100 (0%)	iviean 0%	ال ا
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Small: Site Unspe Carcinoma or Adenoma	ecified:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		4/50 (8%)	2/50 (4%)	25		1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Islets, Pancreatic: Carcinoma		0/50 (00/)	2/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		4/50 (8%)	5/50 (10%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Kidney: Pelvis and Transiti Papilloma	onal Epitheliu							
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	25. 22/		0/50 (0%)	0/50 (0%)	25 20/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
'Kidney: Renal Tubule: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Liposarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male	Male Female				
*Kidney: Renal Tubule: Oncocytoma Benign								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/50 (00/)	0/50 /02/			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma						2(-2)	(20)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50 (00)	0/50 (001)			0/50 /400	0/50 /40/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE
Vehicle: METHYLCELLULOSE

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			Male Female					
*Liver: Hepatocellular Carcino	ma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcino								
	0	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcino Overall Incidence	ma or Hepatocel	O/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%
-	-	lar Adenoma, or Hepatob 0/50 (0%)	0/50 (0%)			2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar A	denoma							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C	arcinoma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
			U/2U (U%)			U/3U (U*/6)	U/3U (U*/o)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female					
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)											
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
	10lal	1/100 (176)		3D 1.41%	10tai	0/100 (0%)		3D 0%			
#Mammary Gland: Adenolipoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Adenoma		0/50 (00)	0/50 (00/)			4/50 (001)	4/50 (00/)				
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	1/50 (2%)	1/50 (2%)	OD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%			
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)			3/50 (6%)	2/50 (4%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	Mean 5%	SD 1.41%			
#Mammary Gland: Carcinoma or Adenoma											
		0/50 (0%)	0/50 (0%)			4/50 (8%)	3/50 (6%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	7/100 (7%)	Mean 7%	SD 1.41%			
#Mammary Gland: Fibroadenoma		2/50 (60/)	0/50 /02/			20/50 /599/\	20/50 /50//				
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	29/50 (58%) 57/100 (57%)	28/50 (56%) Mean 57%	SD 1.41%			
Jveran incluence	IUIAI	3/100 (3%)	IVIEAN 570	SD 4.24%	ı Ulai	31/100 (31%)	IVICALI 31 70	3D 1.41%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Mammary Gland: Fibroma						,		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	na or Adenoma							
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	29/50 (58%) 57/100 (57%)	28/50 (56%) Mean 57%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence	na, Carcinoma, or Total	Adenoma 3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	30/50 (60%) 59/100 (59%)	29/50 (58%) Mean 59%	SD 1.41%
Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary	/nx, Tooth, Gingiva): 0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phary		1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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Male			Female	
*Ovary: Cystadenoma				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Malignant		0/50 (00/)	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (00/)	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Granulosa-Theca Tumor Benign				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Ovary: Luteoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Benigı	n						(00)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Thecoma Benign						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	6/50 (12%) 14/100 (14%)	8/50 (16%) Mean 14%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma		(65)	(05)			(00)	0.000	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE
Vehicle: METHYLCELLULOSE

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		7/50 (14%)	8/50 (16%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	15/100 (15%)	Mean 15%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/49 (0%)	1/49 (2%)	00		0/46 (0%)	0/48 (0%)	05 00/
Overall Incidence	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%	Total	0/94 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignant						2/22 (22)	2/52 (221)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mal								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma		fied Site:						
		12/50 (24%)	10/50 (20%)			20/50 (40%)	21/50 (42%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 2.83%	Total	41/100 (41%)	Mean 41%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%) 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	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Distali Carcinoma or Adenoma												
		12/50 (24%)	10/50 (20%)			20/50 (40%)	21/50 (42%)					
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 2.83%	Total	41/100 (41%)	Mean 41%	SD 1.41%				
Pituitary Gland: Pars Interm Adenoma	edia:											
		0/50 (0%)	1/50 (2%)	25		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:	0/50 (00/)	4/50 (00/)			0/50 (00/)	4/50 (00/)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
		` '				` ,						
Pituitary Gland: Pars Nervo Schwannoma Malignant	sa:											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
Prostate: Adenoma												
		0/50 (0%)	0/50 (0%)									
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Prostate: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Salivary Glands: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
· ·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma		0/50 (00/)	0/50 (09/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma or Overall Incidence	Basosquamous Total	Tumor Benign 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Basal Cell Adenoma, Ba		umor Benign, or Trichoep				0/50 (0%)	1/50 (2%)	
		0/30 (0/8)				0/30 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	Mean 1%	SD 1.41%
Overall Incidence #Skin: Basal Cell Carcinoma	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:	Total Total		` '	SD 0% SD 1.41%	Total Total	` '	` ,	SD 1.41% SD 2.83%
#Skin: Basal Cell Carcinoma Overall Incidence #Skin:	Total	0/100 (0%)	Mean 0% 1/50 (2%) Mean 1%			1/100 (1%) ´ 0/50 (0%)	Mean 1% 2/50 (4%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: PERINATAL AND POSTNATAL GAVAGE

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Basal Cell Carcinoma, B NOS), or Trichoepithelic		oma, Basosquamous Tun	nor (benign, maligna	nt or				
•		0/50 (0%)	1/50 (2%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 4.24%
		a, Basosq. Tumor (M or B ratoacanthoma, Trichoep	ithelioma	na,		0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 6/100 (6%)	5/50 (10%) Mean 6%	SD 5.66%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%
#Skin: Fibroma		4/50 (8%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
Hemangiopericytoma		oma, Myxosarcoma, Maliç 6/50 (12%)	3/50 (6%)		T	0/50 (0%)	0/50 (0%)	OD 004
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myxo	oma, Myxosarcoma, or Ma 6/50 (12%)	alignant Fibrous His 3/50 (6%)	tiocytoma		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/50 (0%)												
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Hemangioma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Hemangiopericytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Keratoacanthoma		4/50 (00/)	0/50 (40)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Lipoma												
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%				
#Skin: Liposarcoma		0.50 (00)	0/50 (051)			0/50 (00)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Malignant Fibrous Hist	iocytoma			,				
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma or								
Troui on Drocar coma cr	Communication (ii	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
tSkin: Neurofibrosarcoma, Ne	eurofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Osteosarcoma		0/50 (00/)					0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0,100 (0,70)				, ,		
Skin: Pilomatrixoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Sarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell (Carcinoma, Basosquamou	us Tumor (malignant	or NOS),		0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Skin: Squamous Cell Papilloma		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma o								
		0/50 (0%)	2/50 (4%)	05 0 000/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, F	Papilloma, S	•		а				
Overall Incidence	Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Squamous Cell Papilloma,	, Papilloma, o		4/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 5/100 (5%)	4/50 (8%) Mean 5%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (001)	0/50 /00:			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Sarcoma		0/50 (00/)	0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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		Male				Female						
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
	, ,			Total	0/100 (0%)	Mean 0%	SD 0%					
ıa					0/50 (00/)	0/50 (00/)						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
	1/50 (2%)	0/50 (0%)										
Total	1/100 (1%)	Mean 1%	SD 1.41%									
	0/46 (09/)	0/49 (09/)			0/40 (0%)	0/50 (09/)						
Total	0/40 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%					
	•••••											
	0/46 (0%)	0/48 (0%)			0/49 (0%)	0/50 (0%)						
Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%					
gnant, NOS												
Total	` '	, ,	SD 0%	Total	` '	` ,	SD 0%					
	Total Total Total Total	7 Total 0/50 (0%) Total 0/100 (0%) Total 0/50 (0%) Total 0/100 (0%) 1/50 (2%) Total 1/100 (1%) 7 Total 0/46 (0%) Total 0/94 (0%) Total 0/94 (0%) Total 0/94 (0%)	Total O/100 (0%) O/50 (0%) Total O/100 (0%) Mean 0% Total O/100 (0%) Mean 0% Total O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% Total O/100 (1%) Mean 1% Total O/46 (0%) O/48 (0%) Total O/94 (0%) Mean 0% Total O/94 (0%) O/48 (0%) Total O/94 (0%) O/48 (0%)	Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% 0/46 (0%) 0/48 (0%) Total 0/94 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0% Total 0/94 (0%) Mean 0% SD 0%	Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total O/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/46 (0%) 0/48 (0%) Total 0/94 (0%) Mean 0% SD 0% Total O/46 (0%) 0/48 (0%) Total 0/94 (0%) Mean 0% SD 0% Total	ma or Papilloma Squamous	ma or Papilloma Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% a 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% 0/46 (0%) 0/48 (0%) SD 0% Total 0/99 (0%) 0/50 (0%) Total 0/94 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% Total 0/94 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% Total 0/94 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% Total 0/94 (0%) 0/48 (0%) Total 0/99 (0%) Mean 0% Total 0/94 (0%) 0/48 (0%) Total 0/99 (0%) Mean 0% Total 0/94 (0%) 0/48 (0%) Total 0/99 (0%) Mean 0% Total 0/94 (0%) 0/48 (0%) SD 0% Total 0/99 (0%) Mean 0% Total 0/94 (0%) 0/48 (0%) SD 0% Total 0/99 (0%) 0/50 (0%) Total 0/94 (0%) 0/48 (0%) SD 0% Total 0/99 (0%) 0/50 (0%)					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
	-	11/50 (22%)	8/50 (16%)	05 4 0 40/	-	9/50 (18%)	16/50 (32%)	00.000
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 4.24%	Total	25/100 (25%)	Mean 25%	SD 9.9%
*Thyroid Gland: C-Cell: Carcinoma		4/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		11/50 (22%)	8/50 (16%)			9/50 (18%)	16/50 (32%)	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 4.24%	Total	25/100 (25%)	Mean 25%	SD 9.9%
*Thyroid Gland: Follicular Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:							
Occupation of decision	T-1-1	0/50 (0%)	2/50 (4%)	00.000/	T-1-1	0/50 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			Female						
#Tissue NOS: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Tongue: Squamous Cell Carcinoma												
	.	0/50 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Tongue: Squamous Cell Carcinoma	or Papillom	a Squamous 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Urinary Bladder: Leiomyosarcoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
#Uterus: Adenocarcinoma												
Overell In eldense					Tatal	2/50 (4%)	2/50 (4%)	CD 00/				
Overall Incidence					Total	4/100 (4%)	Mean 4%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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	Male			Female	
#Uterus: Adenocarcinoma or Adenoma					
Overall Incidence		Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%
#Uterus: Adenoma			0/50 (0%)		
Overall Incidence		Total	2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq	Cell Papilloma		4/50 (00%)	(D)	
Overall Incidence		Total	4/50 (8%) 8/100 (8%)	4/50 (8%) Mean 8%	SD 0%
#Uterus: Deciduoma Benign			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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	Male			Female	
#Uterus: Polyp Stromal					
Overall Incidence		Total	9/50 (18%) 11/100 (11%)	2/50 (4%) Mean 11%	SD 9.9%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal				(00)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal			0/50 /499/\	2/50 (49/)	
Overall Incidence		Total	9/50 (18%) 11/100 (11%)	2/50 (4%) Mean 11%	SD 9.9%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sq Cell Carcinoma or Papilloma Squamous					
Overall Incidence		Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

Page: 173

	Male			Female	
#Uterus: Squamous Cell Carcinoma					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Squamous Cell Papilloma					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Vagina: Granular Cell Tumor Benign			0(50 (00))	0/50 (00)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Polyp			0/50 (0%)	0/50 (00/)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Zymbal's Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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Report Date: 10/05/2022

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
I. I. T. Research Institute	052010556	09/16/12	730	90(1)	25(642)	658.1	Radiofrequency Radiation
					Female		
I. I. T. Research Institute	052010556	09/16/12	737	90(1)	48(659)	462.4	Radiofrequency Radiation

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
		49/90 (54%)				82/90 (91%)		
Overall Incidence	Total	49/90 (54.44%)	Mean 54.44%	SD 0%	Total	82/90 (91.11%)	Mean 91.11%	SD 0%
#All Organs: Malignant Tumors								
		24/90 (27%)				37/90 (41%)		
Overall Incidence	Total	24/90 (26.67%)	Mean 26.67%	SD 0%	Total	37/90 (41.11%)	Mean 41.11%	SD 0%
#All Organs: Malignant and Benign T	umors	57/90 (63%)				89/90 (99%)		
Overall Incidence	Total	57/90 (63.33%)	Mean 63.33%	SD 0%	Total	89/90 (98.89%)	Mean 98.89%	SD 0%
#All Organs: Hemangioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		0/00 /00/)						
Overall Incidence	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%
#All Organs: Hemangiosarcoma or H	emangioma	2/00 /22/				2/00 (20/)		
Overall Incidence	Total	` '	Moon 3 220/	SD 0%	Total	` ,	Moon 2 220/	SD 00/
Overall Incidence	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male	Female				
#All Organs: Histiocytic Sarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic								
-		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M	lonocytic, M	ononuclear, or Undifference 0/90 (0%)	entiated			0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
		` '						
#All Organs: Malignant Lymphoma: Hist	tiocytic, Lym	phocytic, Mixed, NOS, o	or Undifferentiated Ce	II Туре	Total	5/90 (6%) 5/90 (5.56%)	Mean 5 56%	SD 0%
#All Organs: Malignant Lymphoma: Hist		phocytic, Mixed, NOS, o			Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%
#All Organs:	tiocytic, Lym	phocytic, Mixed, NOS, o 2/90 (2%) 2/90 (2.22%)	or Undifferentiated Ce	II Туре	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
#All Organs: Malignant Lymphoma: Hist Dverall Incidence #All Organs: Malignant Schwannoma	tiocytic, Lym Total	2/90 (2%) 2/90 (2.22%) 3/90 (3%)	or Undifferentiated Ce Mean 2.22%	II Type SD 0%		5/90 (5.56%) ´ 4/90 (4%)		
#All Organs: Malignant Lymphoma: Hist Dverall Incidence #All Organs: Malignant Schwannoma	tiocytic, Lym	phocytic, Mixed, NOS, o 2/90 (2%) 2/90 (2.22%)	or Undifferentiated Ce	II Туре	Total Total	5/90 (5.56%)	Mean 5.56% Mean 4.44%	SD 0% SD 0%
#All Organs: Malignant Lymphoma: Hist Overall Incidence #All Organs:	tiocytic, Lym Total Total	2/90 (2%) 2/90 (22%) 2/90 (2.22%) 3/90 (3%) 3/90 (3.33%)	or Undifferentiated Ce Mean 2.22%	II Type SD 0%		5/90 (5.56%) ´ 4/90 (4%)		
#All Organs: Malignant Lymphoma: Hist Overall Incidence #All Organs: Malignant Schwannoma Overall Incidence	tiocytic, Lym Total Total	2/90 (2%) 2/90 (22%) 2/90 (2.22%) 3/90 (3%) 3/90 (3.33%)	or Undifferentiated Ce Mean 2.22%	II Type SD 0%		5/90 (5.56%) ´ 4/90 (4%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#All Organs: Mesothelioma: Malignant								
-		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		1/90 (1%)				1/90 (1%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Adrenal Cortex: Carcinoma								
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Adrenal Medulla: Ganglioneuroma		0/00 /00/				0/00 (00/)		
	-	0/88 (0%)		00.00/	T	0/86 (0%)	14 00/	OD 00/
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: Whole Body Exposure

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Vehicle: AIR

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			Male			Female						
*Adrenal Medulla: Pheochromocytoma Benign												
	3	10/88 (11%)				1/86 (1%)						
Overall Incidence	Total	10/88 (11.36%)	Mean 11.36%	SD 0%	Total	1/86 (1.16%)	Mean 1.16%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Com												
•	•	1/88 (1%)				0/86 (0%)						
Overall Incidence	Total	1/88 (1.14%)	Mean 1.14%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Mali	gnant	1/88 (1%)				0/86 (0%)						
Overall Incidence	Total	1/88 (1.14%)	Mean 1.14%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: Ben						1/86 (1%)						
Overall Incidence	Total	11/88 (12.5%)	Mean 12.5%	SD 0%	Total	1/86 (1.16%)	Mean 1.16%	SD 0%				
#Bone: Osteosarcoma												
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma or Osteom	na	0/00 (00)				0/00 /00/						
O	T-1-1	0/90 (0%)	M 00/	OD 00/	T-1-1	0/90 (0%)	Maran 00/	OD 00/				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male			Female				
*Brain: Glioma Malignant										
· ·		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
*Brain: Granular Cell Tumor Beni	gn									
	•	1/90 (1%)				1/90 (1%)				
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%		
*Brain: Granular Cell Tumor Maliç	gnant	0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
*Brain: Meningioma Benign		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
*Brain: Meningioma Malignant										
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
	ı Ulai	0/30 (0/0)	IVICALI U/0		ıvlai	0/30 (0/0)	IVICALI U/0			
*Brain: Meningioma: Benign, Mal	ignant, NOS									
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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				Male				Female	
*Brain: Oligodendroglioma Malign	nant	0/00	(00()				0/00 /00/		
Overall Incidence	Total	0/90 0/90 (0%)	(0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	toma					•••••		
Overall Incidence	Total	0/90 0/90 (0%)	(0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/90	(0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	` ,	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma Overall Incidence	Total		(0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma									
Overall Incidence	Total	0/88 0/88 (0%)	(0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/88	(0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	(570)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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				Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		2/22					0/0= /00/		
Overall Incidence	Total	0/88 (0%)		Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Papilloma			0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	,	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma		0/90 ((0%)						
Overall Incidence	Total	0/90 (0%)	,	Mean 0%	SD 0%				
#Eye: Leiomyoma		0/90 ((0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	,	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant							0/00 (00)		
Overall Incidence	Total	0/90 (0%)	0%) !	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma		0/90 ((0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	•	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Intestine Large: Cecum: Liposarcoma								
•		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/R Granular Cell Tumor Be								
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Large: Colon/R Leiomyoma	ectum:							
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum Carcinoma	1:							
		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum Leiomyosarcoma	n:							
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Small: Site Uns Carcinoma	pecified:							
		2/90 (2%)				0/90 (0%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: Carcinoma or Adenoma 2/90 (2%)0/90 (0%)**Overall Incidence** Total 2/90 (2.22%) Mean 2.22% SD 0% Total 0/90 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Leiomyosarcoma 0/90 (0%)1/90 (1%) **Overall Incidence** Total 0/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) Mean 1.11% SD 0% *Islets, Pancreatic: Adenoma 5/90 (6%)5/90 (6%)**Overall Incidence** Total 5/90 (5.56%) Mean 5.56% SD 0% Total 5/90 (5.56%) Mean 5.56% SD 0% *Islets, Pancreatic: Carcinoma 8/90 (9%)2/90 (2%)**Overall Incidence** Total Mean 8.89% SD 0% Total 2/90 (2.22%) Mean 2.22% SD 0% 8/90 (8.89%) *Islets, Pancreatic: Carcinoma or Adenoma 13/90 (14%)7/90 (8%)**Overall Incidence** Total 13/90 (14.44%) Mean 14.44% SD 0% Total 7/90 (7.78%) Mean 7.78% SD 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/90 (0%)0/90 (0%)

SD 0%

Total

0/90 (0%)

Total

0/90 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		3/90 (3%)				1/90 (1%)		
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
······								
*Kidney: Renal Tubule: Carcinoma or Adenoma		3/90 (3%)				2/90 (2%)		
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Oncocytoma Benign								
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Polyp Adenomatous		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Lacrimal Gland: Carcinoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma	Tatal	0/90 (0%)	Mana 00/	CD 00/	Tatal	0/90 (0%)	Mann 00/	CD 0W
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/90 (0%)				7/90 (8%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	7/90 (7.78%)	Mean 7.78%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

Page: 187

			Male				Female	
*Liver: Hepatocellular Carcino	ma							
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcino		estoma						
nepatocential Carcinol	па от перасовіа	0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinol Overall Incidence	ma or Hepatoce	Ilular Adenoma 0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	7/90 (8%) 7/90 (7.78%)	Mean 7.78%	SD 0%
*Liver: Hepatocellular Carcino	ma, Hepatocellu Total	lar Adenoma, or Hepato 0/90 (0%) 0/90 (0%)	oblastoma Mean 0%	SD 0%	Total	7/90 (8%) 7/90 (7.78%)	Mean 7.78%	SD 0%
*Lung: Alveolar/Bronchiolar Ad			wear 070		·····			GD 070
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	arcinoma	0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Lung: Alveolar/Bronchiolar Car	cinoma or Alv	eolar/Bronchiolar Adeno 1/90 (1%)	ma			0/90 (0%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		(52)				(40)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	8/90 (9%) 8/90 (8.89%)	Mean 8.89%	SD 0%
#Mammary Gland: Carcinoma		0/90 (0%)				10/90 (11%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	10/90 (11.11%)	Mean 11.11%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	16/90 (18%) 16/90 (17.78%)	Mean 17.78%	SD 0%
#Mammary Gland: Fibroadenoma		0/00 /(551)				00/00 (700)		
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	63/90 (70%) 63/90 (70%)	Mean 70%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

: 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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Mammary Gland: Fibroma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenon	na or Adenoma							
		2/90 (2%)				64/90 (71%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	64/90 (71.11%)	Mean 71.11%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom Overall Incidence	na, Carcinoma, or Total	Adenoma 2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	66/90 (73%) 66/90 (73.33%)	Mean 73.33%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar							
Squamous Cell Carcin		0/90 (0%)				2/90 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
Overall Incidence #Oral Cavity (Oral Mucos	Total sa, Tongue, Phar	0/90 (0%)	Mean 0%	SD 0%	Total	` '	Mean 2.22%	SD 0%
Overall Incidence #Oral Cavity (Oral Mucos	Total sa, Tongue, Phar	0/90 (0%) ynx, Tooth, Gingiva): Squamous, or Papilloma	Mean 0% Mean 0%	SD 0%	Total Total	2/90 (2.22%)	Mean 2.22% Mean 2.22%	SD 0%
Overall Incidence #Oral Cavity (Oral Mucos Squamous Cell Carcin	Total sa, Tongue, Phar oma, Papilloma S	0/90 (0%) ynx, Tooth, Gingiva): Squamous, or Papilloma 0/90 (0%)				2/90 (2.22%) 2/90 (2%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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	Male		Female				
*Ovary: Cystadenoma							
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%		
*Ovary: Granulosa Cell Tumor Benign							
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%		
*Ovary: Granulosa Cell Tumor Malignant							
Overall Incidence		Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%		
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS							
Overall Incidence		Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%		
*Ovary: Granulosa-Theca Tumor Benign							
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
*Ovary: Granulosa-Theca Tumor Malignant							
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female		
*Ovary: Luteoma									
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
*Ovary: Schwannoma Malignant							•••••		
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
*Ovary: Sertoli Cell Tumor Benign									
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
*Ovary: Thecoma Benign									
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	18/90 (20%) 18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
*Pancreas: Carcinoma									
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: Whole Body Exposure

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Vehicle: AIR

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			Male				Female	
*Pancreas: Carcinoma or Adenoma								
		18/90 (20%)				0/90 (0%)		
Overall Incidence	Total	18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	1/83 (1%) 1/83 (1.2%)	Mean 1.2%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma		0/00 (00/)				0/00 /0%		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignant		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mal								
_		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma		ified Site:						
		17/89 (19%)				43/90 (48%)		
Overall Incidence	Total	17/89 (19.1%)	Mean 19.1%	SD 0%	Total	43/90 (47.78%)	Mean 47.78%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

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Report Date: 10/05/2022

Contract/Lab: All Laboratories

Strain: Harlan Sprague-Dawley

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: Whole Body Exposure

Length of Study: CHRONIC

Vehicle: AIR

Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/89 (0%)1/90 (1%)**Overall Incidence** Total 0/89 (0%) Mean 0% SD 0% Total 1/90 (1.11%) SD 0% Mean 1.11% *Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 17/89 (19%)44/90 (49%)**Overall Incidence** Total 17/89 (19.1%) Mean 19.1% SD 0% Total 44/90 (48.89%) Mean 48.89% SD 0% *Pituitary Gland: Pars Intermedia: Adenoma 0/89 (0%)0/90 (0%)Overall Incidence Total 0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/89 (0%)0/90 (0%)**Overall Incidence** Total 0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% *Pituitary Gland: Pars Nervosa: **Schwannoma Malignant** 0/89 (0%)0/90 (0%)**Overall Incidence** Total 0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0%

*Prostate:

Adenoma

2/90 (2%)

Overall Incidence Total 2/90 (2.22%) Mean 2.22% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Prostate: Carcinoma or Adenoma		2/90 (2%)						
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%				
*Salivary Glands: Schwannoma Malignant		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Hemangiosarcoma		0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma		0/00 (00/)				0(00 (00))		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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			Male				Female			
#Skeletal Muscle: Sarcoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin:			•••••	•••••						
Basal Cell Adenoma		1/90 (1%)				0/90 (0%)				
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma or B	•	1/90 (1%)	Maria 4 440/	CD 00/	Tatal	0/90 (0%)	Mana 00/	CD 00/		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Adenoma, Bas	osquamous T	umor Benign, or Trichoe 1/90 (1%)	pithelioma			0/90 (0%)				
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin: Basal Cell Carcinoma or										
		0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
		1/90 (1%)				0/90 (0%)					
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin:											
		a, Basosq. Tumor (M or ratoacanthoma, Trichoe		na,							
		8/90 (9%)				0/90 (0%)					
Overall Incidence	Total	8/90 (8.89%)	Mean 8.89%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Fibroma											
		2/90 (2%)				2/90 (2%)					
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%			
#Skin:		oma, Myxosarcoma, Ma									
Overall Incidence	Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%			
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or 1 5/90 (6%)	Malignant Fibrous His	tiocytoma		5/90 (6%)					
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%			
#Skin: Fibrosarcoma											
		1/90 (1%)				0/90 (0%)					
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: Whole Body Exposure

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Vehicle: AIR

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			Male			Female					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma											
		3/90 (3%)				3/90 (3%)					
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%			
#Skin: Hemangioma											
		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiopericytoma		0/00 /00/				0/00 (00/)					
Overall Incidence	Total	0/90 (0%)	Maan Oo/	CD 00/	Total	0/90 (0%)	Maan Ol/	SD 0%			
Overall incluence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Keratoacanthoma		5/90 (6%)				0/90 (0%)					
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Lipoma											
Overell Insidence	Tatal	2/90 (2%)	Mana 0 000/	CD 00/	Tatal	0/90 (0%)	Mana 00/	CD 00/			
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Liposarcoma		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Overall Incidence

Overall Incidence

Overall Incidence

Osteosarcoma

Overall Incidence

.....

Contract/Lab: All Laboratories

Species: RATS

#Skin:

#Skin:

#Skin:

#Skin:

#Skin:

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Malignant Fibrous Histiocytoma

Total

Total

Total

Total

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Male **Female** (0%)1/90 (1%)0/90 (0%) Mean 0% SD 0% Total 1/90 (1.11%) SD 0% Mean 1.11% Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/90 (0%)0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) (0%)0/90 (0%)0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% (0%)0/90 (0%)0/90 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/90 (0%)

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Report Date: 10/05/2022

Pilomatrixoma

0/90 (0%)0/90 (0%)

0/90

0/90

0/90

Overall Incidence Total 0/90 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0%

#Skin:

Sarcoma

2/90 (2%)2/90 (2%)Total 2/90 (2.22%) Mean 2.22% SD 0% 2/90 (2.22%)

Overall Incidence Mean 2.22% SD 0% Total

*: Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Skin: Schwannoma Malignant								
	T	0/90 (0%)		OD 00/	+	0/90 (0%)		00.007
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma	1	0/00 /00/				0/00 /00/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma Overall Incidence	a, Basal Cell (Carcinoma, Basosquamo 0/90 (0%) 0/90 (0%)	ous Tumor (malignant	e or NOS),	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		2/90 (2%)				0/90 (0%)		
	Tatal	0/00 /0 000/\	M 0 000/	OD 00/				
	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma		íííí					Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma						0/90 (0%) 0/90 (0%) 0/90 (0%)	Mean 0% Mean 0%	SD 0%
#Skin:	or Papilloma Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%		0/90 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: RATS

Route: Whole Body Exposure

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

Vehicle: AIR

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			Male				Female				
#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 7/90 (8%) 0/90 (0%)											
Overall Incidence	Total	7/90 (7.78%)	Mean 7.78%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Trichoepithelioma		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma						2(22)					
Overall Incidence	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		1/90 (1%)				0/90 (0%)					
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
*Spleen: Hemangiosarcoma											
Overall Incidence	Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%			
#Stomach, Forestomach: Sarcoma		0/00 (00/)				4/00 (400)					
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

t2022 Toxicology Data

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: Whole Body Exposure

Vehicle: AIR

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		Male				Female					
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous											
	1/90 (1%)				0/90 (0%)						
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
a											
	1/90 (1%)				0/90 (0%)						
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
T-1-1	` ,	Maran 0.000/	OD 00/								
	, ,		SD 0%								
	0/88 (0%)				1/87 (1%)						
Total	0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1.15%)	Mean 1.15%	SD 0%				
							•••••				
	0/88 (0%)				1/87 (1%)						
Total	0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1.15%)	Mean 1.15%	SD 0%				
ınant, NOS	0/00 /(00/)				0/07 /00/						
Total	` ,	Moon 0%	SD 0%	Total	` '	Moon 2.3%	SD 0%				
	Total Total Total Total	1/90 (1%) Total 1/90 (1.11%) a	Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% Total 1/90 (1.11%) Mean 1.11% 2/90 (2%) Total 2/90 (2.22%) Mean 2.22% O/88 (0%) Total 0/88 (0%) Mean 0% Total 0/88 (0%) Mean 0% O/88 (0%) Total 0/88 (0%) Mean 0%	Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% a	Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total a	Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Total 0/90 (0%) Total 0/90 (0%) Total 0/90 (0%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Total 0/90 (0%) Total 0/90 (0%) Total 0/90 (2%) Total 2/90 (2.22%) Mean 2.22% SD 0% Total 1/87 (1%) Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 0% SD 0% Total 1/87 (1.15%)	Total 1/90 (1%) Total 1/90 (11%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Mean 0% Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Mean 0% Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Mean 0% Total 1/90 (2%) Total 2/90 (2%) Mean 2.22% SD 0% Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1%) Mean 1.15% Mean 1.15%	Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total 0/90 (0%) Total 1/90 (1.11%) Mean 0.11% SD 0% Total 1/90 (1%) Total 1/90 (1.11%) Mean 1.11% SD 0% Total 1/90 (1.11%) Mean 1.11% SD 0% Total 1/90 (2%) Total 2/90 (2%) Total 2/90 (2.22%) Mean 2.22% SD 0% Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 1.15% SD 0% Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 1.15% SD 0% Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 1.15% SD 0% Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 1.15% SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
*Thyroid Gland: C-Cell: Adenoma								
		8/89 (9%)				6/90 (7%)		
Overall Incidence	Total	8/89 (8.99%)	Mean 8.99%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
		2/89 (2%)				0/90 (0%)		
Overall Incidence	Total	2/89 (2.25%)	Mean 2.25%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		10/89 (11%)				6/90 (7%)		
Overall Incidence	Total	10/89 (11.24%)	Mean 11.24%	SD 0%	Total	6/90 (6.67%)	Mean 6.67%	SD 0%
*Thyroid Gland: Follicular Cel Adenoma		0/89 (0%)				0/90 (0%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma								
		0/89 (0%)				1/90 (1%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	l:	0/00 /05**				4/00 (40%)		
	-	0/89 (0%)		OD 00/	.	1/90 (1%)		OD 00/
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Tissue NOS: Schwannoma Malignant								
_		1/90 (1%)				1/90 (1%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tongue: Squamous Cell Carcinoma		2/22 (221)				(101)		
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tongue: Squamous Cell Carcinoma	-	0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Tooth: Odontoma		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
		0/89 (0%)				1/88 (1%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/88 (1.14%)	Mean 1.14%	SD 0%
#Uterus: Adenocarcinoma								
Overall Incidence								
*: Denominator is number of animals								

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley **Length of Study:** CHRONIC

#: Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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	Male	Female
#Uterus: Adenocarcinoma or Adenoma		
Overall Incidence		
#Uterus: Adenoma		
Overall Incidence		
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcir	noma, or Sq Cell Papilloma	
Overall Incidence		
#Uterus: Deciduoma Benign		
Overall Incidence		
#Uterus: Granular Cell Tumor Benign		
Overall Incidence		
#Uterus: Hemangioma		
Overall Incidence		
*: Denominator is number of animals with tissues exam	nined microscopically	

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: Whole Body Exposure

Vehicle: AIR

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	Male	Female
#Uterus: Polyp Stromal		
Overall Incidence		
#Uterus: Sarcoma		
Overall Incidence		
#Uterus: Sarcoma Stromal		
Overall Incidence		
#Uterus: Sarcoma Stromal or Polyp Stromal		
Overall Incidence		
#Uterus: Schwannoma Malignant		
Overall Incidence		
#Uterus: Sq Cell Carcinoma or Papilloma Squamous		
Overall Incidence		
*: Denominator is number of animals with tissues examined #: Denominator is number of animals necropsied		

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: Whole Body Exposure

Vehicle: AIR

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Male			Female	
#Uterus: Squamous Cell Carcinoma				
Overall Incidence				
#Uterus: Squamous Cell Papilloma				
Overall Incidence				
#Vagina: Granular Cell Tumor Benign		0/00 /00/		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Vagina:				
Polyp		0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma				
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Vagina:				
Schwannoma Malignant		1/90 (1%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Zymbal's Gland: Adenoma		0/90 (0%)				0/00 (00/)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied