

NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

December 2020

REPORT DESCRIPTION

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

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: GAVAGE Vehicle: CORN OIL Page: 4

Report Date: 12/30/2020

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	052000603	03/14/07	727	50(3)	20(644)	584.8	Indole-3-carbinol			
Female Female										
Battelle Columbus Laboratory	052000603	03/15/07	729	50(5)	21(637)	353.0	Indole-3-carbinol			

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female					
#All Organs: Benign Tumors												
· ·		27/50 (54%)				40/50 (80%)						
Overall Incidence	Total	27/50 (54%)	Mean 54%	SD 0%	Total	40/50 (80%)	Mean 80%	SD 0%				
#All Organs: Malignant Tumors												
		12/50 (24%)				19/50 (38%)						
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%				
#All Organs: Malignant and Benign Tu	ımors	33/50 (66%)				46/50 (92%)						
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	46/50 (92%)	Mean 92%	SD 0%				
#All Organs: 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%				
#All Organs: Hemangiosarcoma												
		1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
#All Organs: Hemangiosarcoma or He	emangioma	1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL Report Date: 12/30/2020

Page: 6

			Male				Female					
#All Organs: Histiocytic Sarcoma 0/50 (0%) 1/50 (2%)												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
#All Organs: Leukemia: Granulocytic		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: Leukemia: Lymphocytic, M	lonocytic, Mo	nonuclear, or Undifference 0/50 (0%)	entiated			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: Hist						0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#All Organs: Malignant Schwannoma												
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%				
#All Organs: Mesothelioma: Benign, Ma		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

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Mesothelioma: Malignant								
_		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 Osteom	a	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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Carcinoma		` '				` '		
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

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female					
*Adrenal Medulla: Pheochromocytoma Benign												
•	-	5/50 (10%)				0/50 (0%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Co												
		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 Ma	alignant	2/50 (4%)				0/50 (0%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: B						0/50 (0%)						
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	0/50 (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

#: Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 9

	Male	Female
*Brain: Glioma Malignant		
Overall Incidence		
*Brain: Granular Cell Tumor Benign		
Overall Incidence		
*Brain: Granular Cell Tumor Malignant		
Overall Incidence		
*Brain: Meningioma Benign		
Overall Incidence		
*Brain: Meningioma Malignant		
Overall Incidence		
*Brain: Meningioma: Benign, Malignant, NOS		
Overall Incidence		
*: Denominator is number of animals with tissues examined micro	oscopically	

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 10

			Male				Female	
*Brain: Oligodendroglioma, Glioma,	, or Astrocy	toma						
Overall Incidence								
*Brain: Schwannoma Malignant								
Overall Incidence								
*Clitoral/Preputial 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%
*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								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma	• • • • • • • • • • • • • • • • • • • •							
	Total	0/50 (0%)	Maan 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%

^{*:} 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: GAVAGE Vehicle: CORN OIL Page: 11

				Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		,							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma	••••								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma		0/50	(00/)				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant			(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Liposarcoma									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	um:								
Overall Incidence	Total	0/50 0/50 (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

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 12

			Male			0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% otal 0/50 (0%) otal 0/50 (0%) Mean 0% SD 0% otal 0/50 (0%) otal 0/50 (0%) otal 0/50 (0%) Otal 0/50 (0%)							
#Intestine Large: Colon/Rectum: Leiomyoma													
•		0/50 (0%)				0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total			SD 0%					
#Intestine Small: Jejunum: Carcinoma													
		0/50 (0%)				` '							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%					
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)				0/50 (09/)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%					
#Intestine Small: Site Unspec Carcinoma		0/50 (0%)	Mean 0%	SD 0%	Total	` '	Magn 00/	SD 00/					
		0/50 (0%)		3D 0%		0/50 (0%)	wean 0%	טט טא טא					
#Intestine Small: Site Unspec 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 Unspec 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%					

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 13

			Male				Female	
*Islets, Pancreatic: Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: 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%
*Islets, Pancreatic: Carcinoma or Adenoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transition Papilloma						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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%) 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: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	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 (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%
*Kidney: Renal Tubule: Liposarcoma 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: Nephroblastoma								
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: 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%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 15

			Male				Female	
*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: Cholangiocarcinoma		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%
*Liver: Hemangioma		0/50 (0%)		35 0%		0/50 (0%)	ivicali 078	35 0%
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		1/50 (2%)				2/50 (4%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	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: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male				Female				
*Liver: Hepatocellular Carcinoma 0/50 (0%) 0/50 (0%)											
•		0/50 (0	1%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcino	ma or Hepatobla	stoma									
)%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocellular Carcino	ma or Hepatocell		%) Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%			
Overall Incidence		, ,			Total	2/50 (4%)	IVICALI 470	3D 0%			
*Liver: Hepatocellular Carcinol Overall Incidence	ma, Hepatocellul	ar Adenoma, or He 1/50 (2 1/50 (2%)	epatoblastoma %) Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%			
*Liver:	ma, Hepatocellul Total	ar Adenoma, or Ho 1/50 (2 1/50 (2%)	epatoblastoma %) Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%				
*Liver: Hepatocellular Carcinol Overall Incidence *Lung: Alveolar/Bronchiolar Ad	ma, Hepatocellul Total	ar Adenoma, or Ho 1/50 (2 1/50 (2%)	epatoblastoma %) Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%				
*Liver: Hepatocellular Carcino Overall Incidence *Lung:	ma, Hepatocellul Total denoma Total	ar Adenoma, or Ho 1/50 (2 1/50 (2%) 0/49 (0 0/49 (0%)	epatoblastoma 1%) Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%) 1/50 (2%)	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: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
*Lung: Alveolar/Bronchiolar Carc	inoma or Alve							
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Lung: Sarcoma								
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Lung: Squamous Cell Carcinoma	a	0/49 (0%				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		1/50 (2%				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma								
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: Adenoma		0/50 /00//				2/50 (69/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	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: GAVAGE Vehicle: CORN OIL Report Date: 12/30/2020

Page: 18

				Male				Female	
#Mammary Gland: Carcinoma									
		0/50	(0%)				3/50 (6%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Carcinoma or Adenoma									
		0/50	(0%)				6/50 (12%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%
#Mammary Gland: Fibroadenoma		4/50	(00()				00/50 /500/		
Occasional Investment	T-1-1		(2%)	M 00/	OD 00/	T-1-1	29/50 (58%)	Maran 500/	OD 00/
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	29/50 (58%)	Mean 58%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or A	Adenoma								
		1/50	(2%)				30/50 (60%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	30/50 (60%)	Mean 60%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, Ca									
		1/50	(2%)				32/50 (64%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Myoepithelioma		- /							
			(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: GAVAGE Vehicle: CORN OIL **Page:** 19

			Male				Female	
*Nose: Carcinoma		0/50 (001)				0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine		nx, Tooth, Gingiva):						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phary	nx, Tooth, Gingiva): quamous, or Papilloma 1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcine	oma	1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign					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

Contract/Lab: All Laboratories

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

	Male			Female	
*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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign			4/50 (00)		
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: 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: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male			Female			
*Ovary: Sertoli Cell Tumor Benign									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Thecoma Benign									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Tubulostromal Carcinoma									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
*Pancreas: Adenoma									
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Pancreas: 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%	
		` '				' '			
*Pancreas: Carcinoma or Adenoma		5/50 (10%)				0/50 (0%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	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: GAVAGE Vehicle: CORN OIL Page: 22

			Male				Female	
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/43 (0%) 0/43 (0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma								
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, Ma		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 Distal Adenoma							•••••	
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Distal 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%

^{*:} 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: GAVAGE

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

Vehicle: CORN OIL

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			Male				Female	
*Pituitary Gland: Pars Distali Carcinoma or Adenoma	is or Unspeci	fied Site:						
		5/50 (10%)				18/50 (36%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Interm 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 Interm Carcinoma or Adenoma	edia:	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Nervos Schwannoma Malignant	sa:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma								
		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)						
Overall Incidence	Total	, ,	Mean 0%	SD 0%				
Overan incidence	างเลเ	0/50 (0%)	iviean 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: GAVAGE Vehicle: CORN OIL Page: 24

			Male				Female	
*Salivary Glands: Schwannoma Malignant		4/50 (00())				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%
#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%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Liposarcoma Overall Incidence		0/50 (0%)			Total	0/50 (0%)	Mann 00/	SD 00/
Overall incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 (00/)				4/50 (00/)		
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: 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%

^{*:} 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: GAVAGE Vehicle: CORN OIL

Control Animal Groups Report Date: 12/30/2020

Page: 25

			Male				Female		
#Skin:									
Basal Cell Adenoma or I	Basosquamous	_				0/50 (001)			
		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, Ba	sosquamous Ti	umor Benign, or Trich	oepithelioma						
		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 Carcinoma									
Zuoui Con Curomoma		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:									
Basal Cell Carcinoma or	r Basosquamou	s Tumor (malignant or	r NOS)						
	-	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:									
Basal Cell Carcinoma, B	Basal Cell Adenc	oma, Basosquamous 1	Tumor (benign, malign	ant or					
NOS), or Trichoepithelio	oma	•	, , ,						
		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:									
Basal or Sq. Cell Carcine	oma, Carcinoma	a, Basosg. Tumor (M c	or B), Basal Cell Adeno	oma,					
Adenoma, Papilloma, So				,					
		6/50 (12%)				0/50 (0%)			
Overall Incidence	Total	6/50 (12%)	Mean 12%	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

Species: RATS

Toxicology Data Management System

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

Route: GAVAGE

Route: GAVAGE Vehicle: CORN OIL **Page:** 26

Report Date: 12/30/2020

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

			Male				Female	
#Skin: Fibroma								
		5/50 (10%)				1/50 (2%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:								
	a, Sarcoma, Myxo	oma, Myxosarcoma, Mali	gnant Fibrous Histio	cytoma, or				
		7/50 (14%)				2/50 (4%)		
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or M 7/50 (14%)	alignant Fibrous His	tiocytoma		2/50 (4%)		
Overall Incidence	Total	7/50 (1/0/)	Moon 149/	SD 00/	Total	2/50 (49/)	Moon 49/	SD 00/
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Fibrosarcoma	Total		Mean 14%	SD 0%	Total		Mean 4%	SD 0%
#Skin: Fibrosarcoma	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%) 1/50 (2%) 1/50 (2%)	Mean 4% Mean 2%	SD 0% SD 0%
#Skin: Fibrosarcoma Overall Incidence #Skin:	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)		
#Skin: Fibrosarcoma Overall Incidence #Skin:	Total	1/50 (2%) 1/50 (2%) , or Malignant Fibrous H	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)		
#Skin: Fibrosarcoma Overall Incidence #Skin:	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)		
#Skin: Fibrosarcoma Overall Incidence #Skin: Fibrosarcoma, Sarcom	Total na, Myxosarcoma	1/50 (2%) 1/50 (2%) , or Malignant Fibrous Hi	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma Overall Incidence #Skin: Fibrosarcoma, Sarcom Overall Incidence #Skin:	Total na, Myxosarcoma	1/50 (2%) 1/50 (2%) , or Malignant Fibrous Hi	Mean 2%	SD 0%	Total	1/50 (2%) 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: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
#Skin: Hemangiopericytoma		0/50 /00/\				0/50 (09/)		
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: Hemangiosarcoma		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: 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: 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%
#Skin: Liposarcoma	Total	0/50 (0%)				0/50 (0%)	Modif 070	32 0%
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histion	cytoma	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

Contract/Lab: All Laboratories

Species: RATS

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

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 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: Neurofibrosarcoma, Neu	rofibroma, or S	chwannoma (benign, m 0/50 (0%)	alignant or NOS)			1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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		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											
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: 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%			

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

^{#:} Denominator is number of animals necropsied

#Skin:

#Skin:

#Skin:

#Skin:

#Skin:

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female Squamous Cell Carcinoma** 1/50 (2%)0/50 (0%)Total Total 1/50 (2%) Mean 2% SD 0% 0/50 (0%) SD 0% Overall Incidence Mean 0% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma (0%)2/50 (4%)0/50 Mean 4% Mean 0% **Overall Incidence** Total 2/50 (4%) SD 0% Total 0/50 (0%) SD 0% **Squamous Cell Papilloma** (0%) 1/50 (2%)0/50 Overall Incidence Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% **Squamous Cell Papilloma or Papilloma** 1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0% SD 0% Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma

.....

5/50 (10%) 0/50 (0%)**Overall Incidence** Total 5/50 (10%) Mean 10% SD 0% Total 0/50 (0%)

#Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 5/50 (10%)0/50 (0%)

Overall Incidence Total 5/50 (10%) Mean 10% SD 0% Total 0/50 (0%) Mean 0% SD 0%

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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: GAVAGE Vehicle: CORN OIL **Page:** 30

			Male				Female	
#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		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: 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%
#Spinal Cord: Astrocytoma 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%
*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		0/50 (0%)				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%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 31

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma	ı							
-		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		3/49 (6%)						
Overall Incidence	Total	3/49 (6.12%)	Mean 6.12%	SD 0%				
*Thymus: Thymoma Benign								
_		1/46 (2%)				0/47 (0%)		
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/46 (00/)				0/47 (00/)		
Overall Incidence	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	Total	0/47 (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: GAVAGE Vehicle: CORN OIL Report Date: 12/30/2020

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			Male				Female				
*Thymus: Thymoma: Benign, Malignant, NOS											
Occupation of the second	T-1-1	1/46 (2%)	Mara 0.470/	00,000	T-1-1	0/47 (0%)	M 00/	00.00/			
Overall Incidence	Total	1/46 (2.17%)	Mean 2.17%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%			
*Thyroid Gland: C-Cell: Adenoma											
		13/50 (26%)				11/49 (22%)					
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22.45%)	Mean 22.45%	SD 0%			
*Thyroid Gland: C-Cell: 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%			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma											
		13/50 (26%)				11/49 (22%)					
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	11/49 (22.45%)	Mean 22.45%	SD 0%			
*Thyroid Gland: Follicular Ce Adenoma											
		0/50 (0%)				0/49 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
*Thyroid Gland: Follicular Ce 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%			

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 33

				Male				Female			
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%		
#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	(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 c		a Squamous					0/50 (00/)				
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Tooth: Odontoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Urinary Bladder: Leiomyosarcoma		0/50	(00/)				0/40 /09/				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (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: GAVAGE Vehicle: CORN OIL **Page:** 34

Male			Female	
#Uterus: Adenocarcinoma				
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Adenocarcinoma or Adenoma				
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	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 Papilloma				
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Deciduoma Benign				
Overall Incidence	Total	0/50 (0%) 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%

^{*:} 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: GAVAGE Vehicle: CORN OIL **Page:** 35

	Male		Female				
#Uterus: Hemangioma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Papilloma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Polyp Stromal							
Overall Incidence		Total	10/50 (20%) 10/50 (20%)	Mean 20%	SD 0%		
#Uterus: Sarcoma							
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sarcoma Stromal							
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%		
#Uterus: Sarcoma Stromal or Polyp Stromal							
Overall Incidence		Total	12/50 (24%) 12/50 (24%)	Mean 24%	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: GAVAGE Vehicle: CORN OIL **Page:** 36

	Male		Female				
#Uterus: Schwannoma Malignant			0/50 (00/)				
Overall Incidence	To		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Sq Cell Carcinoma or Papilloma Squamous			0/50 (0%)				
Overall Incidence	To	otal	0/50 (0%)	Mean 0%	SD 0%		
#Uterus: Squamous Cell Carcinoma			0/50 (0%)				
Overall Incidence	To	otal	0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Granular Cell Tumor Benign			0/50 (0%)				
Overall Incidence			0/50 (0%)	Mean 0%	SD 0%		
#Vagina: Polyp							
Overall Incidence	Тс	otal	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
#Vagina: Sarcoma			0/50 (09/)				
Overall Incidence	To	otal	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: GAVAGE Vehicle: CORN OIL **Page:** 37

			Male			Female			
#Vagina: Schwannoma Malignant									
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Zymbal's 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%	
#Zymbal's Gland: 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%	
#Zymbal's Gland: Carcinoma or 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%	

^{*:} 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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Report Date: 12/30/2020

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

Contract/Lab: 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: Benign Tumors								
•		30/50 (60%)				39/50 (78%)		
Overall Incidence	Total	30/50 (60%)	Mean 60%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%
#All Organs: Malignant Tumors								
_		12/50 (24%)				11/50 (22%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	11/50 (22%)	Mean 22%	SD 0%
#All Organs: Malignant and Benign To	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								
		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	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

Contract/Lab: 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%)				0/50 (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%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo Total	3/50 (6%) 3/50 (6%)		SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lym _l	phocytic, Mixed, NOS 0/50 (0%)	S, or Undifferentiated C	ell Type		0/50 (0%)		00.00
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Schwannoma		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Mesothelioma: Benign, Ma	ignant, NOS							
		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

Contract/Lab: 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: Mesothelioma: Malignant										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 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 Osteoma		0/50 (004)				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%		
*Adrenal Cortex: Adenoma		3/50 (6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	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

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			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 Comple												
		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 Maligna	ant	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: Benigr						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 Osteoma		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%				
		0/50 (0%)				` ,		3D 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 2/50 (4%) 1/50 (2%)											
Overell Insidense	Tatal	2/50 (4%)	Mann 40/	CD 00/	Tatal	1/50 (2%)	Mana 20/	CD 00/			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Brain: Granular Cell Tumor Ben	ign	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: Granular Cell Tumor Mali	gnant	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											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Brain: Meningioma: Benign, Ma	lignant, NOS										
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: INHALATION Vehicle: AIR

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				Male				Female				
*Brain: Oligodendroglioma, Glioma, or Astrocytoma												
		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%)	NA 00/	OD 00/	+	0/50 (0%)		OD 00/			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Clitoral/Preputial Gland: Carcinoma												
			(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%			
*Clitoral/Preputial Gland: Squamous Cell Carcinoma			4									
		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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			M	ale			Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		2/52				272 (221)		
Overall Incidence	Total	0/50 (0° 0/50 (0%)	Mean 0%	% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma		1/50 (2'						
Overall Incidence	Total	1/50 (2%)	Mean 29	% SD 0%				
#Eye: Leiomyoma		1/50 (2'	o/ \			0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 29	% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (0'	%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	6 SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Liposarcoma								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	um:	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%

^{*:} 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: 46

				Male				Female	
#Intestine Large: Colon/Rect	um:								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: Leiomyosarcoma		4/50	(20/)				0/50 (0%)		
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec 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%
#Intestine Small: Site Unspec Carcinoma or Adenoma									
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: Site Unspec Leiomyosarcoma			(00()				0/50 (00/)		
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	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: INHALATION Vehicle: AIR

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			Male				Female	
*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						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*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		0/50 /00/				0/50 (00/)		
Occasional descriptions	T-1-1	0/50 (0%)	M 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%

^{*:} 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: 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 (00()				0/50 (00/)		
Overell Insidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
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/)		
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: Nephroblastoma								
		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: Oncocytoma Benign		0/50 (09/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	` '	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: 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: Cholangiocarcinoma		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%
*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 Carcino	ma							
•		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 Carcino	ma or Hepatobla	stoma		•••••		•••••		
Tropatoconalar caronio	ma or moparobia	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 Carcinol Overall Incidence	ma or Hepatocel	lular Adenoma 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Liver: Hepatocellular Carcinol Overall Incidence				SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Ad								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	arcinoma							
		0/50 (0%)		05 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: INHALATION Vehicle: AIR

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				Male				Female	
*Lung: Alveolar/Bronchiolar Carcii	noma or Alve						0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0%) Mean		0% To	otal (()	Mean 0%	SD 0%
*Lung: Sarcoma									
Overall Incidence	Total	0/50 (0%)	0%) Mean	0% SD	0% To		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma		0/50 ((0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean	0% SD	0% To		` '	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma			0%)	•••••			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean			otal (0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma									
Overall Incidence	Total	0/50 (0%)	0%) Mean	0% SD	0% To		0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma									
Overall Incidence	Total	0/50 (0%)	0%) Mean	0% SD	0% To		4/50 (8%) 4/50 (8%)	Mean 8%	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	
#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%	Total	20/50 (40%)	Mean 40%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o		2/50 (4%)				23/50 (46%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	23/50 (46%)	Mean 46%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C		Adenoma 2/50 (4%)				27/50 (54%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	27/50 (54%)	Mean 54%	SD 0%
#Mammary Gland: Myoepithelioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Overall incluence	TULAT	, ,				0/50 (0%)		3D 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		
*Nose: Carcinoma		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%	
#Oral Cavity (Oral Mucos Squamous Cell Carcin		nx, Tooth, Gingiva):							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Cavity (Oral Mucos	sa, Tongue, Phary	rnx, Tooth, Gingiva): equamous, or Papilloma 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Carcin		0/50 (0%)	weall 070	35 0%	·····	0/50 (0%)	inean 070		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Cystadenoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Ovary: Granulosa Cell Tumor	Benign					2/50 /60/			
						3/50 (6%)			

^{*:} 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: 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			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: 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: INHALATION Vehicle: AIR

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			Male				Female	
*Ovary: Sertoli Cell Tumor Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Tubulostromal Carcinoma						0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: 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%
*Pancreas: 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%
*Pancreas: Carcinoma or 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%

^{*:} 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	
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma								
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	lignant, 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%
*Pituitary Gland: Pars Distali Adenoma								
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 Distali Carcinoma	s or Unspeci	fied Site:						
Ja. Jillollia		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	
*Pituitary Gland: Pars Dist	•	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%
*Pituitary Gland: Pars Inte 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%
*Pituitary Gland: Pars Inte Carcinoma or Adenoma		0/50 (09/)				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 Ner Schwannoma Malignant	vosa:							
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 (0%)		05.00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		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		
*Salivary Glands: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (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 (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%	
#Skeletal Muscle: Liposarcoma		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#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 (09/)			
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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Basal Cell Adenoma or	Basosquamous	Tumor 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%
#Skin: Basal Cell Adenoma, Ba								
		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 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 Basosquamous	s Tumor (malignant or N	ios)					
Basal Cell Carcinoma o	r Basosquamous	s Tumor (malignant or N 0/50 (0%)	ios)			1/50 (2%)		
	r Basosquamous Total	` •	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%			` '	Mean 2%	SD 0%
Overall Incidence #Skin: Basal Cell Carcinoma, I	Total	0/50 (0%) 0/50 (0%)	Mean 0%			` '	Mean 2%	SD 0%
Overall Incidence #Skin: Basal Cell Carcinoma, I NOS), or Trichoepithelid	Total Basal Cell Adenooma Total	0/50 (0%) 0/50 (0%) oma, Basosquamous Tu 0/50 (0%) 0/50 (0%)	Mean 0% mor (benign, maligna	ant or	Total	1/50 (2%)	Mean 2% Mean 2%	SD 0% SD 0%
Overall Incidence #Skin: Basal Cell Carcinoma, I NOS), or Trichoepitheli	Total Basal Cell Adeno Total Toma, Carcinoma	0/50 (0%) 0/50 (0%) ma, Basosquamous Tu 0/50 (0%) 0/50 (0%)	Mean 0% mor (benign, maligna Mean 0% B), Basal Cell Adeno	ant or SD 0%	Total	1/50 (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: INHALATION Vehicle: AIR

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			Male				Female	
#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 Hemangiopericytoma	a, Sarcoma, Myxo	oma, Myxosarcoma, Mali	gnant Fibrous Histic	ocytoma, or				
		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: Fibroma, Fibrosarcoma	a, Sarcoma, Myxc	oma, Myxosarcoma, or N 1/50 (2%)	alignant Fibrous His	stiocytoma		0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma								
		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: Fibrosarcoma, Sarcom		or Malignant Fibrous H						
		1/50 (2%)		05.00/		0/50 (0%)		00.00
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		4/50 (001)				0/50 (00)		
O	Tatal	1/50 (2%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
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

Contract/Lab: 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: Hemangiopericytoma		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%	
#Skin: Hemangiosarcoma		0/50 (0%)				0/50 (09/)			
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: Keratoacanthoma		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Lipoma		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: 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%	
#Skin: Malignant Fibrous Histio									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	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: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Neurofibrosarcoma or Sci	hwannoma (m	alignant or 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%
#Skin: Neurofibrosarcoma, Neur								
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: 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	Total	0/50 (0%)	M 00/	OD 004	Total	0/50 (0%)	M 00/	00.00
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 (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%
#Skin: 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%

^{*:} 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 Carcinom	a							
-		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: Squamous Cell Carcinom or Carcinoma	a, Basal Cell C	arcinoma, Basosquamo		at or NOS),				
		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: Squamous Cell Papilloma Overall Incidence	ı Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	ı or Papilloma	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: Squamous Cell Papilloma						0/50 (0%)		
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	ı, Papilloma, oı	r 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%

^{*:} 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: Trichoepithelioma								
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: Adenoma								
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: 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%
#Spinal Cord: Astrocytoma Malignant		0/50 (0%)				0/50 (0%)		22
Overall Incidence	Total	0/50 (0%)	Mean 0%	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 (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: INHALATION Vehicle: AIR

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				Male				Female	
#Stomach, Forestomach: Squamous 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%
#Stomach, Forestomach: Squamous Cell Carcinoma									
•	•		(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%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		0/50	(0%)						
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%				
*Thymus: Thymoma Benign							•••••	•••••	
		0/48	(0%)				0/50 (0%)		
Overall Incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/40	(00/)				0/50 (00())		
Overell Incidence	Tatal		(0%)	Maara 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/48 (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	
*Thymus: Thymoma: Benign, Malign	ant, NOS	0/10 /22/				0/50 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)) Mean 4%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		1/50 (2%				0/50 (0%)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma Overall Incidence	Total	3/50 (6% 3/50 (6%)		SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: Follicular Ce 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%
*Thyroid Gland: Follicular Ce Carcinoma	ell:	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%

^{*:} 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	
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:								
Overall Incidence	Total	0/50 (0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: 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%
#Tongue: Squamous 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%
#Tongue: Squamous Cell Carcinoma of		a Squamous	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	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		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(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	
#Uterus: Adenocarcinoma				
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#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 Cell Papilloma				
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Deciduoma Benign				
Overall Incidence	Total	0/50 (0%) 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%

^{*:} 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: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Papilloma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#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%

^{*:} 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: Schwannoma Malignant			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sq Cell Carcinoma or Papilloma Squamous			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Uterus: Squamous Cell Carcinoma			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina: Granular Cell Tumor Benign			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma			0/50 (09/)		
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: INHALATION Vehicle: AIR

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			Male	Female				
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Zymbal's 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%
#Zymbal's Gland: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%

^{*:} 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: 72

Report Date: 12/30/2020

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

Contract/Lab: 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

rol Animal Groups Report Date: 12/30/2020

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			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		(2001)				(222)			
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	umors	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									
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		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

Contract/Lab: 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: 74

			Male			Female			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%	5)			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	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Leukemia: Lymphocytic	,,								
Leukeilla. Lymphocytic	,oooyo,o	•							
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 #All Organs:	Total	0/50 (0% 0/50 (0%) phocytic, Mixed, NO	Mean 0% S, or Undifferentiated Ce		Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence #All Organs: Malignant Lymphoma: I	Total	0/50 (0% 0/50 (0%)	Mean 0% S, or Undifferentiated Ce		Total Total	` '	Mean 0% Mean 2%	SD 0%	
Overall Incidence #All Organs:	Total Histiocytic, Lymp Total	0/50 (0% 0/50 (0%) phocytic, Mixed, NO 2/50 (4%	Mean 0% S, or Undifferentiated Ce	ell Type		0/50 (0%) 1/50 (2%)			
Overall Incidence #All Organs: Malignant Lymphoma: H Overall Incidence #All Organs:	Total Histiocytic, Lymp Total	0/50 (0% 0/50 (0%) phocytic, Mixed, NO 2/50 (4%	Mean 0% S, or Undifferentiated Co Mean 4%	ell Type		0/50 (0%) 1/50 (2%)			
Overall Incidence #All Organs: Malignant Lymphoma: H Overall Incidence #All Organs:	Total Histiocytic, Lymp Total	0/50 (0% 0/50 (0%) ohocytic, Mixed, NO 2/50 (4%) 2/50 (4%)	Mean 0% S, or Undifferentiated Co Mean 4%	ell Type		0/50 (0%) 1/50 (2%) 1/50 (2%)			
#All Organs: Malignant Lymphoma: H Overall Incidence #All Organs: Malignant Schwannoma	Total Histiocytic, Lymp Total Total	0/50 (0% 0/50 (0%) ohocytic, Mixed, NO 2/50 (4%) 2/50 (4%)	Mean 0% S, or Undifferentiated Ce Mean 4% Mean 6%	sll Type SD 0%	Total	0/50 (0%) 1/50 (2%) 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: ORAL Vehicle: FEED **Page:** 75

				Male			Female			
#All Organs: Mesothelioma: Malignant										
Overall Incidence	Total	2/50 2/50 (4%)	(4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(078)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Adrenal Cortex: 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%	
*Adrenal Medulla: Ganglioneuroma		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%	

^{*:} 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:** 76

		Male						Female			
*Adrenal Medulla: Pheochromocytoma Benign											
		4/50 ((8%)				1/50 (2%)				
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Co	mplex										
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Ma	alignant	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: Be				Mean 10%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
	Total						1/30 (2/6)				
#Bone: Osteosarcoma											
O	T-1-1		(0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	Maran 00/	OD 00/		
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%)	(U /O)	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: 77 Report Date: 12/30/2020

				Male			Female			
*Brain: Glioma Malignant		4/50	(00()				0/50 (00/)			
Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Brain: Granular Cell Tumor Benig	n									
Overall Incidence	Total	3/50 3/50 (6%)	(6%)	Mean 6%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	
*Brain: Granular Cell Tumor Malig	nant	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%)		CD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Malignant		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%	
*Brain: Meningioma: Benign, Maliç	nant, NOS	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(570)	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:** 78 Report Date: 12/30/2020

			Male			Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma											
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 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%) 1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*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%			

^{*:} 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**: 79

			Male			Female				
*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		3/50 (6%)				1/50 (2%)				
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Intestine Large: Cecum: Liposarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Rectu Granular Cell Tumor Benig	um:	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: 80

			Male				Female			
#Intestine Large: Colon/Rect Leiomyoma	um:									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: 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%		
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 /00	······			0/50 (09/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspec 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%		
#Intestine Small: Site Unspec Carcinoma or Adenoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspec Leiomyosarcoma			····			0/50 (09/)				
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:** 81

			Male			Female			
*Islets, Pancreatic: 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%	
*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 Transition									
		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: 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: 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%	

^{*:} 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: 82

			Male			Female			
*Kidney: Renal Tubule: Carcinoma or 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: Hemangioma									
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: Lipoma		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%	
*Kidney: Renal Tubule: Liposarcoma 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: Nephroblastoma								0.00	
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*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%	

^{*:} 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: 83

			Male				Female	
*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: Cholangiocarcinoma		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	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*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

Contract/Lab: 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: 84

				Male			Female			
*Liver: Hepatocellular Carcinoma		0/50 (0%)					0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma	or Henatobla	stoma								
nepatocential Carcillonia	и перасовіа	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%	
*Liver: Hepatocellular Carcinoma of Overall Incidence	or Hepatocel	lular Adenoma 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma, Overall Incidence	Hepatocellu l	ar Adenoma, or 0/50 0/50 (0%)	Hepatob (0%)	lastoma Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Aden		0/50								
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Carcii	noma	0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(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: ORAL Vehicle: FEED Page: 85

			Male				Female					
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%) 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%				
*Lung: 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%				
*Lung: Squamous Cell Carcinom	a	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Lymph Node, Mesenteric: 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%				
#Mammary Gland: Adenolipoma												
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: 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: ORAL Vehicle: FEED Page: 86

				Male				Female	
#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									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%
#Mammary Gland: Fibroadenoma		0/50	(00/)				25/50 /500/\		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma	- /	()						
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	25/50 (50%) 25/50 (50%)	Mean 50%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,		Adenoma							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%
#Mammary Gland: Myoepithelioma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50	(070)	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:** 87

			Male				Female	
*Nose: Carcinoma								
		0/50 (0%)	••	25.00/		0/50 (0%)		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcing	a, Tongue, Phary							
		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	oma, Papilloma S	quamous, or Papilloma 0/50 (0%)				0/50 (0%)		
Squamous Cell Carcino Overall Incidence	oma, Papilloma S		Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Carcino Overall Incidence #Oral Mucosa: Squamous Cell Carcino	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Carcino Overall Incidence #Oral Mucosa:	Total	0/50 (0%) 0/50 (0%)		SD 0% SD 0%	Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0%
Squamous Cell Carcino Overall Incidence #Oral Mucosa: Squamous Cell Carcino	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%			0/50 (0%) 0/50 (0%) 0/50 (0%)		
Squamous Cell Carcino Overall Incidence #Oral Mucosa: Squamous Cell Carcino Overall Incidence *Ovary:	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%			0/50 (0%)		
Squamous Cell Carcino Overall Incidence #Oral Mucosa: Squamous Cell Carcino Overall Incidence *Ovary: Cystadenoma	Total Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%		Total	0/50 (0%) 0/50 (0%) 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: 88

	Male			Female	
*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			4/50 (00)		
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign			0/50 (00/)		
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%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Schwannoma Malignant			0/50 (000)		
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: 12/30/2020

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	
*Ovary: Sertoli Cell Tumor Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign		•••••			•••••			
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: 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%
*Pancreas: 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%
*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%

^{*:} 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:** 90

				Male				Female	
*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%)				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%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mal			(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 Distali									
		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 Distali									
		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: ORAL Vehicle: FEED Page: 91

				Male				Female			
Pituitary Gland: Pars Distalis or Unspecified Site: 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											
		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 Interm Carcinoma or Adenoma	nedia:	1/50	(2%)				0/49 (0%)				
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Nervos Schwannoma Malignant	sa:	•••••									
		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%)								
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%						
*Prostate: Carcinoma or Adenoma		1/50	(20/.)								
Overall Incidence	Total		(2%)	Mean 2%	SD 0%						
Overali incluence	างเลเ	1/50 (2%)		iviean 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:** 92

			Male			Female			
*Salivary Glands: Schwannoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)) Mean 0%	SD 0%	Total	0/49 (0%) 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%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Liposarcoma		0/50 (0%	,	0D 0W	Total	0/50 (0%)	M 00/	05.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Sarcoma		0/50 /00/	N			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%	
#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%	

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

^{#:} Denominator is number of animals necropsied

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Basal Cell Carcinoma

......

#Skin:

#Skin:

#Skin:

#Skin:

Contract/Lab: All Laboratories

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

Basal Cell Adenoma or Basosquamous Tumor Benign

Total

Total

Total

Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)

Total

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) SD 0% Mean 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% (0%) 0/50 Mean 0% SD 0% Total SD 0% 0/50 (0%) Mean 0%

0/50

(0%)

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Report Date: 12/30/2020

SD 0%

#Skin:		
Basal Cell Carcinoma,	Basal Cell Adenoma, Basosquan	nous Tumor (benign, malignant or

0/50

0/50 (0%)

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(0%)

(0%)

NOS), or Trichoepithelioma

0/50 (0%)

Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%

#Skin:

Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma,

Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

1/50 (2%)0/50 (0%)**Overall Incidence** 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

Contract/Lab: 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

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3/50 al 3/50 (6%	······	Mean 6%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
al 3/50 (6%	ó)		SD 0%	Total	` '	Mean 0%	SD 0%
	······		SD 0%	rotai	0/50 (0%)	wean 0%	511 11%
, Myxoma, Myxosaro	coma, Malignar						
, Myxoma, Myxosaro	coma, Malignar						
		t Fibrous Histio	ocytoma, or				
3/50	(6%)				1/50 (2%)		
al 3/50 (6%	(o)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
3/50	(6%)	nant Fibrous His Mean 6%	stiocytoma SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
0/50	(0%)				0/50 (0%)		
al 0/50 (0%	(6)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		cytoma					
	(0%)				` '		
al 0/50 (0%	(o)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
0/50	(00/)				0/50 (00/)		
	` '	Moon 0%	SD 0%	Total	` '	Moon 0%	SD 0%
r	al 3/50 (6% a, Myxoma, Myxosare 3/50 al 3/50 (6% 0/50 al 0/50 (0% rcoma, or Malignant 0/50 al 0/50 (0%	al 3/50 (6%) a, Myxoma, Myxosarcoma, or Maligra 3/50 (6%) al 3/50 (6%) 0/50 (0%) al 0/50 (0%) crcoma, or Malignant Fibrous Histion 0/50 (0%) al 0/50 (0%)	al 3/50 (6%) Mean 6% a, Myxoma, Myxosarcoma, or Malignant Fibrous His 3/50 (6%) al 3/50 (6%) Mean 6% 0/50 (0%) al 0/50 (0%) Mean 0% rcoma, or Malignant Fibrous Histiocytoma 0/50 (0%) al 0/50 (0%) Mean 0% 0/50 (0%)	al 3/50 (6%) Mean 6% SD 0% a, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 3/50 (6%) al 3/50 (6%) Mean 6% SD 0% 3/50 (0%) al 0/50 (0%) Mean 0% SD 0% croma, or Malignant Fibrous Histiocytoma 0/50 (0%) al 0/50 (0%) Mean 0% SD 0%	All 3/50 (6%) Mean 6% SD 0% Total A, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 3/50 (6%) All 3/50 (6%) Mean 6% SD 0% Total O/50 (0%) All 0/50 (0%) Mean 0% SD 0% Total O/50 (0%) All 0/50 (0%) Mean 0% SD 0% Total O/50 (0%) All 0/50 (0%) Mean 0% SD 0% Total	All 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) All Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 3/50 (6%) 1/50 (2%) All 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) All 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Arcoma, or Malignant Fibrous Histiocytoma 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Arcoma, or Malignant Fibrous Histiocytoma 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) All 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%)	al 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) Mean 2% 1, Myxoma, Myxosarcoma, or Malignant Fibrous Histiocytoma 3/50 (6%) Mean 6% SD 0% Total 1/50 (2%) Mean 2% 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 1/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% 1/50 (0%) Mean 0% 1/50 (2%) Mean 0% 1/50 (2%) Mean 0% 1/50 (0%) Mean 0% 1/50 (2%) Mean 0% 1/50 (2%) Mean 0% 1/50 (2%) Mean 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: ORAL Vehicle: FEED Page: 95

			Male				Female	
#Skin: Hemangiopericytoma								
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: 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%
#Skin: Keratoacanthoma		1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		•••••						
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: Malignant Fibrous Histion								
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:** 96

			Male				Female				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or 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%			
#Skin: Neurofibrosarcoma, Neur						0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	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		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											
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: 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%			

^{*:} 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:** 97

			Male				Female	
#Skin: Squamous Cell Carcinoma Overall Incidence	a Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma or Carcinoma	a, Basal Cell C	arcinoma, Basosquam	ous Tumor (malignar	nt or 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%
#Skin: Squamous Cell Papilloma								
		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: Squamous Cell Papilloma	or Papilloma	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%
#Skin: Squamous Cell Papilloma,	Papilloma, So		na or Keratoacanthor	ma		0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,		Keratoacanthoma				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

Contract/Lab: 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:** 98

				Male				Female	
#Skin: Trichoepithelioma		0/50	00()				0/50 (00/)		
Overall Incidence	Total	0/50 (0%)	0%) !	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma			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: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	ſ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma 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%
*Spleen: Hemangiosarcoma									
Overall Incidence	Total	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) I	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: 99

			1	Male			Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%	o)			0/50 (0	0%)	
Overall Incidence	Total	0/50 (0%)	Mean (Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
•	•	0/50 (0%	b)			0/50 (0	0%)	
Overall Incidence	Total	0/50 (0%)	Mean (0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%					0%)	
Overall Incidence	Total	0/50 (0%)	Mean (% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		7/50 (14%						
Overall Incidence	Total	7/50 (14%)	Mean 1					
*Thymus: Thymoma Benign								
-		0/48 (0%	o)			0/49 (0	0%)	
Overall Incidence	Total	0/48 (0%)	Mean 0			0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/48 (0%)	,)% SD 0%	T-4-1	,)%) Maan 0%	SD 00/
Overali incidence	Total	0/48 (0%)	Mean 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: ORAL Vehicle: FEED Page: 100

			Male				Female	
*Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma								
		13/50 (26%)	••	05.00/		12/50 (24%)		00.00
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%) 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 Ce 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 Ce 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%

^{*:} 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: 101

				Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:								
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant									
			(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			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma Overall Incidence		a Squamous	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(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

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 102

Report Date: 12/30/2020

Route: ORAL Vehicle: FEED

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

	Male			Female	
#Uterus: Adenocarcinoma			0/50 /40/		
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Adenocarcinoma or Adenoma			2/50 (4%)		
Overall Incidence		Total	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 Papilloma			2/50 (4%)		
Overall Incidence		Total	2/50 (4%)	Mean 4%	SD 0%
#Uterus: Deciduoma Benign					
Overall Incidence		Total	0/50 (0%) 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%

^{*:} 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: 103

	Male			Female	
#Uterus: Hemangioma			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Papilloma			0/50 (00)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal			5/50 (10%)		
Overall Incidence		Total	5/50 (10%)	Mean 10%	SD 0%
#Uterus: Sarcoma			1/50 (2%)		
Overall Incidence		Total	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					
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	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

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Species: RATS
Strain: Harlan Sprague-Dawley

Route: ORAL Vehicle: FEED Page: 104

	Male			Female	
#Uterus: Schwannoma Malignant			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sq Cell Carcinoma or Papilloma Squamous			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Squamous Cell Carcinoma			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Granular Cell Tumor Benign			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp				•••••	
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma			0/50 (09/)		
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: 105

			Male				Female	
#Vagina: Schwannoma Malignant						0(50 (00))		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%
#Zymbal's Gland: 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%
#Zymbal's Gland: Carcinoma or 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%

^{*:} 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: 12/30/2020

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 051098701 051026001 052061401 052061402 052071203	06/27/11 08/30/10 11/08/10 10/27/08 07/27/09 12/12/11	729 729 729 N/A 743 729	50(2) 49(2) 50(2) 0(0) 50(2) 50(2)	25(648) 27(672) 30(706) 0(0) 36(684) 25(652)	593.4 628.3 615.3 N/A 609.5 589.0	Di(2-ethylhexyl) Phthalate Dibutyl Phthalate 2-Hydroxy-4-methoxybenzophenone Perfluorooctanoic Acid Perfluorooctanoic Acid Tris(Chloropropyl)phosphate
					Female		
Battelle Columbus Laboratory	051018802 051098701 051026001 052061401 052061402 052071203	06/28/11 08/31/10 11/09/10 10/28/08 N/A 12/13/11	732 730 730 744 N/A 731	50(4) 50(4) 50(4) 50(4) 0(0) 50(4)	31(684) 29(668) 30(657) 23(649) 0(0) 22(629)	376.1 397.3 379.6 385.9 N/A 380.1	Di(2-ethylhexyl) Phthalate Dibutyl Phthalate 2-Hydroxy-4-methoxybenzophenone Perfluorooctanoic Acid Perfluorooctanoic Acid 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

ELICINATAL AND 1 00

Vehicle: FEED

Page: 107

			Male				Female	
#All Organs: Benign Tumors								
		28/50 (56%)	35/49 (71%) 32/50 (64%)	38/50 (76%) 25/50 (50%)		41/50 (82%) 39/50 (78%)	40/50 (80%)	41/50 (82%) 41/50 (82%)
Overall Incidence	Total	158/249 (63.45%)	Mean 63.49%	SD 10.7%	Total	202/250 (80.8%)	Mean 80.8%	SD 1.79%
#All Organs: Malignant Tumors								
		15/50 (30%)	14/49 (29%) 9/50 (18%)	11/50 (22%) 9/50 (18%)		14/50 (28%) 14/50 (28%)	13/50 (26%)	15/50 (30%) 10/50 (20%)
Overall Incidence	Total	58/249 (23.29%)	Mean 23.31%	SD 5.71%	Total	66/250 (26.4%)	Mean 26.4%	SD 3.85%
#All Organs: Malignant and Benign T								
		36/50 (72%)	41/49 (84%) 37/50 (74%)	42/50 (84%) 30/50 (60%)		44/50 (88%) 47/50 (94%)	44/50 (88%)	47/50 (94%) 46/50 (92%)
Overall Incidence	Total	186/249 (74.7%)	Mean 74.73%	SD 9.89%	Total	228/250 (91.2%)	Mean 91.2%	SD 3.03%
#All Organs: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#All Organs: Hemangiosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: 108

			Male				Female	
#All Organs: Hemangiosarcoma or H	lemangioma							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Granulocytic	•							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#All Organs: Leukemia: Lymphocytic	c, Monocytic, M	ononuclear, or Undiffere	ntiated					
		0/50 (0%)	0/49 (0%) 3/50 (6%)	0/50 (0%) 1/50 (2%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 2/50 (4%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6%	SD 2.61%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
#All Organs: Malignant Lymphoma: I	Histiocytic, Lym	nphocytic, Mixed, NOS, o	r Undifferentiated Cel	l Type				
	, - y	0/50 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 1.68%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

^{*:} 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%)	3/49 (6%) 1/50 (2%) 1/50 (2%) 0/50 (0%)	3/50 (6%) 2/50 (4%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	11/249 (4.42%)	Mean 4.42% SD 4.79%	Total 5/250 (2%) Mean 2% SD 2.83%
#All Organs: Mesothelioma: Benign, Mali				
		1/50 (2%)	1/49 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2.01% SD 0.02%	Total 0/250 (0%) Mean 0% SD 0%
#All Organs: Mesothelioma: Malignant				
		1/50 (2%)	1/49 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2.01% SD 0.02%	Total 0/250 (0%) Mean 0% SD 0%
#All Organs: Osteosarcoma				
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/250 (0.4%) Mean 0.4% SD 0.89%
#All Organs: Osteosarcoma or Osteoma				
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/250 (0.4%) Mean 0.4% SD 0.89%

^{*:} 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

Male **Female** *Adrenal Cortex: Adenoma 0/50 (0%)0/49 (0%)3/50 (6%)0/50 (0%)0/50 (0%)3/50 (6%)(0%) 0/50 (0%)0/50 2/50 (4%)0/50 (0%)3/249 (1.2%) 5/250 (2%) **Overall Incidence** Total Mean 1.2% SD 2.68% Total Mean 2% SD 2.83% *Adrenal Cortex: Carcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% *Adrenal Medulla: Ganglioneuroma 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% 1/250 (0.4%) SD 0.89% Total Mean 0.4% *Adrenal Medulla: Pheochromocytoma Benign 5/50 (10%)7/49 (14%)9/50 (18%)0/50 (0%)0/50 (0%)3/50 (6%)8/50 (16%)6/50 (12%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 35/249 (14.06%) Mean 14.06% SD 3.16% Total 4/250 (1.6%) Mean 1.6% SD 2.61% *Adrenal Medulla: **Pheochromocytoma Complex** 1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/249 (0.4%) Mean 0.4% SD 0.89% Total 0/250 (0%) Mean 0% SD 0%

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^{*:} 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%)	1/49 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 2.61%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
*Adrenal Medulla: Pheochromocytoma: Benign	ı, Complex	, Malignant, NOS						
	•	6/50 (12%)	8/49 (16%) 8/50 (16%)	12/50 (24%) 6/50 (12%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	5/50 (10%) 0/50 (0%)
Overall Incidence	Total	40/249 (16.06%)	Mean 16.07%	SD 4.9%	Total	6/250 (2.4%)	Mean 2.4%	SD 4.34%
#Bone: Osteosarcoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Bone: Osteosarcoma or Osteoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Ɓrain: Glioma Malignant								
		0/50 (0%)	2/49 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.22%	SD 1.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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 Benig	gn							
		0/50 (0%)	0/49 (0%) 2/50 (4%)	2/50 (4%) 1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2%	SD 2%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
*Brain: Granular Cell Tumor Malig								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (0%)	Mean 0%	SD 0%
······································								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Brain: Meningioma: Benign, Mali	gnant, NOS							
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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, Gliom	a, or Astrocy	/toma						
		0/50 (0%)	2/49 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.22%	SD 1.82%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/49 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/243 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	1/49 (2%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/243 (0.41%)	Mean 0.4%	SD 0.89%
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	1/49 (2%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.82%	SD 1.12%	Total	1/243 (0.41%)	Mean 0.4%	SD 0.89%

^{*:} 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

Report Date: 12/30/2020 Female

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			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/49 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%	Total	0/243 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		1/50 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	4/049 (0.40/)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%)	Mean 0%	0/46 (0%) SD 0%
	Total	1/248 (0.4%)		3D 0.89%	Total	0/243 (0%)		טט טא U%
Epididymis: Sarcoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)				
			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%				
Eye: Leiomyoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
_		2/50 (4%)	2/49 (4%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		=(=,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,0,	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2.02%	SD 2.02%	Total	0/248 (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		Fema	le
#Intestine Large: Cecum: Liposarcoma						
		0/50 (0%)	0/49 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	` '	1/250 (0.4%) Mean 0.4	(,
#Intestine Large: Colon/R Granular Cell Tumor Be	ectum:					
		0/50 (0%)	0/49 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%		0/250 (0%) Mean 0%	
#Intestine Large: Colon/R Leiomyoma						
		0/50 (0%)	0/49 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	% Total	0/250 (0%) Mean 0%	6 SD 0%
#Intestine Small: Jejunum Carcinoma						
		2/50 (4%)	0/49 (0%) 1/50 1/50 (2%) 0/50	(2%) (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6% SD 1.67	7% Total	1/250 (0.4%) Mean 0.4	% SD 0.89%
#Intestine Small: Jejunum Leiomyosarcoma	1:					
-		0/50 (0%)	0/49 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	% Total	0/250 (0%) Mean 0%	6 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: Site Uns Carcinoma	specified:							
		2/50 (4%)	0/49 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Uns Carcinoma or Adenoma	specified:							
		2/50 (4%)	0/49 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.6%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Site Uns Leiomyosarcoma	specified:							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma	•••••							
		2/50 (4%)	4/49 (8%) 5/50 (10%)	3/50 (6%) 4/50 (8%)		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	18/249 (7.23%)	Mean 7.23%	SD 2.3%	Total	5/248 (2.02%)	Mean 2.02%	SD 2.5%
Islets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

^{*:} 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: Carcinoma or Adenoma								
		2/50 (4%)	4/49 (8%) 5/50 (10%)	3/50 (6%) 4/50 (8%)		3/49 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%) 0/49 (0%)
Overall Incidence	Total	18/249 (7.23%)	Mean 7.23%	SD 2.3%	Total	6/248 (2.42%)	Mean 2.42%	SD 2.24%
*Kidney: Pelvis and Transitio Papilloma	nal Epitheli	um:			•••••			
·		0/50 (0%)	0/49 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma					•••••			
		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21%	SD 1.1%	Total	0/250 (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: Hemangioma						
		0/50 (0%)	` ,	%) 0/50 %) 0/50	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	•	(0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma						
		0/50 (0%)	` ,	%) 0/50 %) 0/50	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%) (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Liposarcoma						
		0/50 (0%)	` ,	9%) 0/50 9%) 0/50	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8% SD 1.1%	Total 0/250	(0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma						
		0/50 (0%)	` ,	%) 0/50 %) 0/50	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4% SD 0.89%	Total 0/250	0 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign						
_		0/50 (0%)	` ,	%) 0/50 %) 0/50	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/250	0 (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: Polyp Adenomatous					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/250 (0%)	Mean 0% SD 0%
#Lacrimal Gland: Carcinoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0 0/50 (0%)	/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%		Mean 0.4% SD 0.89%
Liver: Cholangiocarcinoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/49 (0%) 0 0/50 (0%)	/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4% SD 0.89%	Total 0/249 (0%)	Mean 0% SD 0%
Liver: Cholangioma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/49 (2%) 0 1/50 (2%)	/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 3/249 (1.2%)	Mean 1.21% SD 1.1%
Liver: Hemangioma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0 0/50 (0%)	/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/249 (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: 12/30/2020

1/50

SD 2.45%

Mean 2.01%

(2%)

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female** *Liver: Hepatocellular Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 1/249 (0.4%) Mean 0.4% SD 0.89% Total 4/249 (1.61%) Mean 1.61% SD 1.68% *Liver: **Hepatocellular Carcinoma** (0%) 1/50 (2%)1/49 (2%)0/50 0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% Total 1/249 (0.4%) Mean 0.4% SD 0.89% *Liver: Hepatocellular Carcinoma or Hepatoblastoma 1/50 (2%)1/49 (2%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% 1/249 (0.4%) SD 0.89% Total Mean 0.4% *Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 0/50 (2%)(0%)1/49 (2%)0/50 0/50 (0%)1/50 (2%)1/49 (0%)0/50 (0%)1/50 (2%)3/50 (6%)1/50 (2%)**Overall Incidence** Total 3/249 (1.2%) Mean 1.21% SD 1.1% Total 5/249 (2.01%) Mean 2.01% SD 2.45% *Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (2%)1/49 (2%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)

1/50

SD 1.1%

(2%)

Total

3/50

5/249 (2.01%)

(6%)

0/50

Mean 1.21%

(0%)

Total

3/249 (1.2%)

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: FEED

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			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/248 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar C	arcinoma							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%) 3/249 (1.2%)	1/49 (2%) 0/50 (0%) Mean 1.21%	1/50 (2%) 1/50 (2%) SD 1.1%	Total	0/49 (0%) 0/50 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	0/49 (0%) 0/50 (0%) SD 0%
*Lung: Sarcoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Sarcoma	Total	0/50 (0%)	0/49 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/49 (0%) 0/50 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	0/49 (0%) 0/50 (0%) SD 0%
Sarcoma Overall Incidence		0/249 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	,	0/50 (0%) SD 0%
Sarcoma Overall Incidence *Lung:		,	0/50 (0%)	0/50 (0%)	Total	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

Male **Female** #Lymph Node, Mesenteric: Hemangiosarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Mammary Gland: Adenolipoma (0%) 0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% **#Mammary Gland:** Adenoma 0/50 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 2/250 (0.8%) Mean 0.8% SD 1.1% **#Mammary Gland:** Carcinoma 2/50 1/50 (2%)0/49 (0%)(4%)1/50 (2%)4/50 (8%)7/50 (14%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)**Overall Incidence** Total 3/249 (1.2%) Mean 1.2% SD 1.79% Total 16/250 (6.4%) Mean 6.4% SD 4.98% #Mammary Gland: Carcinoma or Adenoma 2/50 1/50 (2%)0/49 (0%)(4%)2/50 (4%)4/50 (8%)7/50 (14%)0/50 (0%)0/50 (0%)4/50 (8%)1/50 (2%)

SD 1.79%

Total

18/250 (7.2%)

Total

3/249 (1.2%)

Mean 1.2%

Overall Incidence

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Mean 7.2%

SD 4.6%

^{*:} 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: Fibroadenoma								
		2/50 (4%)	1/49 (2%) 2/50 (4%)	2/50 (4%) 2/50 (4%)		28/50 (56%) 21/50 (42%)	33/50 (66%)	32/50 (64%) 29/50 (58%)
Overall Incidence	Total	9/249 (3.61%)	Mean 3.61%	SD 0.88%	Total	143/250 (57.2%)	Mean 57.2%	SD 9.44%
#Mammary Gland: Fibroma, Fibroadenom								
		2/50 (4%)	1/49 (2%) 2/50 (4%)	2/50 (4%) 2/50 (4%)		29/50 (58%) 22/50 (44%)	33/50 (66%)	32/50 (64%) 29/50 (58%)
Overall Incidence	Total	9/249 (3.61%)	Mean 3.61%	SD 0.88%	Total	145/250 (58%)	Mean 58%	SD 8.6%
#Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, o	or Adenoma						
Fibroma, Fibroadenom	,	3/50 (6%)	1/49 (2%) 2/50 (4%)	3/50 (6%) 2/50 (4%)	Total	30/50 (60%) 25/50 (50%)	35/50 (70%)	36/50 (72%) 30/50 (60%) SD 8 88%
Fibroma, Fibroadenom	na, Carcinoma, o Total	3/50 (6%) 11/249 (4.42%)	,	2/50 (4%) SD 1.66%	Total	` ,	Mean 62.4%	` ,
Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	,	3/50 (6%)	2/50 (4%) Mean 4.41% 0/49 (0%)	2/50 (4%) SD 1.66% 0/50 (0%)	Total	25/50 (50%) 156/250 (62.4%) 0/50 (0%)	(111,	30/50 (60%) SD 8.88% 0/50 (0%)
Fibroma, Fibroadenom Overall Incidence #Mammary Gland: Myoepithelioma	,	3/50 (6%) 11/249 (4.42%)	2/50 (4%) Mean 4.41%	2/50 (4%) SD 1.66%	Total Total	25/50 (50%) 156/250 (62.4%)	Mean 62.4%	30/50 (60%) SD 8.88%
Fibroma, Fibroadenom Overall Incidence #Mammary Gland:	Total	3/50 (6%) 11/249 (4.42%) 0/50 (0%) 0/249 (0%)	2/50 (4%) Mean 4.41% 0/49 (0%) 0/50 (0%)	2/50 (4%) SD 1.66% 0/50 (0%) 0/50 (0%)		25/50 (50%) 156/250 (62.4%) 0/50 (0%) 0/50 (0%)	Mean 62.4%	30/50 (60%) SD 8.88% 0/50 (0%) 0/50 (0%)
Fibroma, Fibroadenom Overall Incidence #Mammary Gland: Myoepithelioma Overall Incidence *Nose:	Total	3/50 (6%) 11/249 (4.42%) 0/50 (0%)	2/50 (4%) Mean 4.41% 0/49 (0%) 0/50 (0%)	2/50 (4%) SD 1.66% 0/50 (0%) 0/50 (0%)		25/50 (50%) 156/250 (62.4%) 0/50 (0%) 0/50 (0%)	Mean 62.4%	30/50 (60%) SD 8.88% 0/50 (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

Species: RATS

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

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

Vehicle: FEED

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			Male				Female	
Oral Cavity (Oral Mucos Squamous Cell Carcing		ynx, Tooth, Gingiva):						
•		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phar	rynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	0/50 (0%) Mean 0.41%	0/50 (0%) SD 0.91%	Total	0/50 (0%) 0/250 (0%)	Mean 0%	0/50 (0%) SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma							
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor l	Benign							
						1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

^{*:} 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	
Ovary: Granulosa Cell Tumor Malignant				
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
'Ovary: Granulosa-Theca Tumor Benign				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Ovary: Granulosa-Theca Tumor Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%
'Ovary: Luteoma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	Mean 0%	0/50 (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: Schwannoma Malignant								
						0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Ovary: Sertoli Cell Tumor Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
		10/50 (20%)	4/49 (8%) 3/50 (6%)	5/50 (10%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	31/249 (12.45%)	Mean 12.43%	9/50 (18%) SD 6.2%	Total	0/50 (0%) 0/248 (0%)	Mean 0%	0/49 (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%)	2/49 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.82%	SD 1.83%	Total	0/248 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		10/50 (20%)	6/49 (12%) 3/50 (6%)	5/50 (10%) 9/50 (18%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	33/249 (13.25%)	Mean 13.25%	SD 5.75%	Total	0/248 (0%)	Mean 0%	SD 0%
Parathyroid Gland: Adenoma								
		0/42 (0%)	0/48 (0%) 0/41 (0%)	0/49 (0%) 0/49 (0%)		0/42 (0%) 0/47 (0%)	0/45 (0%)	1/41 (2%) 0/44 (0%)
Overall Incidence	Total	0/229 (0%)	Mean 0%	SD 0%	Total	1/219 (0.46%)	Mean 0.49%	SD 1.09%
Peripheral Nerve: Paraganglioma								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant								
		0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (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	S						
<u> </u>	•	0/50 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/250 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
		4/50 (8%)	15/48 (31%) 5/50 (10%)	14/50 (28%) 7/50 (14%)		15/49 (31%) 22/50 (44%)	12/50 (24%)	19/50 (38%) 11/50 (22%)
Overall Incidence	Total	45/248 (18.15%)	Mean 18.25%	SD 10.67%	Total	79/249 (31.73%)	Mean 31.72%	SD 9.29%
*Pituitary Gland: Pars Dis Carcinoma	stalis or Unspec	o/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		ified Site:						
		4/50 (8%)	15/48 (31%) 5/50 (10%)	14/50 (28%) 7/50 (14%)		16/49 (33%) 22/50 (44%)	13/50 (26%)	19/50 (38%) 11/50 (22%)
Overall Incidence	Total	45/248 (18.15%)	Mean 18.25%	SD 10.67%	Total	81/249 (32.53%)	Mean 32.53%	SD 8.87%
*Pituitary Gland: Pars Into	ermedia:							
		0/50 (0%)	0/48 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%	Total	0/249 (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

			Male				Female	
Pituitary Gland: Pars Interm Carcinoma or Adenoma	edia:							
		0/50 (0%)	0/48 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%	Total	0/249 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Nervo Schwannoma Malignant								
		0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Prostate: Adenoma		0/50 (0%)						
		0/30 (0%)	1/49 (2%) 3/50 (6%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 2.61%				
Prostate: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%) 3/50 (6%)	0/50 (0%) 0/50 (0%)				
verall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 2.61%				
Salivary Glands: Schwannoma Malignant								
		2/50 (4%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%	Total	0/246 (0%)	Mean 0%	SD 0%

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

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^{#:} 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%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangioma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skeletal Muscle: Liposarcoma			•••••					
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma								
		0/50 (0%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/250 (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

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

Vehicle: FEED

Male **Female** #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/250 (0%) **Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% Total Mean 0% SD 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma (0%) (2%)1/49 (2%)0/50 (0%)0/50 0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 1.21% **Overall Incidence** Total 3/249 (1.2%) SD 1.1% Total 0/250 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)

Basal Cell Carcinoma or Basosquamous	Tumor	(malig	nant or NOS)
	(7/50	(0%)

Total

onia oi	Dasosquamous i	union (mang	jiiaiit oi r	1 03)										
		0/50	(0%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
				0/50	(0%)	0/50	(0%)		0/50	(0%)			0/50	(0%)
	Total	0/249 (0%	5)	Mean	0%	SD 0%		Total	0/250 (0	0%)	Mea	n 0%	SD	0%

(0%)

0/50

0/250 (0%)

Total

(0%)

#Skin:

#Skin:

Overall Incidence

Overall Incidence

Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or

0/249 (0%)

NOS), or Trichoepithelioma

, ,		1/50 (2%)	1/49 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%

0/50

SD 0%

0/50

Mean 0%

(0%)

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Mean 0%

Report Date: 12/30/2020

0/50

SD 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: FEED

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			Male				Female	
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	noma, Carcinon Sq Papilloma, Ko	na, Basosq. Tumor (M or E eratoacanthoma, Trichoep	B), Basal Cell Adenon oithelioma	na,				
		4/50 (8%)	9/49 (18%) 6/50 (12%)	4/50 (8%) 3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	26/249 (10.44%)	Mean 10.47%	SD 4.92%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Skin: Fibroma								
		3/50 (6%)	3/49 (6%) 1/50 (2%)	3/50 (6%) 4/50 (8%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	14/249 (5.62%)	Mean 5.62%	SD 2.2%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
	a, Sarcoma, Myx	xoma, Myxosarcoma, Mali						
Fibroma, Fibrosarcoma Hemangiopericytoma		3/50 (6%)	4/49 (8%) 2/50 (4%)	3/50 (6%) 4/50 (8%)	Tatal	1/50 (2%) 1/50 (2%)	1/50 (2%)	0/50 (0%) 2/50 (4%)
Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence	Total	3/50 (6%) 16/249 (6.43%)	4/49 (8%) 2/50 (4%) Mean 6.43%	3/50 (6%) 4/50 (8%) SD 1.71%	Total	1/50 (2%) 5/250 (2%)	Mean 2%	` ,
Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence #Skin:	Total	3/50 (6%) 16/249 (6.43%)	4/49 (8%) 2/50 (4%) Mean 6.43%	3/50 (6%) 4/50 (8%) SD 1.71%		1/50 (2%) 5/250 (2%)	Mean 2%	2/50 (4%)
Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence #Skin: Fibroma, Fibrosarcoma	Total a, Sarcoma, Myx Total	3/50 (6%) 16/249 (6.43%) xoma, Myxosarcoma, or M 3/50 (6%) 16/249 (6.43%)	4/49 (8%) 2/50 (4%) Mean 6.43% lalignant Fibrous Hist 4/49 (8%) 2/50 (4%) Mean 6.43%	3/50 (6%) 4/50 (8%) SD 1.71% stiocytoma 3/50 (6%) 4/50 (8%) SD 1.71%	Total	1/50 (2%) 5/250 (2%) 1/50 (2%) 1/50 (2%) 5/250 (2%)	Mean 2% 1/50 (2%) Mean 2%	2/50 (4%) SD 1.41% 0/50 (0%) 2/50 (4%) SD 1.41%
Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence #Skin: Fibroma, Fibrosarcoma	Total a, Sarcoma, Myx Total	3/50 (6%) 16/249 (6.43%) xoma, Myxosarcoma, or M 3/50 (6%) 16/249 (6.43%)	4/49 (8%) 2/50 (4%) Mean 6.43% lalignant Fibrous Hist 4/49 (8%) 2/50 (4%) Mean 6.43%	3/50 (6%) 4/50 (8%) SD 1.71% stiocytoma 3/50 (6%) 4/50 (8%) SD 1.71%	Total	1/50 (2%) 5/250 (2%) 1/50 (2%) 1/50 (2%) 5/250 (2%)	Mean 2% 1/50 (2%) Mean 2%	2/50 (4%) SD 1.41% 0/50 (0%) 2/50 (4%) SD 1.41%
Hemangiopericytoma Overall Incidence #Skin: Fibroma, Fibrosarcoma Overall Incidence #Skin:	Total a, Sarcoma, Myx Total	3/50 (6%) 16/249 (6.43%) xoma, Myxosarcoma, or M 3/50 (6%) 16/249 (6.43%)	4/49 (8%) 2/50 (4%) Mean 6.43% lalignant Fibrous Hist 4/49 (8%) 2/50 (4%) Mean 6.43%	3/50 (6%) 4/50 (8%) SD 1.71% stiocytoma 3/50 (6%) 4/50 (8%) SD 1.71%	Total	1/50 (2%) 5/250 (2%) 1/50 (2%) 1/50 (2%) 5/250 (2%)	Mean 2% 1/50 (2%) Mean 2%	2/50 (4%) SD 1.41% 0/50 (0%) 2/50 (4%) 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

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Mean 0%

SD 0%

Report Date: 12/30/2020

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

Male **Female** #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma (0%)1/49 (2%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)4/250 (1.6%) **Overall Incidence** Total 2/249 (0.8%) Mean 0.81% SD 1.11% Total Mean 1.6% SD 0.89% #Skin: Hemangioma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Skin: Hemangiopericytoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) SD 0% Mean 0% #Skin: Hemangiosarcoma 0/50 0/50 (0%)0/49 (0%)(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 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Skin: Keratoacanthoma 2/50 (4%)8/49 (16%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)5/50 (10%)2/50 (4%)0/50 (0%)0/50 (0%)

SD 5.49%

Total

0/250 (0%)

Total

19/249 (7.63%)

Mean 7.67%

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: FEED

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			Male				Female	
#Skin: Lipoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Liposarcoma								
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Hist								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Neurofibrosarcoma or			0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Skin:		Schwannoma (benign, ma						
		2/50 (4%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.79%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

^{*:} 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: Osteosarcoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/250 (0%) Mean 0%	SD 0%
#Skin: Pilomatrixoma					
		0/50 (0%)	3/49 (6%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.22% SD 2.74%	Total 0/250 (0%) Mean 0%	SD 0%
#Skin: Sarcoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/250 (0.4%) Mean 0.4%	SD 0.89%
#Skin: Schwannoma Malignant					
		2/50 (4%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8% SD 1.79%	Total 2/250 (0.8%) Mean 0.8%	SD 1.1%
#Skin: Squamous Cell Carcinoma					
		1/50 (2%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4% SD 0.89%	Total 1/250 (0.4%) Mean 0.4%	SD 0.89%

^{*:} 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

Vehicle: FEED

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female		
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	
#Skin: Squamous Cell Papillo	oma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/250 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillo	oma or Papillom	a							
	-	0/50 (0%)	0/49 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/250 (0%)	Mean 0%	SD 0%	
#Skin: Squamous Cell Papillo	oma, Papilloma,	Squamous Cell Carcinon	na or Keratoacanthoma	1					
		3/50 (6%)	8/49 (16%) 5/50 (10%)	4/50 (8%) 3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	23/249 (9.24%)	Mean 9.27%	SD 4.28%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	
#Skin: Squamous Cell Papillo	oma, Papilloma,	or Keratoacanthoma	•••••						
•		2/50 (4%)	8/49 (16%) 5/50 (10%)	4/50 (8%) 3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	22/249 (8.84%)	Mean 8.87%	SD 4.73%	Total	0/250 (0%)	Mean 0%	SD 0%	

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

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^{#:} 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%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4% SD 0.89%	Total 0/250 (0%) M	ean 0% SD 0%
#Skin: Sebaceous Gland: Adenoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/250 (0%) M	ean 0% SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/250 (0%) M	ean 0% SD 0%
#Spinal Cord: Astrocytoma Malignant					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 1/50 (2%)	(0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/250 (0.4%) Me	an 0.4% SD 0.89%
*Spleen: Hemangiosarcoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/49 (2%) 0/50 0/50 (0%)	(0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	* *	an 0.41% SD 0.91%

^{*:} 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

Male **Female #Stomach**, Forestomach: Sarcoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Stomach, Forestomach: **Squamous Cell Carcinoma** (0%) 0/50 (0%)0/49 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 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Stomach, Forestomach: **Squamous Cell Carcinoma or Papilloma Squamous** (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) SD 0% Mean 0% #Stomach, Forestomach: Squamous Cell Papilloma 0/50 0/50 (0%)0/49 (0%)(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 0/249 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% *Testis: Adenoma 3/49 (6%)2/49 (4%)1/50 (2%)0/50 (0%)0/50 (0%)

SD 2.66%

Total

6/248 (2.42%)

Mean 2.44%

Overall Incidence

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^{*:} 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								
		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%) 0/49 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/238 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant								
		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%) 0/49 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/238 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Thymus: Thymoma: Benign, Maligr								
		0/47 (0%)	0/48 (0%) 0/48 (0%)	0/46 (0%) 0/49 (0%)		0/46 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/238 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	8/49 (16%) 11/49 (22%)	7/50 (14%) 9/50 (18%)		8/49 (16%) 9/50 (18%)	12/50 (24%)	5/50 (10%) 10/50 (20%)
Overall Incidence	Total	45/248 (18.15%)	Mean 18.16%	SD 3.26%	Total	44/249 (17.67%)	Mean 17.67%	SD 5.15%
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)		0/49 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%) 2/50 (4%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.21%	SD 1.1%	Total	5/249 (2.01%)	Mean 2%	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: FEED

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			Male				Female	
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		10/50 (20%)	8/49 (16%) 11/49 (22%)	8/50 (16%) 9/50 (18%)		8/49 (16%) 9/50 (18%)	13/50 (26%)	6/50 (12%) 12/50 (24%)
Overall Incidence	Total	46/248 (18.55%)	Mean 18.56%	SD 2.7%	Total	48/249 (19.28%)	Mean 19.27%	SD 5.72%
*Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%)	1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
*Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	:							
		0/50 (0%)	1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (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	
#Tongue: Squamous Cell Carcino	ma							
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcino	ma or Papillom	a Squamous						
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Leiomyosarcoma								
		0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
#Uterus: Adenocarcinoma								
						3/50 (6%) 1/50 (2%)		5/50 (10%) 3/50 (6%)
Overall Incidence					Total	12/200 (6%)	Mean 6%	SD 3.27%

^{*:} 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: Adenocarcinoma or Adenoma								
			3/50 (6%)		5/50 (10%)			
			2/50 (4%)		3/50 (6%)			
Overall Incidence		Total	13/200 (6.5%)	Mean 6.5%	SD 2.52%			
#Uterus: Adenoma								
			0/50 (0%)		0/50 (0%)			
			1/50 (2%)		0/50 (0%)			
Overall Incidence		Total	1/200 (0.5%)	Mean 0.5%	SD 1%			
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq								
· · · · · · · · · · · · · · · · · · ·	•		3/50 (6%)		5/50 (10%)			
			2/50 (4%)		3/50 (6%)			
Overall Incidence		Total	13/200 (6.5%)	Mean 6.5%	SD 2.52%			
#Uterus: Deciduoma 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%			
#Uterus: Granular 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%			

^{*:} 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: Hemangioma						
			0/50 (0%)		0/50 (0%)	
Overall Incidence		Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	1/50 (2%) SD 1%	
#Uterus: Papilloma						
·			0/50 (0%)		0/50 (0%)	
			0/50 (0%)		0/50 (0%)	
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%	
#Uterus: Polyp Stromal						
,,			8/50 (16%)		8/50 (16%)	
			16/50 (32%)		5/50 (10%)	
Overall Incidence		Total	37/200 (18.5%)	Mean 18.5%	SD 9.43%	
#Uterus: Sarcoma						
Gardenia			0/50 (0%)		0/50 (0%)	
			0/50 (0%)		0/50 (0%)	
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal						
			0/50 (0%)		0/50 (0%)	
			1/50 (2%)		0/50 (0%)	
Overall Incidence		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					
fUterus: Sarcoma Stromal or Polyp Stromal								
			8/50 (16%)		8/50 (16%)			
Overall Incidence		Total	16/50 (32%) 37/200 (18.5%)	Mean 18.5%	5/50 (10%) SD 9.43%			
Uterus: 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%			
fUterus: Sq Cell Carcinoma or Papilloma Squamous								
			0/50 (0%)		0/50 (0%)			
			0/50 (0%)		0/50 (0%)			
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%			
fUterus: Squamous Cell Carcinoma								
			0/50 (0%)		0/50 (0%)			
			0/50 (0%)		0/50 (0%)			
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%			
ŧVagina: Granular Cell Tumor Benign								
			0/50 (0%)	0/50 (0%)	0/50 (0%)			
			0/50 (0%)		0/50 (0%)			
Overall Incidence		Total	0/250 (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	
#Vagina: Polyp								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/50 (0%) 0/250 (0%)	Mean 0%	0/50 (0%) SD 0%
#Vagina: Sarcoma			•••••					
						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence					Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Vagina: Schwannoma Malignant						1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Zymbal's Gland: Adenoma			•••••					
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
≠Zymbal's Gland: Carcinoma								
		1/50 (2%)	1/49 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/250 (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				
#Zymbal's Gland: Carcinoma or Adenoma		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		1/30 (2/6)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/30 (0 /8)	0/50 (0%)		
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/250 (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: 12/30/2020

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

Contract/Lab: 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%)				39/50 (78%)				
Overall Incidence	Total	29/50 (58%)	Mean 58%	SD 0%	Total	39/50 (78%)	Mean 78%	SD 0%		
#All Organs: Malignant Tumors										
		14/50 (28%)				17/50 (34%)				
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%		
#All Organs: Malignant and Benign Tume	ors	36/50 (72%)				47/50 (94%)				
Overall Incidence	Total	36/50 (72%)	Mean 72%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%		
#All Organs: 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%		
#All Organs: Hemangiosarcoma										
		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 or Hema	angioma	4/50 (00)				0/50 /00/				
Overall Insidence	Tatal	1/50 (2%)	Mana 20/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/		
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

Contract/Lab: 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%)				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								
		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: Leukemia: Lymphocytic, M Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lymր	phocytic, Mixed, NOS, or 1/50 (2%)				2/50 (4%)		
<u> </u>		4/50 (00/)		00 00/	+	` '	14 40/	OD 00/
	Total	1/50 (2%)	Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
						2/50 (4%)		SD 0%
#All Organs: Malignant Schwannoma		1/50 (2%)				2/50 (4%)		
#All Organs: Malignant Schwannoma						2/50 (4%)		SD 0% SD 0%
#All Organs: Malignant Schwannoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)				2/50 (4%)		
Overall Incidence #All Organs:	Total	1/50 (2%) 1/50 (2%)				2/50 (4%)		

^{*:} 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									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#All Organs: Osteosarcoma or Osteoma		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Adenoma Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: 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%
*Adrenal Medulla: Ganglioneuroma		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	(~ /0)	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

Contract/Lab: 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 Benign													
,		10/50 (20%)				1/50 (2%)							
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
*Adrenal Medulla: Pheochromocytoma Comple													
		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: Pheochromocytoma Maligna	ınt	2/50 (4%)				1/50 (2%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%					
*Adrenal Medulla: Pheochromocytoma: Benign						2/50 (4%)							
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	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 Osteoma		0/50 (00/)				0/50 (09/)							
Overall Incidence	Total	0/50 (0%)	Moon 0%	SD 0%	Total	0/50 (0%)	Moan 0%	SD 00/					
	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Brain: Glioma Malignant								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig	ın							
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor 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%
*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								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maliç	gnant, NOS							
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: PERINATAL AND POSTNATAL

TERMATAL AND LOST

Vehicle: WATER

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			Male				Female						
*Brain: Oligodendroglioma, Glioma, or Astrocytoma													
		2/50 (4%	b)			0/50 (0%)							
Overall Incidence	Total	2/50 (4%)	Mean 4%	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		0/50 (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%	o)		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%					
*Clitoral/Preputial Gland: Carcinoma or Adenoma		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%					
*Clitoral/Preputial Gland: Squamous 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%					

^{*:} 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 Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Epididymis: Sarcoma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%) 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		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Intestine Large: Cecum: Liposarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Colon/Rectu Granular Cell Tumor Benig	ım:	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female	
#Intestine Large: Colon/Re Leiomyoma	ctum:								
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	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		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: Site Unsp Carcinoma									
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:								
Overall Incidence	Total	0/50 0/50 (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

Contract/Lab: 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			
	,	4%)				1/50 (2%)		
Total	, ,		lean 4%	SD 0%	Total	, ,	Mean 2%	SD 0%
	•	,				` '		
Total	1/50 (2%)	٨	lean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
	3/50 (6	3%)				2/50 (4%)		
Total	3/50 (6%)	,	lean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
onal Epitheliu	m : 0/50 (0	0%)	Maan 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
					10tai	0/30 (0/8)		
	•	,				0/50 (0%)		
Total	2/50 (4%)	Λ	lean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 //	D0/)				0/50 (09/)		
Total	0/50 (C 0/50 (0%)	,	lean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	Total Total	Total 2/50 (4%) 1/50 (2 Total 1/50 (2%) 3/50 (6%) Total 3/50 (6%) Onal Epithelium: 0/50 (0%) Total 2/50 (4%) Total 2/50 (4%)	Total 2/50 (4%) N 1/50 (2%) Total 1/50 (2%) N 3/50 (6%) Total 3/50 (6%) N Ponal Epithelium: 0/50 (0%) Total 0/50 (0%) N Total 2/50 (4%) Total 2/50 (4%) O/50 (0%)	2/50 (4%) Total 2/50 (4%) Mean 4% 1/50 (2%) Total 1/50 (2%) Mean 2% 3/50 (6%) Total 3/50 (6%) Mean 6% Onal Epithelium: 0/50 (0%) Total 0/50 (0%) Mean 0% 2/50 (4%) Total 2/50 (4%) Mean 4%	2/50 (4%) Total 2/50 (4%) Mean 4% SD 0% 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% 3/50 (6%) Total 3/50 (6%) Mean 6% SD 0% Donal Epithelium: 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% 2/50 (4%) Mean 4% SD 0%	Total 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% Total 3/50 (6%) SD 0% Total Total 3/50 (6%) Mean 6% SD 0% Total Total 5/50 (0%) Mean 0% SD 0% Total 2/50 (4%) Mean 0% SD 0% Total 2/50 (4%) Mean 4% SD 0% Total	Total 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Total 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) Total 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Total 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%) Total 2/50 (4%) Mean 4% SD 0% Total 0/50 (0%)	Total 2/50 (4%) Mean 4% SD 0% Total 1/50 (2%) Mean 2% Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% Total 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) Mean 4% Total 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) Mean 4% Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 2/50 (4%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% Total 2/50 (4%) 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: WATER

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			Male		0/50 (0%) 0 0% Total 0/50 (0%) Mean 0% 0/50 (0%) 0 0% Total 0/50 (0%) Mean 0% 0/50 (0%) 0 0% Total 0/50 (0%) 0 0% Total 0/50 (0%)			Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma											
		2/50 (4%)				0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Hemangioma											
		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%)				` '		00.00			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		, ,		SD 0%			
*Kidney: Renal Tubule: Liposarcoma		0/50 (00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%			
*Kidney: Renal Tubule: Nephroblastoma											
		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: 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%			

^{*:} 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: Polyp Adenomatous		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%
#Lacrimal Gland: Carcinoma		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%
*Liver: Cholangiocarcinoma		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	1/50 (2%)) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma								GE 078
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		1/50 (2%				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				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 Carcino	ma or Hepatobla	stoma									
			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	()	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Liver: Hepatocellular Carcino	•	1/50	(2%)	Mana 20/	CD 00/	Total	1/50 (2%)	Mean 2%	SD 0%		
	Total	1/50 (2%)		Mean 2%	SD 0%	Total	1/50 (2%)	wear 2%	3D 0%		
*Liver: Hepatocellular Carcino Overall Incidence	ma, Hepatocellul	ar Adenoma, or I 1/50 1/50 (2%)	Hepatoblas (2%)	t oma Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%		
*Liver: Hepatocellular Carcino Overall Incidence	ma, Hepatocellul Total	ar Adenoma, or I 1/50 1/50 (2%)	Hepatoblas (2%)	t oma Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%			
*Liver: Hepatocellular Carcino Overall Incidence *Lung:	ma, Hepatocellul Total	ar Adenoma, or I 1/50 1/50 (2%)	Hepatoblas (2%)	t oma Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%			
*Liver: Hepatocellular Carcino Overall Incidence *Lung: Alveolar/Bronchiolar A	ma, Hepatocellul Total denoma Total	ar Adenoma, or I 1/50 1/50 (2%) 1/50 (2%) 1/50 (2%)	Hepatoblas (2%)	doma Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%) 0/50 (0%)	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female			
*Lung: Alveolar/Bronchiolar Care	cinoma or Alve		ma						
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Lung: 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%	
*Lung: Squamous Cell Carcinom	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%	
#Lymph Node, Mesenteric: 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%	
#Mammary Gland: Adenolipoma									
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: Adenoma		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	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

e. I EKINATAL AND I OS

Vehicle: WATER

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	Male						Female 2/50 (4%) Total 2/50 (4%) Mean 4% SD 0% 5/50 (10%) Total 5/50 (10%) Mean 10% SD 0% Total 30/50 (60%) Total 30/50 (60%) Mean 60% SD 0% Total 32/50 (64%) Total 32/50 (64%) Mean 64% SD 0% 34/50 (68%) Total 34/50 (68%) Mean 68% SD 0%		
#Mammary Gland: Carcinoma									
		0/50 (0	%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%		, ,		SD 0%
#Mammary Gland: Carcinoma or Adenoma									
		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: Fibroadenoma									
		0/50 (0	,				` ,		
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%		30/50 (60%)	Mean 60%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma or	Adenoma								
		0/50 (0	,				` ,		
Overall Incidence	Total	0/50 (0%)	Mean		SD 0%		, ,		
#Mammary Gland: Fibroma, Fibroadenoma, C		Adenoma							
Overell Insidence	Tatal	0/50 (0	,	00/	CD 00/	Tatal	` ,	Mana 000/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean	U% 	SD 0%	ı otal	34/30 (68%)	iviean 68%	บ _พ
#Mammary Gland: Myoepithelioma		0/50 (0	0/)				0/50 (00/)		
Overell Insidence	Tatal	,	%)	00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean		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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male			Female Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%) Mean 0% SD 0%		
*Nose: 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%
#Oral Cavity (Oral Mucos Squamous Cell Carcine		nx, Tooth, Gingiva):						
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Squamous Cell Carcino Overall Incidence	oma, Papilloma S	quamous, or Papilloma 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcine		0,00 (0,0)				0.00 (0.0)		
		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (00)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign					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

Contract/Lab: 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: Granulosa Cell Tumor Malignant					
Overall Incidence	To	otal	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence	To	otal	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Granulosa-Theca Tumor Benign					
Overall Incidence	To	otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant					
Overall Incidence		otal	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Luteoma					
Overall Incidence	To	otal	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Schwannoma Malignant					
Overall Incidence	To	otal	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
*Ovary: Sertoli Cell Tumor Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	14/50 (28%) 14/50 (28%)	Mean 28%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Pancreas: 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%
*Pancreas: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	14/50 (28%) 14/50 (28%)	Mean 28%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male		Female O/46 (0%) Total 0/46 (0%) Mean 0% SD 0% O/50 (0%) Total 0/50 (0%) Mean 0% SD 0% O/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%				
*Parathyroid Gland: Adenoma									
		0/43 (0%)				0/46 (0%)			
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%		` ,		SD 0%	
#Peripheral Nerve: Paraganglioma									
		0/50 (0%)		05.00/		` ,		00.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Peripheral Nerve: Schwannoma Malignan	t	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%	
#Peripheral Nerve: Schwannoma: 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%	
*Pituitary Gland: Pars Dis Adenoma									
		8/50 (16%)				16/50 (32%)			
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	16/50 (32%)	Mean 32%	SD 0%	
*Pituitary Gland: Pars Dis Carcinoma	talis or Unspecit								
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female		
*Pituitary Gland: Pars Dist		fied Site:							
		9/50 (18%)				17/50 (34%)			
Overall Incidence	Total	9/50 (18%)	Mean 18%	SD 0%	Total	17/50 (34%)	Mean 34%	SD 0%	
*Pituitary Gland: Pars Inte 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%	
*Pituitary Gland: Pars Inte 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%	
*Pituitary Gland: Pars Ner Schwannoma Malignant	vosa:	1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma									
		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
*Prostate: Carcinoma or Adenoma		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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male		Female			
*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								
		1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
#Skeletal Muscle: Hemangioma		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%
		, ,				0/30 (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%
#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%

^{*:} 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 Adenoma or E	Basosquamous	•						
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	05.00/		0/50 (0%)	••	05 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, Bas	sosquamous Ti	umor Benign, or Trichoe	pithelioma					
	•	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 Carcinoma								
Basar son saremena		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 Carcinoma or	Rasosquamou	s Tumor (malignant or N	IOS)					
Basar Gen Garenionia or	Dasosquamou	0/50 (0%)	100)			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, Basal Cell Carcinoma, Basal NOS), or Trichoepithelio		oma, Basosquamous Tu	mor (benign, maligna	ant or				
NOO), or Trichoepitheno	ilia	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 or Sq. Cell Carcino	oma, Carcinoma	a, Basosq. Tumor (M or	B), Basal Cell Adeno	ma,				
Adenoma, Papilloma, Sq	Papilloma, Ker		pithelioma			0/50 (00/)		
Overell Incidence	Tatal	1/50 (2%)	Mana 20/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
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

Contract/Lab: 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: Fibroma		3/50 (6%)				1/50 (2%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myxo	oma, Myxosarcoma, Ma	ignant Fibrous Histic	ocytoma, or				
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
#Skin: Fibroma, Fibrosarcoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, or I 3/50 (6%) 3/50 (6%)	Malignant Fibrous His	stiocytoma	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Skin: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
	-	, or Malignant Fibrous F	-	CD 00/	Takal	1/50 (2%)	M 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
ŧSkin: Hemangioma		0/50 (0%)				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: WATER

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			Male				Female	
#Skin: Hemangiopericytoma								
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: 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%
#Skin: Keratoacanthoma		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: 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%
#Skin: Liposarcoma								
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: Malignant Fibrous Histio	cytoma							
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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female					
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%) 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, Neuro	ofibroma, or S	0/50 (0%)	llignant 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												
		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: 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%				
#Skin: 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%				

^{*:} 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 Carcinoma 0/50 (0%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%											
Overall Incidence	Total	` '	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%			
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell C	_	ous Tumor (malignar	nt or NOS),							
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: Squamous Cell Papilloma		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: Squamous Cell Papilloma o	r Papilloma	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%			
#Skin: Squamous Cell Papilloma, I	Papilloma, S	quamous Cell Carcinon 1/50 (2%)	na or Keratoacanthor	na		0/50 (0%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma, I	Papilloma, o	r Keratoacanthoma 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

Contract/Lab: 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: 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								
		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: Carcinoma or Adenoma		0/50 (001)				0/50 (00/)		
Overall lesidenes	Tatal	0/50 (0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Malignant		2/22 (221)				2(72)		
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%
*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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female	
#Stomach, Forestomach: Squamous 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%
#Stomach, Forestomach: Squamous Cell Carcinoma									
•	•		(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%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		1/50	(2%)						
Overall Incidence	Total	1/50 (2%)	(270)	Mean 2%	SD 0%				
*Thymus: Thymoma Benign		•••••							
-		0/48	(0%)				0/47 (0%)		
Overall Incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/40	(00()				0/47 (00/)		
Overell Incidence	Total		(0%)	Maan 00/	CD 00/	Total	0/47 (0%)	Maan OO/	CD 00/
Overall Incidence	Total	0/48 (0%)		Mean 0%	SD 0%	Total	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	
*Thymus: Thymoma: Benign, Maligna	ant, NOS								
Overall Incidence	Total	0/48 0/48 (0%)	(0%)	Mean 0%	SD 0%	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
		` ,							
*Thyroid Gland: C-Cell: Adenoma									
		4/50	(8%)				5/50 (10%)		
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma									
	T		(0%)		00.00/	-	2/50 (4%)		OD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
			(8%)				7/50 (14%)		
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	7/50 (14%)	Mean 14%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma	II:								
		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 Ce Carcinoma	III:	•••••							
			(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: PERINATAL AND POSTNATAL

Vehicle: WATER

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				Male				Female				
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma 0/50 (0%) Overall Incidence Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%												
			(0%)				` '					
Overall Incidence	Total	, ,			SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tissue NOS: Schwannoma Malignant							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		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(078)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tongue: Squamous Cell Carcinoma	or Papilloma	a Squamous 0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(078)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Tooth: Odontoma												
		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Urinary Bladder: Leiomyosarcoma		0/50	(0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	(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: PERINATAL AND POSTNATAL

Vehicle: WATER

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M	ale		Female	
#Uterus: Adenocarcinoma		2/22 (22)		
Overall Incidence	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
#Uterus: Adenocarcinoma or Adenoma		3/50 (6%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%
#Uterus: Adenoma		0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinoma, or Sq Cell Papilloma		E/E0 (400/\		
Overall Incidence	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Deciduoma Benign				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Granular Cell Tumor Benign		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

Contract/Lab: 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: Hemangioma					
			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Papilloma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal					
Overall Incidence		Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Sarcoma					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	6/50 (12%) 6/50 (12%)	Mean 12%	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	
#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	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Uterus: Squamous Cell Carcinoma			0/50 (40)		
Overall Incidence		Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
#Vagina: Granular Cell Tumor Benign					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Sarcoma					
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: PERINATAL AND POSTNATAL

Vehicle: WATER

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			Male				Female	
#Vagina: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%
#Zymbal's Gland: Carcinoma								
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's 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%

^{*:} 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: 12/30/2020

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								
		30/50 (60%)	33/50 (66%)			44/50 (88%)	43/50 (86%)	
Overall Incidence	Total	63/100 (63%)	Mean 63%	SD 4.24%	Total	87/100 (87%)	Mean 87%	SD 1.41%
#All Organs: Malignant Tumors		10/50 (20%)	13/50 (26%)			7/50 (14%)	10/50 (20%)	
Overall Incidence	Total	23/100 (23%)	Mean 23%	SD 4.24%	Total	17/100 (17%)	Mean 17%	SD 4.24%
						······		
#All Organs: Malignant and Benign Tu	imors	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%)	45/50 (90%) Mean 91%	SD 1.41%
All Organs: Hemangioma	•••••							
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%
All Organs: Hemangiosarcoma								
		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%
All Organs: Hemangiosarcoma or He	mangioma							
		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%

^{*:} 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								
Overell Incidence	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, M Overall Incidence	onocytic, Mo	ononuclear, or Undifferen 0/50 (0%) 0/100 (0%)	tiated 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#All Organs: Malignant Lymphoma: Hist	iocytic, Lym	phocytic, Mixed, NOS, or 0/50 (0%)	Undifferentiated Cel	I Туре		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%
tAll Organs: Malignant Schwannoma								
O	Taral	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	1/50 (2%)	1/50 (2%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS							
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence		3/100 (3%)	, ,	SD 1.41%		0/100 (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 GAVAGE

Vehicle: METHYLCELLULOSE

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		Male				Female		
Total	` '	` ,	SD 1.41%	Total	, ,	` ,	SD 0%	
	,				` ,			
	0/50 (00/)	4/50 (20/)			0/50 (00/)	0/50 (09/)		
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)		
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (001)	0/50 (051)			0/50 (00)	0/50 /00/		
Total		` ,	SD 0%	Total	` ,	` '	SD 0%	
	Total Total	0/50 (0%) Total 1/100 (1%) 0/50 (0%) Total 1/100 (1%) 0/50 (0%) Total 0/50 (0%) Total 0/50 (0%) Total 1/100 (1%)	2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% 1/50 (2%) Total 1/100 (1%) Mean 1% 0/50 (0%) 1/50 (2%) Total 0/50 (0%) 1/50 (2%) Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Total 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.41% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%) Total 0/50 (0%) Mean 0% SD 0%	Total 3/100 (3%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.41% Total O/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total O/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% Total Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total O/50 (0%) Mean 0% SD 0% Total O/50 (0%) Mean 1% SD 1.41% Total	Total 3/100 (3%) 1/50 (2%)	Total 3/100 (3%)	

^{*:} 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	nign							
		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								
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	llignant	0/50 (0%)	1/50 (20/)			0/50 /09/\	0/50 (09/)	
Overall Incidence	Total	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: Be			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 (00)	4/50 (00%)			0/50 (00/)	0/50 (00/)	
		0/50 (0%)	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	
*Brain: Glioma Malignant								
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: Granular Cell Tumor Ben	nign							
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Mali	ignant	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								
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%
Ɓrain: Meningioma: Benign, Ma	llignant, 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 GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	rtoma						
		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								
One will be add on a co	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/49 (0%)	0/48 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (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%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			1/49 (2%)	1/48 (2%)	
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/97 (2.06%)	Mean 2.06%	SD 0.03%

^{*:} 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 Papilloma								
• "' ''	T	0/50 (0%)	1/50 (2%)	00 4 440/	-	0/49 (0%)	0/48 (0%)	00.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/97 (0%)	Mean 0%	SD 0%
Epididymis: Sarcoma		2/22 (221)	0/50 (00)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
	10tal	0/100 (0%)	iviean 0%	טט ט%				
#Eye: Leiomyoma		2/22 (221)	2(22)			2(72)	2/52 (221)	
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant		0/50 (001)	2/52 (221)			4/50 (001)	0/50 (00/)	
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%
			ivieaii 070					
#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/Rectu Granular Cell Tumor Benigi		•••••						
		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	
#Intestine Large: Colon/Re Leiomyoma	ectum:							
		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	:							
		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: 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	pecified:							
		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 Unsp Carcinoma or Adenoma	pecified:							
		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 Unsp Leiomyosarcoma	pecified:							
		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	
*Islets, Pancreatic: Adenoma		4/50 (001)	0/50 //60			4/50 (00)	0/50 (40)	
Overall Incidence	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%
*Islets, Pancreatic: Carcinoma		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (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 Transitio Papilloma		ım:					(24)	
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: Adenoma								
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								
Occupation of the sec	Tatal	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	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: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	25 22/		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%
*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								
	-	1/50 (2%)	0/50 (0%)	05 4 440/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (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%
*Kidney: Renal Tubule: Nephroblastoma								
		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%
*Kidney: Renal Tubule: Oncocytoma Benign		(20)						
Overall Incidence	Total	1/50 (2%)	0/50 (0%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
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	
*Kidney: Renal Tubule: Polyp Adenomatous				,				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	ıotai	0/100 (0%)	iviean 0%		ı olal	0/100 (0%)		0%
#Lacrimal Gland: Carcinoma		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%
*Liver: Cholangiocarcinoma		2/22 (224)	2/22 (224)			0/50 (00/)	0(70 (00))	
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	22.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (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								
_		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 Adenoma		0/50 (001)	0/50 (001)			0/50 /400	0/50 //0/	
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	2/50 (4%)	2/50 (4%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	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	
*Liver: Hepatocellular Carcino	oma							
		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	oma or Henatohla	astoma						
ricpatocciiaiai Garonic	ina or ricpatoble	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	oma or Hepatoce	Ilular Adenoma 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%
		0,100 (0,0)			·····			
	ma, Hepatocellu	ılar Adenoma, or Hepatob	lastoma					
•	•	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	ıdenoma							
		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%)	
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					
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 0/50 (0%) 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%				
*Lung: 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%				
*Lung: Squamous Cell Carcinom	a	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%				
#Lymph Node, Mesenteric: 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%				
#Mammary Gland: Adenolipoma												
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		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (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: PERINATAL AND POSTNATAL GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female					
#Mammary Gland: Carcinoma 0/50 (0%) 0/50 (0%) 3/50 (6%) 2/50 (4%)												
		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												
		3/50 (6%)	0/50 (0%)			29/50 (58%)	28/50 (56%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	57/100 (57%)	Mean 57%	SD 1.41%				
#Mammary Gland: Fibroma, Fibroadenoma c	or Adenoma	0/50 (001)	0/50 (00/)			00/50 (500/)	00/50 (500()					
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, Fibroadenoma,												
.,		3/50 (6%)	0/50 (0%)			30/50 (60%)	29/50 (58%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	59/100 (59%)	Mean 59%	SD 1.41%				
#Mammary Gland: Myoepithelioma		0/50 (051)	0/50 (05.1)			0/50 (05.)	0/50 (00%)					
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	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%				

^{*:} 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					
*Nose: 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%) 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	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Oral Cavity (Oral Mucos Squamous Cell Carcin	sa, Tongue, Phary	ynx, Tooth, Gingiva):				0/50 (001)	0/50 (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%				
#Oral Cavity (Oral Mucos Squamous Cell Carcin		Squamous, or Papilloma				0/50 (09/)	0/50 (0%)					
	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%				
		` '	` ,	SD 1.41%	Total	` '	` '	SD 0%				
#Oral Mucosa: Squamous Cell Carcin		1/100 (1%)	Mean 1%	SD 1.41% SD 1.41%	Total Total	0/100 (0%)	Mean 0%	SD 0%				
#Oral Mucosa: Squamous Cell Carcin Overall Incidence	oma	1/100 (1%) 0/50 (0%)	Mean 1%			0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%					
#Oral Mucosa: Squamous Cell Carcin Overall Incidence *Ovary: Cystadenoma	oma	1/100 (1%) 0/50 (0%)	Mean 1%			0/100 (0%) 0/50 (0%)	Mean 0%					
Overall Incidence *Ovary:	oma Total	1/100 (1%) 0/50 (0%)	Mean 1%		Total	0/100 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%)	Mean 0% 0/50 (0%) Mean 0% 0/50 (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: 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 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Ovary: Granulosa-Theca Tumor Benign		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor Malignant		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Schwannoma Malignant		0/50 (00/)	0/50 (00/)	
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: Sertoli Cell Tumor Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Thecoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas:					•••••		•••••	
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								
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%
*Pancreas: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	7/50 (14%) 15/100 (15%)	8/50 (16%) Mean 15%	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					
*Parathyroid Gland: Adenoma 0/49 (0%) 1/49 (2%) 0/46 (0%) 0/48 (0%)												
		0/49 (0%)	1/49 (2%)			0/46 (0%)	0/48 (0%)					
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						-/						
	-	0/50 (0%)	0/50 (0%)	OD 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%				
#Peripheral Nerve: Schwannoma: Benign, Ma	ilignant, NOS		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%				
Pituitary Gland: Pars Distal Adenoma	is or Unspeci											
		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 Distal Carcinoma	is or Unspeci											
		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						
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma 12/50 (24%) 10/50 (20%) 20/50 (40%) 21/50 (42%)													
		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													
		0/50 (0%)	1/50 (2%)			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	nedia:	2(72 (221)	(22)			0.170 (004)	(20)						
O	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
*Pituitary Gland: Pars Nervo Schwannoma Malignant	sa:												
		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%					
*Prostate: Adenoma													
		0/50 (0%)	0/50 (0%)										
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%									
*Prostate: Carcinoma or 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	
*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 (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%
#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%
#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	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	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					
#Skin: Basal Cell Adenoma or Basosquamous Tumor Benign												
	•	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, F	Basosquamous Ti	umor Benign, or Trichoep	ithelioma									
Basar Gen Adenoma, E	ousosquamous i	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 Carcinoma												
		0/50 (0%)	1/50 (2%)			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: Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or NO										
		0/50 (0%)	1/50 (2%)			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:												
Basal Cell Carcinoma, NOS), or Trichoepithel		oma, Basosquamous Tur	or (benign, maligna	nt or								
nooj, or monoopiaio.		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%				
#Skin: Basal or Sq. Cell Carci	inoma, Carcinoma	a, Basosq. Tumor (M or B ratoacanthoma, Trichoepi 1/50 (2%)), Basal Cell Adenon			0/50 (0%)	3/50 (6%)					
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	3/100 (3%)	Mean 3%	SD 4.24%				

^{*:} 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: 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%
#Skin:								
Fibroma, Fibrosarcom Hemangiopericytoma	a, Sarcoma, Myx	oma, Myxosarcoma, Malig	nant Fibrous Histio	cytoma, or				
ggp		6/50 (12%)	3/50 (6%)			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:					•••••			
Fibroma, Fibrosarcom	a, Sarcoma, Myx	oma, Myxosarcoma, or Ma	alignant Fibrous His	tiocytoma				
		6/50 (12%)	3/50 (6%)			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		(-2 (-2))	. (== (== ()			0/=0 (00/)	0.700 (001)	
	T	1/50 (2%)	1/50 (2%)	OD 00/	-	0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:								
Fibrosarcoma, Sarcom	ia, Myxosarcoma	, or Malignant Fibrous His	stiocytoma					
		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								
-		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	
#Skin: Hemangiopericytoma								
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: 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%
#Skin: Keratoacanthoma		1/50 (2%)	2/50 (4%)			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: Lipoma						4/50 (00/)	4/50 (00)	
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								
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: Malignant Fibrous Histioo	cytoma							
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: Neurofibrosarcoma or Schwannoma (malignant 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, Neuro					•••••								
rear on brosar coma, recare	nibionia, or c	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: 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%					
#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%)						
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%					
#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%					

^{*:} 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 Carcino	oma							
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	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%
#Skin: Squamous Cell Carcino or Carcinoma	oma, Basal Cell C	Carcinoma, Basosquamo	us Tumor (malignant	or NOS),				
or Carcinoma		0/50 (0%)	1/50 (2%)			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 Papillor	ma	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 Papillor	na or 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 Papillor	ma, Papilloma, S	quamous Cell Carcinoma	or Keratoacanthom	a		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillor	ma, Papilloma, o	r Keratoacanthoma 1/50 (2%)	4/50 (8%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	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: 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								
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%
	ı Olai	0/100 (0%)		3D 0%	TOlai	0/100 (0%)	iviean 0%	3D 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		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%
		` '						
#Spinal Cord: Astrocytoma 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%
*Spleen: 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%
#Stomach, Forestomach: Sarcoma		- (ac)	(00)				(00)	
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 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	
#Stomach, Forestomach: Squamous Cell Carcinom	na							
		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%
#Stomach, Forestomach: Squamous Cell Carcinom								
•	•	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%
#Stomach, Forestomach: Squamous Cell Papilloma	a	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%
Testis: Adenoma		1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
Thymus: Thymoma Benign			•••••					
		0/46 (0%)	0/48 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant		040 (051)	0/40 (05:)			0(40 (00))	0/50 (00)	
O	T-1-1	0/46 (0%)	0/48 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/94 (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 GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Thymus: Thymoma: Benign, Maligna	ant, NOS							
Overall Incidence	Total	0/46 (0%) 0/94 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '				` '		
*Thyroid Gland: C-Cell: Adenoma								
Overall Incidence	Total	11/50 (22%) 19/100 (19%)	8/50 (16%) Mean 19%	SD 4.24%	Total	9/50 (18%) 25/100 (25%)	16/50 (32%) Mean 25%	SD 9.9%
*Thyroid Gland: C-Cell: Carcinoma								
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%
		` ,			ı Ulai	0/100 (0%)		3D 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		44/50 (000()	0/50 (400()			0/50 /400/	40/50 (000/)	
Overall Incidence	Total	11/50 (22%) 19/100 (19%)	8/50 (16%) Mean 19%	SD 4.24%	Total	9/50 (18%) 25/100 (25%)	16/50 (32%) Mean 25%	SD 9.9%
*Thyroid Gland: Follicular Ce Adenoma								
		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%
*Thyroid Gland: Follicular Ce Carcinoma	ell:							
		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						
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma													
		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%					
#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	0/50 (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%					
#Tongue: Squamous Cell Carcinoma	or Papilloma	•	0/50 (0%)			0/50 (00/)	0/50 (0%)						
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%					
#Tooth: Odontoma													
		0/50 (0%)	0/50 (0%)	25 22/		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%					
*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%)	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 GAVAGE

Vehicle: METHYLCELLULOSE

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

^{*:} 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: 212

	Male			Female	
#Uterus: Hemangioma			2/20 (201)	2(-2)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Papilloma					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Polyp Stromal					
Overall Incidence		Total	9/50 (18%) 11/100 (11%)	2/50 (4%) Mean 11%	SD 9.9%
#Uterus: Sarcoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	9/50 (18%) 11/100 (11%)	2/50 (4%) Mean 11%	SD 9.9%

^{*:} 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: 213

	Male			Female	
#Uterus: Schwannoma Malignant			0/50 (0%)	0/50 (/00/)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sq Cell Carcinoma or Papilloma Squamous			2/50 (4%)	0/50 (0%)	
Overall Incidence		Total	2/100 (2%)	Mean 2%	SD 2.83%
#Uterus: Squamous Cell Carcinoma			4/50 (20()		
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
≇Vagina: Granular Cell Tumor Benign			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Sarcoma			0/50 (00%)	0/50 (00/)	
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	
#Vagina:								
Schwannoma Malignant						0/50 (0%)	1/50 (2%)	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Zymbal's Gland: Adenoma								
		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%
#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: 12/30/2020

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 To	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		0/00 (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%
#All Organs: Hemangiosarcoma								
		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%
#All Organs: Hemangiosarcoma or He	emangioma							
		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%

^{*:} 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: 217 Report Date: 12/30/2020

			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		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: Malignant Lymphoma: F	listiocytic, Lym	phocytic, Mixed, NOS, o	r Undifferentiated Cel	I Туре		5/90 (6%)			
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	
#All Organs: Malignant Schwannoma									
		3/90 (3%)	M 0.000/	SD 0%	Total	4/90 (4%) 4/90 (4.44%)	Mean 4.44%	SD 0%	
Overell Institutes	Takal					4/MII (4.4/4%)	Mean 4.44%	>11 11%	
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%						
#All Organs: Mesothelioma: Benign,			Mean 3.33%	30 0%	- Total	0/90 (0%)	Mean 4.4470	GD 0/8	

^{*:} 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: 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										
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 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		0/88 (0%)				0/86 (0%)				
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

Contract/Lab: 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					
*Adrenal Medulla: Pheochromocytoma Beni	gn										
	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/	00.00/			
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

Page: 220

			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 Beniq	gn									
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%		
*Brain: Granular Cell Tumor Malig		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		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, Mali	gnant, NOS									
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

Contract/Lab: 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, Glioma, or Astrocytoma											
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											
Overall Incidence	Total	0/90 0/90 (0%)	(0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Adenoma		0/00	(00/)				0/07 (00/)				
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	Total		(0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mann 00/	SD 0%		
		` '			SD 0%	ı otal	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%)	(070)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%		
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/88	(0%)				0/87 (0%)				
Overall Incidence	Total	0/88 (0%)	(370)	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 Papilloma								
Overall Incidence	Total	0/88 (0%) 0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%) 0/87 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Eye: Leiomyoma		2/22 (22)				(20)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*Heart: 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%
#Intestine Large: Cecum: 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%
#Intestine Large: Colon/Rectu Granular Cell Tumor Benig								
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

Toxicology Data Management System

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

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			Male			Female			
#Intestine Large: Colon/Red	ctum:								
•		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									
		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									
Overall Incidence	Tatal	0/90 (0%)	Mana 00/	CD 00/	Tatal	1/90 (1%)	Mann 4 440/	CD 00/	
Overall incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	
#Intestine Small: Site Unspe Carcinoma	ecified:	0/00 (00/)				0/00 /00/)			
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspe 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 Unspe Leiomyosarcoma									
Overell Insidence	Tatal	0/90 (0%)	Maga 00/	CD 00/	Tatal	1/90 (1%)	Mann 4 440/	CD 00/	
Overall Incidence	Total	0/90 (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	
*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	8/90 (8.89%)	Mean 8.89%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
*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 Transitio Papilloma		um:				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%
*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		1/90 (1%)				1/90 (1%)		
Overall Incidence	Total	` '	Moon 1 110/	SD 00/	Total	` '	Moon 1 110/	SD 00/
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	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			
*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%	
*Kidney: Renal Tubule: Nephroblastoma									
		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: Oncocytoma Benign									
		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

Contract/Lab: 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	
*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: Cholangiocarcinoma		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 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: Hemangioma								
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

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			Male			Female				
*Liver: Hepatocellular Carcinoma 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 Carcinon	ia or Hepatobia	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 Carcinom Overall Incidence	na or Hepatocel Total	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 Carcinom Overall Incidence	na, Hepatocellu Total	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		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%		
*Lung: Alveolar/Bronchiolar Ca	rcinoma	0/90 (0%)				0/90 (0%)				
Overall Incidence	Total	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

Contract/Lab: 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 Carcinoma or Alveolar/Bronchiolar 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%			
*Lung: Sarcoma		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%			
*Lung: Squamous 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%			
#Lymph Node, Mesenteric: Hemangiosarcoma		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: 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		0/90 (0%)				8/90 (9%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	8/90 (8.89%)	Mean 8.89%	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: 229 Report Date: 12/30/2020

			Male				Female	
#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	a							
Owner Haller and America	T-1-1	0/90 (0%)	Mara 2007	00.00/	Tatal	16/90 (18%)	Maria 47 700/	OD 00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	16/90 (17.78%)	Mean 17.78%	SD 0%
#Mammary Gland: Fibroadenoma		2/90 (2%)				63/90 (70%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	63/90 (70%)	Mean 70%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	a or Adenoma	0/00 /00/				04/00 (748/)		
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	64/90 (71%) 64/90 (71.11%)	Mean 71.11%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, o	r Adenoma 2/90 (2%)				66/90 (73%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	66/90 (73.33%)	Mean 73.33%	SD 0%
#Mammary Gland: Myoepithelioma								
		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	
*Nose: Carcinoma		0/89 (0%)				0/90 (0%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino		nx, Tooth, Gingiva):					•••••	
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					2/90 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
Overall Incidence #Oral Mucosa: Squamous Cell Carcino		0/90 (0%)						
#Oral Mucosa:		0/90 (0%)				` ,		
#Oral Mucosa: Squamous Cell Carcino	oma	0/90 (0%)				1/90 (1%) 1/90 (1.11%)		
#Oral Mucosa: Squamous Cell Carcino Overall Incidence *Ovary:	oma	0/90 (0%)				1/90 (1%)		
#Oral Mucosa: Squamous Cell Carcino Overall Incidence *Ovary: Cystadenoma	oma Total	0/90 (0%)			Total	1/90 (1%) 1/90 (1.11%) 1/90 (1%)	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	
*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			0(00 (00))		
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%
*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%

^{*:} 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: Sertoli Cell Tumor Benigi	n							
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%
*Ovary: Tubulostromal Carcinom	a					0/00 (00/)		
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				•••••		•••••		
		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%
*Pancreas: Carcinoma or 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%

^{*:} 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	
*Parathyroid Gland: Adenoma								
		1/83 (1%)				0/87 (0%)		
Overall Incidence	Total	1/83 (1.2%)	Mean 1.2%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Paraganglioma								
		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 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%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali								
		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%
*Pituitary Gland: Pars Distali Carcinoma		fied Site:						
		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%

^{*:} 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

Carcinoma or Adenoma

*Pituitary Gland: Pars Intermedia:

*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma

..... *Pituitary Gland: Pars Nervosa: **Schwannoma Malignant**

......

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Overall Incidence

Adenoma

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Male **Female** *Pituitary Gland: Pars Distalis or Unspecified Site: 17/89 (19%)44/90 (49%)17/89 (19.1%) Mean 19.1% SD 0% Total 44/90 (48.89%) Mean 48.89% SD 0% 0/89 (0%)0/90 (0%)0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% 0/89 (0%)0/90 (0%)0/89 (0%) Mean 0% SD 0% Total 0/90 (0%) Mean 0% SD 0% 0/89 (0%)0/90 (0%)0/89 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/90 (0%) 2/90 (2%)2/90 (2.22%) Mean 2.22% SD 0%

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Report Date: 12/30/2020

*Prostate:

*Prostate: Adenoma

Carcinoma or Adenoma

2/90 (2%)

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

Total

Total

Total

Total

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	
*Salivary Glands: Schwannoma 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%
#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: Liposarcoma		0/90 (0%)	M 00/	OD 00/	T-1-1	0/90 (0%)	M 00/	OD OV
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
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: Basal Cell Adenoma		1/90 (1%)				0/90 (0%)		
Overall Incidence	Total	1/90 (1%)	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

Contract/Lab: 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 Adenoma or	Basosquamous	s Tumor Benign							
	•	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, Ba	asosquamous T	umor Benign, or Trichoe 1/90 (1%)	epithelioma			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 o	r Basosquamou	us Tumor (malignant or N 0/90 (0%)	NOS)			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, I NOS), or Trichoepitheli		oma, Basosquamous Tu	mor (benign, maligna	nt or					
NOS), or Trichoephnen	Oilia	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 or Sq. Cell Carcir	noma, Carcinom	a, Basosq. Tumor (M or	B), Basal Cell Adenor						
Adenoma, Papilloma, S	q rapiliollia, Ke	8/90 (9%)	•			0/90 (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: 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: Fibroma, Fibrosarcoma, Hemangiopericytoma	Sarcoma, Myx	oma, Myxosarcoma, Mal	ignant Fibrous Histio	cytoma, or				
		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%
#Skin: Fibroma, Fibrosarcoma, Overall Incidence	Sarcoma, Myx	oma, Myxosarcoma, or N 5/90 (6%) 5/90 (5.56%)	Malignant Fibrous His	tiocytoma SD 0%	Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%
#Skin: Fibrosarcoma	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: Fibrosarcoma, Sarcoma	, Myxosarcoma	a, or Malignant Fibrous H 3/90 (3%)	listiocytoma			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		0/00 (0%)				0/00 (09/)		
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Maan Oo/	CD 00/	Total	0/90 (0%) 0/90 (0%)	Maan OO/	CD 00/
Overall incluence	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: Hemangiopericytoma		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: Hemangiosarcoma		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: 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		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%
#Skin: Liposarcoma		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: Malignant Fibrous Histion	cytoma	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%

^{*:} 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: Neurofibrosarcoma or Sc	chwannoma (m	•						
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: Neurofibrosarcoma, Neu	rofibroma, or S	Schwannoma (benign, m	alignant or NOS)					
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: Osteosarcoma								
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: Pilomatrixoma		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: Sarcoma								
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Skin: Schwannoma Malignant		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%

^{*:} 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: Squamous Cell Carcinoma	Total	0/90 (0%)	Macr. 00/	CD 00/	Total	0/90 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma	Basal Cell	-	ous Tumor (malignan	t or NOS),				
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 Papilloma		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%
#Skin: Squamous Cell Papilloma c	r Papilloma							
Overall Incidence	Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, I	Papilloma, S	Squamous Cell Carcinom 7/90 (8%)	a or Keratoacanthon	na		0/90 (0%)		
Overall Incidence	Total	7/90 (7.78%)	Mean 7.78%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, I	Papilloma, o	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%

^{*:} 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: 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								
		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: 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%
#Spinal Cord: Astrocytoma Malignant						2(22)		
	-	0/90 (0%)		00.00/	+	0/90 (0%)	NA 00/	OD 00/
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		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%
#Stomach, Forestomach: Sarcoma								
		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%

^{*:} 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						
#Stomach, Forestomach: Squamous 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%		
#Stomach, Forestomach: Squamous Cell Carcinom		a Squamous								
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%		
#Stomach, Forestomach: Squamous Cell Papilloma		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%		
*Testis: Adenoma		2/90 (2%)								
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%						
*Thymus: Thymoma Benign										
		0/88 (0%)				1/87 (1%)				
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1.15%)	Mean 1.15%	SD 0%		
*Thymus: Thymoma Malignant										
Overall Incidence	Total	0/88 (0%) 0/88 (0%)	Mean 0%	SD 0%	Total	1/87 (1%) 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				
*Thymus: Thymoma: Benign, Malignant, NOS 0/88 (0%) 2/87 (2%)										
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	2/87 (2.3%)	Mean 2.3%	SD 0%		
*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%) 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 Ce Adenoma										
Overall Incidence	Total	0/89 (0%) 0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%		
*Thyroid Gland: Follicular Ce 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%		

^{*:} 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: Follicular Cell: Carcinoma or Adenoma										
	0/89 (0%)				1/90 (1%)					
Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%			
	` '				` '					
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%			
	0/00 /09/)				1/00 /19/)					
Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1%)	Mean 1.11%	SD 0%			
or Papillom	-				1/90 (1%)					
Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%			
	0/90 (0%)				0/90 (0%)					
Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
	0/80 (0%)				1/09 /10/)					
Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/88 (1.14%)	Moon 1 149/	SD 0%			
	Total Total or Papillom Total Total	0/89 (0%) Total 0/89 (0%) 1/90 (1%) Total 1/90 (1.11%) 0/90 (0%) Total 0/90 (0%) or Papilloma Squamous 0/90 (0%) Total 0/90 (0%) Total 0/90 (0%) Total 0/90 (0%) 0/90 (0%)	10	1		1/90 (1%)	1/90 (1%) 1/90 (1%) Mean 1.11% Mean			

^{*:} 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
#Uterus: Adenocarcinoma		
Overall Incidence		
#Uterus: Adenocarcinoma or Adenoma		
Overall Incidence		
#Uterus: Adenoma		
Overall Incidence		
#Uterus: Adenoma, Adenocarcinoma, Sq Cell Carcinor	na, or Sq Cell Papilloma	
Overall Incidence		
#Uterus: Deciduoma Benign		
Overall Incidence		
#Uterus: Granular Cell Tumor Benign		
Overall Incidence		
*: Denominator is number of animals with tissues examine #: Denominator is number of animals necropsied	d microscopically	

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: Hemangioma		
Overall Incidence		
#Uterus: Papilloma		
Overall Incidence		
#Uterus: Polyp Stromal		
Overall Incidence		
#Uterus: Sarcoma		
Overall Incidence		
#Uterus: Sarcoma Stromal		
Overall Incidence		
#Uterus: Sarcoma Stromal or Polyp Stromal		
Overall Incidence		
* Denominator is number of animals with tissues examined		

Contract/Lab: 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: Schwannoma Malignant					
Overall Incidence					
#Uterus: Sq Cell Carcinoma or Papilloma Squamous					
Overall Incidence					
#Uterus: Squamous Cell Carcinoma					
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			•••••	•••••	
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
*: Denominator is number of animals with tissues examined micros	scopically				

^{#:} 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			
#Vagina: Schwannoma Malignant										
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%		
#Zymbal's Gland: 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%		
#Zymbal's 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%		
#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