

# NTP Historical Controls Report

By Route and Vehicle

Harlan Sprague-Dawley RATS

November 2017

# 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: 01/20/2018

# **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%)				14/50 (28%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	14/50 (28%)	Mean 28%	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	mangioma	1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 6

			Male				Female	
#All Organs: Histiocytic 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%
#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%
#All Organs: Leukemia: Lymphocytic, M 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: Malignant Lymphoma: Hist	iocytic, Lym <sub>l</sub>	phocytic, Mixed, NOS, o	r Undifferentiated Ce	ell Type	<b>T</b>	0/50 (0%)		OD 001
WAII Organs: Malignant Schwannoma	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
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, Mal	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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: Maligna	nt							
		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 Cortex: Adenoma								
		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%
*Adrenal Cortex: Carcinoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Be		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	lignant	2/50 (4%)				0/50 (09/)		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Page: 8

Report Date: 01/20/2018

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male			Female						
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  8/50 (16%)  0/50 (0%)												
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Glioma Malignant												
Overall Incidence												
*Brain: Granular Cell Tumor Benig	n						•••••					
Overall Incidence												
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	rtoma			•••••		•••••					
Overall Incidence												
*Brain: Schwannoma Malignant												
Overall Incidence												
*Clitoral/Preputial Gland: Carcinoma		0/50 (09/)				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%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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**: 9

			Male				Female	
*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%
					Total		ivican 070	
*Epididymis: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
		0/30 (0 /8)	ivican 070					
#Eye: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,		3D 0%	ı Olai	0/50 (0%)	Wearr 0%	
*Heart: Schwannoma Malignant								
		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%
#Intestine Large: Colon/Rectu Granular Cell Tumor Benig	um:							
J		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 Large: Colon/Rectu Leiomyoma								
		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: 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%
#Intestine Small: Site Unspec Carcinoma	ified:							
		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 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%
#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%
*Islets, Pancreatic: 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 01/20/2018

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			Male				Female	
*Islets, Pancreatic: 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%
*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 Transitic Papilloma	onal Epitheliu					0(50 (00))		
Overall Incidence	Total	0/50 (0%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)	Mean 0%		ı otal	0/50 (0%)	wiean 0%	טע עא טא טא טא
*Kidney: Renal Tubule: 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%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%	)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
	<b>.</b>	1/50 (2%)		<b>OD</b> 00/	<b>+</b>	0/50 (0%)		00.00/
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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				Female	
*Kidney: Renal Tubule: Lipoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign		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%
*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%
*Liver: Hepatocellular Carcinoma		lular 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%
*Liver: Hepatocellular Carcinoma,		ar Adenoma, or	Hepatob	lastoma			2/50 (4%)		
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Lung: Alveolar/Bronchiolar Aden	oma	0/49	(0%)				1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	(070)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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

			Ma	le			Female	
*Lung: Alveolar/Bronchiolar Ca	arcinoma							
		0/49 (	(0%)			0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca	arcinoma or Alve							
		0/49 (	(0%)			1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Lung: Sarcoma		0/49 (	(0%)			1/50 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Lymph Node, Mesenterio Hemangiosarcoma	<b>:</b> :	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								
-		0/50 (	(0%)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (	(0%)			3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
#Mammary Gland: Carcinoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
#Mammary Gland: Carcinoma or Adenoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%
#Mammary Gland: Fibroadenoma		4/50	(20/)				20/50 (599/)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	29/50 (58%) 29/50 (58%)	Mean 58%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o							00/50 (000)		
Overall Incidence	Total	1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, (		Adenoma							
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Myoepithelioma		0/50	(00()				4/50 (00()		
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
#Oral Cavity (Oral Mucos Squamous Cell Carcing		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 Squamous Cell Carcing		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 Mucosa: Squamous Cell Carcino	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						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Benign							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Malignant					0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 01/20/2018

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

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

			Male				Female	
*Ovary: Granulosa Cell Tumor: B	enign, Maligna	ant, NOS						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumor								
Overall Incidence	·				Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Ovary: Sertoli Cell Tumor Benig								
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 Carcinom								
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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
*Pancreas: 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%
*Pancreas: Carcinoma or Adenoma	1							
		5/50 (10%)				0/50 (0%)		
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
		0/43 (0%)				0/47 (0%)		
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma								
		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 Dis 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%
*Pituitary Gland: Pars Dis Carcinoma or Adenoma		ied 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 18

			Male			Female			
media:	,								
		(0%)				0/50 (0%)			
	, ,					, ,			
		(0%)				0/50 (0%)			
Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
	0/50	(09/)							
Total	0/50 (0%)	,	Mean 0%	SD 0%					
Total	0/50 (0%)	,	Mean 0%	SD 0%					
		(2%)				0/50 (0%)			
	` '					()			
Total		(0%)	Moon 0%	SD 0%	Total	` ,	Moon 0%	SD 0%	
	rmedia:  Total  Total  Total	0/50 Total 0/50 (0%)  rmedia:  0/50 Total 0/50 (0%)  0/50 Total 0/50 (0%)  Total 0/50 (0%)  1/50 Total 1/50 (2%)	0/50 (0%) Total 0/50 (0%)  rmedia:  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 1/50 (2%)  Total 1/50 (2%)  0/50 (0%)	7media:  0/50 (0%)  Total 0/50 (0%)  Mean 0%  7media:  0/50 (0%)  Total 0/50 (0%)  Mean 0%  0/50 (0%)  Total 0/50 (0%)  Mean 0%  1/50 (0%)  Total 0/50 (0%)  Mean 0%  1/50 (2%)  Total 1/50 (2%)  Mean 2%	Tredia:    O/50 (0%)	Treedia:  Total 0/50 (0%) Mean 0% SD 0% Total  Treedia:  Total 0/50 (0%) Mean 0% SD 0% Total  Total 0/50 (0%) Mean 0% SD 0% Total  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%	Tredia:    Total	Tredia:    Total   0/50 (0%)   Mean 0%   SD 0%   Total   0/50 (0%)   Mean 0%	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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			
#Skeletal Muscle: Sarcoma										
		0/50	(0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Skin: Basal Cell Adenoma										
		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma or B Overall Incidence	<b>asosquamous</b> Total	Tumor Benign 0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Adenoma, Bas					SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		, ,					` '			
#Skin: Basal Cell 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%	
#Skin: Basal Cell Carcinoma or										
			(2%)				0/50 (0%)			
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 20

Report Date: 01/20/2018

Route: GAVAGE

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

Vehicle: CORN OIL

			Male				Female					
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma												
Overell Incidence	Tatal	1/50 (2%)	Maar 20/	SD 0%	Tatal	0/50 (0%)	Maga 00/	SD 0%				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
		a, Basosq. Tumor (M or l ratoacanthoma, Trichoep 6/50 (12%)		ma,		0/50 (0%)						
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#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%				
Hemangiopericytoma		oma, Myxosarcoma, Mali 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 N 7/50 (14%)	lalignant Fibrous His	tiocytoma		2/50 (4%)						
Overall Incidence	Total	7/50 (14%)	Mean 14%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%				
#Skin: Fibrosarcoma		1/50 (2%)				1/50 (2%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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					
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  2/50 (4%)  1/50 (2%)											
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%			
#Skin: 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%			
#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: Malignant Fibrous Histi	ocytoma	4/50 (601)				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%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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				
#Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS)											
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: Neurofibrosarcoma, No	ourofibroma or S	chwannoma (honian in	nalignant or NOS)	•••••							
Neuronbrosarcoma, N	suronbronia, or 3	0/50 (0%)	langhant of NOS)			1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	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 Malignar	nt	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:			• • • • • • • • • • • • • • • • • • • •	•••••							
Squamous Cell Carcin	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:		•••••		•••••							
Squamous Cell Carcinor Carcinoma	oma, Basal Cell C	Carcinoma, Basosquam	ous Tumor (malignan	it or NOS),							
		2/50 (4%)				0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 23

			Male			Female						
#Skin: Squamous Cell Papilloma  1/50 (2%)  0/50 (0%)												
		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	or Panilloma											
oquamous ocn i upmoma	or r apinoma	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, Overall Incidence	Papilloma, S	quamous Cell Carcinom 5/50 (10%) 5/50 (10%)	a or Keratoacanthon	na SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma,						0/50 (0%)						
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma												
		0/50 (0%)		<b>OD</b> 00/	<b>-</b>	0/50 (0%)		00.007				
	<b>T</b>		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
Overall Incidence	Total	0/50 (0%)	IVICALI U70									
Overall Incidence #Skin: Sebaceous Gland: Carcinoma or Adenoma	Total											
#Skin: Sebaceous Gland:	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
*Spleen: Hemangiosarcoma		,							
Overall Incidence	Total	0/50 0/50 (0%)	(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%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma			(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 c		a Squamous	(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									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		3/49	(6%)						
Overall Incidence	Total	3/49 (6.12%		Mean 6.12%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 25

			Male				Female	
*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 (0%)				0/47 (0%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malign								
		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%
*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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 26

				Male				Female	
*Thyroid Gland: Follicular C Carcinoma	ell:								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular C Carcinoma or Adenoma	ell:								
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma			(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		a Squamous							
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		•••••	•••••						
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
*Urinary Bladder: Leiomyosarcoma		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma						0/50 /00/		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma						0/50 /00/		
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 Stromal						0/50 /40/		
Overall Incidence					Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Page: 28

Report Date: 01/20/2018

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

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

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
carcoma caromar or r cryp caromar			12/50 (24%)		
Overall Incidence		Total	12/50 (24%)	Mean 24%	SD 0%
#Uterus:					
Schwannoma Malignant			2/52 (22/)		
			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%
#M =2					
#Vagina: Granular Cell Tumor Benign					
Grandial Cell Fullion Belligh			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina:					
Polyp			4/50 (001)		
Occupation of the second		T-1-1	1/50 (2%)	M 00/	OD 00/
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina:					
Schwannoma Malignant					
-			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 29

₹	epc	ort	Date:	01/2	0/20	118

			Male			Female			
#Zymbal's 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%	
#Zymbal's 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%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 30

Report Date: 01/20/2018

# **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

**Page:** 31

			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 Tu	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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 32

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

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

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 33

			Male				Female				
#All Organs: Mesothelioma: Malignant  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%			
							·······································				
*Adrenal Cortex: Adenoma											
, idonoma		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%			
		* *				, ,		30 0%			
*Adrenal Medulla: Pheochromocytoma Ben	ign										
Overall Incidence	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%			
*Adrenal Medulla: Pheochromocytoma Con											
•	•	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 Mali	ignant	2/50 (4%)				0/49 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 34

			Male				Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  14/50 (28%)  Overall Incidence  Total  14/50 (28%)  Overall Incidence  Total  14/50 (28%)  Overall Incidence  Total  14/50 (28%)  Noan 28%  SD 0%  Total  14/50 (28%)												
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%				
*Brain: Glioma Malignant		0/50 (400)				4/50 (00)						
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Brain: Granular Cell Tumor Benig	n	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Brain: Oligodendroglioma, Glioma						1/50 (2%)						
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Brain: Schwannoma Malignant												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%				
*Clitoral/Preputial 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%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 35

			Male				Female	
*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%
*Epididymis: Sarcoma								
Overell Incidence	Tatal	1/50 (2%)	Mana 200/	CD 00/				
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%				
#Eye: Leiomyoma								
Occupation of the sec	T-1-1	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%
*Heart: Schwannoma Malignant								
Overall Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	SD 0%
Overali incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	
#Intestine Large: Colon/Rectu Granular Cell Tumor Benigi								
		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 Large: Colon/Rectu Leiomyoma	ım:							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 36

		Male				Female		
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: Leiomyosarcoma								
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	ified:	2/20 (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%
#Intestine Small: Site Unspec Carcinoma or Adenoma						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								
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		8/50 (16%)				1/50 (2%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 37

			Male				Female	
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
*Kidney: Pelvis and Transitio Papilloma	nal Epitheliu					0/20 (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: Adenoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 38

				Male				Female			
*Kidney: Renal Tubule: Lipoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Oncocytoma Benign		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%		
*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%		
*Liver: Hepatocellular Carcinoma		lular Adenoma	(0%)				2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Liver: Hepatocellular Carcinoma,		ar Adenoma, or					2/50 (4%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
*Lung: Alveolar/Bronchiolar Aden	oma	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%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 39

			Male				Female					
*Lung: Alveolar/Bronchiolar 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%				
*Lung: Alveolar/Bronchiolar C												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Lung: 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%				
#Lymph Node, Mesenteri 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												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Mammary Gland: Adenoma		0/50 /00/				4/50 (00)						
O	Tatal	0/50 (0%)	Maran 00/	OD 00/	Tatal	4/50 (8%)	Maran 00/	OD 00/				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
						, ,		
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	9/50 (18%) 9/50 (18%)	Mean 18%	SD 0%
#Mammary Gland: Fibroadenoma		2/50 (40/)				20/50 (400/)		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	20/50 (40%) 20/50 (40%)	Mean 40%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma						22/50 (469/)		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	23/50 (46%) 23/50 (46%)	Mean 46%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,						07/50 /540()		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	27/50 (54%) 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%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 41

			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcing		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 Squamous Cell Carcing		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 Mucosa: Squamous Cell Carcino	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%
*Ovary: Cystadenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Benign							
Overall Incidence					Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa Cell Tumor I	Malignant					0/50 (0%)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

ce for Selected Control Animal Groups

Route: INHALATION

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Report Date: 01/20/2018

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

Vehicle: AIR

			Male				Female	
*Ovary: Granulosa Cell Tumor: Ber	nign, Maligna	nt, NOS						
Overall Incidence					Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%
*Ovary: Granulosa-Theca Tumor B	enian					•••••		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*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								
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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 43

			Male				Female	
*Pancreas: 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%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/48 (0%)				0/45 (00/)		
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/45 (0%) 0/45 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Dista Adenoma Overall Incidence	alis or Unspeci Total	fied Site: 11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%) 18/50 (36%)	Mean 36%	SD 0%
*Pituitary Gland: Pars Dista 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%
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		fied Site:						
		11/50 (22%)				18/50 (36%)		
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	18/50 (36%)	Mean 36%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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			
media:								
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
media:								
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	0/50 (0%)	Mean 0%	SD 0%					
•••••	0/50 (00/)							
Total	0/50 (0%)	Mean 0%	SD 0%					
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Total	, ,	Maan 00/	CD 00/	Total	` '	Maan 20/	SD 0%	
	Total media: Total  Total  Total	0/50 (0%) Total 0/50 (0%)  media:  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  0/50 (0%)	media:           0/50 (0%)         Mean 0%           media:           0/50 (0%)         Mean 0%           Total         0/50 (0%)         Mean 0%           O/50 (0%)         Mean 0%	media:           0/50 (0%)         Mean 0%         SD 0%           media:           0/50 (0%)         Mean 0%         SD 0%           Total 0/50 (0%)         Mean 0%         SD 0%	media:           0/50 (0%)         Mean 0%         SD 0%         Total           media:           Total         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%         Total	Mean 0% SD 0% Total	Total	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 45

				Male				Female	
#Skeletal Muscle: Sarcoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Basal Cell Incidence	asosquamous Total	_	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas	osquamous T	umor Benign, or 0/50		thelioma	CD 00/	Tatal	0/50 (0%)	M 00/	CD 00
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma		0/50	(00)				(20)		
Owner Haller at James	T-1-1		(0%)	Mara 2007	OD 00/	T-1-1	1/50 (2%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal Cell Carcinoma or I	Basosquamou		nant or NO:	S)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	(0/0)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
		0/50 (0%)					, ,		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli	Basal Cell Adendoma	oma, Basosquamous To	umor (benign, maligna	ant or					
		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 or Sq. Cell Carci Adenoma, Papilloma, S		ratoacanthoma, Trìcho		ma,		1/50 (2%)			
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Skin: Fibroma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence	a, Sarcoma, Myxo	oma, Myxosarcoma, Ma 1/50 (2%) 1/50 (2%)	lignant Fibrous Histio	ocytoma, or SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or 1/50 (2%)	Malignant 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%)			
		0/50 (0%)				0/30 (0/6)			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  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: Hemangioma											
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Hemangiosarcoma			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Keratoacanthoma			(6%)				0/50 (0%)				
Overall Incidence	Total	3/50 (6%)	,	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Lipoma											
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Skin: Malignant Fibrous Histic											
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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Report Date: 01/20/2018

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibrosarcoma or Scl	hwannoma (m	nalignant 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, Neuro						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%
#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		Carcinoma, Basosquamo		it 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 49

			Male				Female	
#Skin: Squamous Cell Papillom	a							
		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 Papillom								
oquamous cen i apinom	a or r apinoma	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 Papillom Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom	a, Papilloma, or	Keratoacanthoma 4/50 (8%)	Magn 90/	SD 00/	Total	0/50 (0%)	Mann 00/	SD 09/
#Skin:	a, <b>Papilloma, or</b> Total	Keratoacanthoma 4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom Overall Incidence	a, <b>Papilloma, or</b> Total	Keratoacanthoma 4/50 (8%) 4/50 (8%)		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillom Overall Incidence  #Skin: Sebaceous Gland: Adenoma	a, Papilloma, or Total	Keratoacanthoma 4/50 (8%) 4/50 (8%)				0/50 (0%)		
#Skin: Squamous Cell Papillom Overall Incidence  #Skin: Sebaceous Gland:	a, <b>Papilloma, or</b> Total	Keratoacanthoma 4/50 (8%) 4/50 (8%)		SD 0% SD 0%	Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
#Skin: Squamous Cell Papillom  Overall Incidence  #Skin: Sebaceous Gland: Adenoma	a, Papilloma, or Total	Keratoacanthoma 4/50 (8%) 4/50 (8%)				0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 50

				Male				Female	
*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									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50	(09/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o	or Papilloma		(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%
#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%)	(0/0)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 51

			Male	1			Female	
*Thymus: Thymoma Benign								
		0/48 (0%	,	05.00		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	<b>25</b>
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		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: Benign, Maligna	ant, NOS	0/48 (0%	)			0/50 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma						•••••		
		2/50 (4%	,	05.00/		2/50 (4%)		00.00
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
*Thyroid Gland: C-Cell: 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%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	••••							
		3/50 (6%	,	00.004		2/50 (4%)		00.00
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 52

0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
0/50 (0%) 0/50	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	` '						
	` '						
0/50 (0%)					0/50 (0%)		
	ا	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0/50	(0%)				0/50 (0%)		
0/50 (0%)	` ′		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
					0/50 (0%)		
0/50 (0%)	` ′		SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
					•••••		
	` '				0/50 (0%)		
, ,	-		SD 0%	Total	` '	Mean 0%	SD 0%
	` '	Maan 2%	SD 0%	Total	` '	Mean 0%	SD 0%
	0/50 (0%)  0/50 0/50 (0%)  na Squamous 0/50 0/50 (0%)  1/50 1/50 (2%)	0/50 (0%)  0/50 (0%)  0/50 (0%)  1  1/50 (2%)  1/50 (2%)	0/50 (0%) Mean 0%  0/50 (0%) Mean 0%  1/50 (0%) Mean 0%  1/50 (2%)  1/50 (2%) Mean 2%	0/50 (0%) Mean 0% SD 0%  0/50 (0%) Mean 0% SD 0%  na Squamous 0/50 (0%) Mean 0% SD 0%  1/50 (0%) Mean 0% SD 0%	0/50 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total  na Squamous 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total  1/50 (2%) 1/50 (2%) Mean 2% SD 0% Total	0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  na Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  na Squamous 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  0/50 (0%) Mean 0%  1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

**Page:** 53

Report Date: 01/20/2018

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

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

			Male			Female			
*Urinary Bladder: Leiomyosarcoma									
One will be at town as	T-1-1	0/50 (0%)	Mara 00/	OD 00/	T-1-1	0/50 (0%)	Magaza 007	<b>OD</b> 00/	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
						1/50 (2%)			
Overall Incidence					Total	1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Hemangiosarcoma									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Polyp Stromal									
,,						7/50 (14%)			
Overall Incidence					Total	7/50 (14%)	Mean 14%	SD 0%	
#Uterus: Sarcoma Stromal									
						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 54

	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
			7/50 (14%)		
Overall Incidence		Total	7/50 (14%)	Mean 14%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Squamous Cell Carcinoma					
Overall Incidence		Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Granular Cell Tumor Benign					
Grandia Gon Famor Bonigh			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%
#Vagina: Polyp					
			0/50 (0%)		
Overall Incidence		Total	0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant					
			1/50 (2%)		
Overall Incidence		Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 55

			Male				Female	
#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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 56

Report Date: 01/20/2018

## **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	051026001	11/08/10	729	50(2)	30(706)	615.3	2-Hydroxy-4-methoxybenzophenone
					Female		
Battelle Columbus Laboratory	051026001	11/09/10	730	50(4)	30(657)	379.6	2-Hydroxy-4-methoxybenzophenone

Contract/Lab: 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:** 57

			Male			Female				
#All Organs: Benign Tumors										
-		38/50 (76%)				41/50 (82%)				
Overall Incidence	Total	38/50 (76%)	Mean 76%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%		
#All Organs: Malignant Tumors										
		11/50 (22%)				15/50 (30%)				
Overall Incidence	Total	11/50 (22%)	Mean 22%	SD 0%	Total	15/50 (30%)	Mean 30%	SD 0%		
#All Organs: Malignant and Benign Tum	ors	42/50 (84%)				47/50 (94%)				
Overall Incidence	Total	42/50 (84%)	Mean 84%	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										
		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 Hema	angioma	0(50 (00()				0/50 /00/				
Overall 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%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 58

Report Date: 01/20/2018

SD 0%

0/50 d 0/50 (0' 0/50 d 0/50 (0'	(0%) %) (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
0/50 (0° 0/50 al 0/50 (0°	%) `	Mean 0%	SD 0%	Total	()	Mean 0%	SD 0%
0/50 (09	(0%)						
0/50 (09	(070)				0/50 (0%)		
	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
0/50 Il 0/50 (0º	(0%) %)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
					0/50 (0%)		
ol 0/50 (0°	%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
4/50	(20/)				0/50 (00/)		
	, ,	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 al 0/50 (09 cs, <b>Lymphocytic, Mix</b> 0/50 (09 cs) al 0/50 (09 cs)	0/50 (0%)  al 0/50 (0%)  c, Lymphocytic, Mixed, NOS, or 0/50 (0%)  al 0/50 (0%)	al 0/50 (0%) Mean 0%  c, Lymphocytic, Mixed, NOS, or Undifferentiated Ce 0/50 (0%) al 0/50 (0%) Mean 0%	0/50 (0%) al 0/50 (0%) Mean 0% SD 0%  c, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%) al 0/50 (0%) Mean 0% SD 0%  1/50 (2%)	0/50 (0%)  al 0/50 (0%)  Mean 0%  SD 0%  Total  Total  Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type  0/50 (0%)  al 0/50 (0%)  Mean 0%  SD 0%  Total	0/50 (0%)  al 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type  0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  al 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  1/50 (2%)	0/50 (0%)  al 0/50 (0%)  Mean 0%  SD 0%  Total 0/50 (0%)  Mean 0%  Mean 0%  Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type  0/50 (0%)  al 0/50 (0%)  Mean 0%  SD 0%  Total 0/50 (0%)  Mean 0%  1/50 (2%)  0/50 (0%)

SD 0%

0/50

Total

0/50 (0%)

(0%)

Mean 0%

Total

1/50

1/50 (2%)

(2%)

Mean 2%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 59

		Male				Female		
nt								
	1/50 (2%)				0/50 (0%)			
Total	, ,				, ,		SD 0%	
	, ,		05.00/		` '		05.00/	
Total	3/50 (6%)	Mean 6%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
	0/50 (0%)				0/50 (0%)			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
nign Total	9/50 (18%) 9/50 (18%)	Mean 18%	SD 0%	Total	3/50 (6%) 3/50 (6%)	Mean 6%	SD 0%	
	` ,							
mplex								
	, ,				, ,			
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
lignant	2/50 /69/\				2/50 (40/)			
Total	` ,	Mean 6%	SD 0%	Total	, ,	Mean 4%	SD 0%	
	Total  Total  nign  Total  mplex  Total	1/50 (2%) Total 1/50 (2%)  3/50 (6%)  Total 3/50 (6%)   0/50 (0%)  Total 0/50 (0%)  Total 9/50 (18%)  Total 9/50 (18%)  mplex  0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)	1/50 (2%) Total 1/50 (2%) Mean 2%  3/50 (6%) Total 3/50 (6%) Mean 6%  0/50 (0%) Total 0/50 (0%) Mean 0%  nign 9/50 (18%) Total 9/50 (18%) Mean 18%  mplex 0/50 (0%) Total 0/50 (0%) Mean 0%	1/50 (2%) Total 1/50 (2%) Mean 2% SD 0%  3/50 (6%) Total 3/50 (6%) Mean 6% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  1ign 9/50 (18%) Total 9/50 (18%) Mean 18% SD 0%  mplex 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%	Total 1/50 (2%) Mean 2% SD 0% Total  3/50 (6%) Mean 6% SD 0% Total  3/50 (6%) Mean 6% SD 0% Total  0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total  nign 9/50 (18%) Mean 18% SD 0% Total  mplex 0/50 (0%) Mean 0% SD 0% Total  iignant 3/50 (6%)	tt  1/50 (2%) Mean 2% SD 0% Total 0/50 (0%)  7 total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%)  7 total 3/50 (6%)  Total 3/50 (6%)  Mean 6% SD 0% Total 3/50 (6%)  Total 0/50 (0%)  Total 0/50 (0%)  Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (18%)  Total 9/50 (18%) Mean 18% SD 0% Total 3/50 (6%)  Mean 18% SD 0% Total 3/50 (6%)	tt  1/50 (2%) Total 1/50 (2%) Mean 2% SD 0% Total 0/50 (0%) Mean 0%  3/50 (6%) Total 3/50 (6%) Mean 6% SD 0% Total 3/50 (6%) Mean 6%  SD 0% Total 0/50 (0%) Mean 6%  5D 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  SD 0% Total 0/50 (0%) Mean 0%  Mean 0%  Total 0/50 (0%) Mean 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: Beni	gn, Complex,	, <b>Malignant, NOS</b> 12/50 (24%)				5/50 (10%)		
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%
*Brain: Glioma Malignant	•••••	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig	jn	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: Oligodendroglioma, Gliom						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: 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%
*Clitoral/Preputial Gland: Carcinoma		1/49 (2%)				0/48 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 61

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma		1/49 (2%)				0/48 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/48 (0%)	Mean 0%	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		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Granular Cell Tumor Benig	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 Large: Colon/Rect 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 62

			Male				Female	
#Intestine Small: Jejunum: 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%
#Intestine Small: Jejunum: 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%
#Intestine Small: Site Unspec Carcinoma	ified:							
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec 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%
#Intestine Small: Site Unspec Leiomyosarcoma	ified:							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		3/50 (6%)				0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 63

eport	Date:	01/20/2016	

			Male				Female				
*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											
		3/50 (6%)				1/50 (2%)					
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
*Kidney: Pelvis and Transition Papilloma	onal Epitheliu					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%			
		, ,			TOTAL	0/30 (0 /6)		JD 0/6			
*Kidney: Renal Tubule: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 /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%			
Overall incluence	างเลเ	0/30 (0%)	iviedii U%	0% بری	TOTAL	0/30 (0%)	iviean 0%	3D 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 64

			Male				Female	
*Kidney: Renal Tubule: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Oncocytoma Benign	•••••							
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		0/50 (0%	٠٠٠٠٠٠			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma o	or Hepatocell	ular Adenoma 0/50 (0%	······			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma,						0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Adend	oma	0/50 (0%	6)			0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 65

			Mal	e			Female	
*Lung: Alveolar/Bronchiolar Ca	arcinoma							
		1/50 (29	%)			0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ca								
		1/50 (29	%)			0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma		0/50 /0	0()			0/40 (/00/)		
0	T-1-1	0/50 (09	,	OD 00/	T-1-1	0/49 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenterio Hemangiosarcoma	c:	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								
•		0/50 (09	%)			1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Adenoma		0/50 /0	D/ \			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%
Overall incluence	ıotai	0/50 (0%)	iviean 0%	ას 0%	I Olal	0/50 (0%)	wean 0%	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 66

			Male				Female	
#Mammary Gland: Carcinoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%
#Mammary Gland: Fibroadenoma		0/50 /40/				20/50 (049())		
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	32/50 (64%) 32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o		2/50 (4%)				32/50 (64%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	32/50 (64%)	Mean 64%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma,		Adenoma 3/50 (6%)				36/50 (72%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	36/50 (72%)	Mean 72%	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%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 67

			Male				Female	
#Oral Cavity (Oral Mucos Squamous Cell Carcing		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 Squamous Cell Carcino		quamous, or 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%
#Oral Mucosa: Squamous Cell Carcino	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%
*Ovary: Cystadenoma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	3enign							
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Malignant					0/50 (00)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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

Page: 68

			Male				Female	
*Ovary: Granulosa Cell Tumor: I	Benign, Maligna	nt, NOS						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa-Theca Tumo								
Overall Incidence	_				Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Ovary: Sertoli Cell Tumor Beniç	gn	•••••						
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 Carcinor								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 69

			Male				Female	
*Pancreas: 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%
*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%
*Parathyroid Gland: Adenoma								
		0/49 (0%)				1/41 (2%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/41 (2.44%)	Mean 2.44%	SD 0%
*Pituitary Gland: Pars Dist Adenoma	alis or Unspeci	fied Site:						
		14/50 (28%)				19/50 (38%)		
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%
*Pituitary Gland: Pars Dist								
		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 Dist Carcinoma or Adenoma	talis or Unspeci	fied Site:						
		14/50 (28%)				19/50 (38%)		
Overall Incidence	Total	14/50 (28%)	Mean 28%	SD 0%	Total	19/50 (38%)	Mean 38%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 70

			Male				Female					
*Pituitary Gland: Pars Intermedia: 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%				
*Pituitary Gland: Pars Intern Carcinoma or 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%				
*Prostate: Adenoma		0/50 (0%)										
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%								
*Prostate: Carcinoma or Adenoma		0/50 (00/)										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%								
*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%				
#Skeletal Muscle: 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%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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	
#Skeletal Muscle: Sarcoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	·	0/50	(0%)	M 004	<b>OD</b> 201	<del>-</del>	0/50 (0%)		<b>OD</b> 007
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	Trichoep (0%)		SD 00/	Total	0/50 (0%)	Maan 00/	CD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma									
Overell Incidence	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%
#Skin: Basal Cell Carcinoma o	r Basosquamou	s Tumor (maligi 0/50	nant or No	os)			0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

#### **Toxicology Data Management System**

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

Vehicle: FEED

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		Male				Female		
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or 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:								
Basal or Sq. Cell Carcii Adenoma, Papilloma, S	noma, Carcinoma 3q Papilloma, Ker	atoacanthoma, Trichoe	B), Basal Cell Adeno pithelioma	oma,		2/22 (224)		
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	CD 00/	Total	0/50 (0%) 0/50 (0%)	Maan 00/	CD 00/
	Total	` '		SD 0%	Total	` ,	Mean 0%	SD 0%
#Skin: Fibroma								
		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: Fibroma, Fibrosarcoma Hemangiopericytoma	a, Sarcoma, Myxo	oma, Myxosarcoma, Ma 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: Fibroma, Fibrosarcoma	a, Sarcoma, Myxo	oma, Myxosarcoma, or 3/50 (6%)	Malignant Fibrous His	stiocytoma		0/50 (0%)		
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma		0/50 (00)				0/50 (00/)		
Overell Incidence	Tatal	0/50 (0%)	Mana 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: PERINATAL AND POSTNATAL

Vehicle: FEED

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			Male				Female	
#Skin: Fibrosarcoma, Sarcoma	a, Myxosarcoma		istiocytoma			(201)		
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: 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%
#Skin: 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%
#Skin: Keratoacanthoma		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Malignant Fibrous Histi	ocytoma	0/50 (651)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 01/20/2018

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			Male				Female	
#Skin: Neurofibrosarcoma or Sch	nwannoma (m	nalignant 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, Neuro	ofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: 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%
#Skin: Squamous Cell Carcinoma	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 Carcinoma or Carcinoma	a, Basal Cell (	Carcinoma, Basosquamo	us Tumor (malignan	et 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 75

				Male				Female	
#Skin: Squamous Cell Papilloma							,		
		2/50	(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)		Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma									
oquamous cen i apinoma	or rapilionia	2/50	(4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	(170)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma, Overall Incidence	Total	4/50 4/50 (8%)	(8%)	Mean 8%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma,	Papilloma, or	r <b>Keratoacantho</b> 4/50				Total	0/50 (0%)	M 00/	<b>05</b> .0%
Overall Incidence	Total	4/50 (8%)		Mean 8%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma									
		0/50	(0%)				0/50 (0%)		
						Total	0/50 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/30 (0/8)	IVICALI U/0	30 0%
Overall Incidence #Skin: Sebaceous Gland: Carcinoma or Adenoma	Total		(00/)	Mean 0%	SD 0%	Total		Weall 0/6	35 0%
#Skin: Sebaceous Gland:	Total Total		(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 76

				Male				Female	
*Spleen: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(076)	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 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#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 o	or Papilloma	a Squamous 0/50	(0%)		<b></b>		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									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Testis: Adenoma		1/50	(2%)						
Overall Incidence	Total	1/50 (2%)	(= / = /	Mean 2%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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								
Overall Incidence	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/46 (0%)				0/49 (0%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/46 (0%)				0/49 (0%)		
Overall Incidence	Total	0/46 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma Overall Incidence	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
*Thyroid Gland: C-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%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		8/50 (16%)				6/50 (12%)		
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 78

				Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	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 or Adenoma	II:								
			(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		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	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		a Squamous					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%
#Tooth: Odontoma		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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**: 79

			Male				Female	
*Urinary Bladder: Leiomyosarcoma								
•		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%
#Uterus: Hemangiosarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal								
Overall Incidence					Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%
#Uterus: Sarcoma Stromal						2/52 (22)		
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

#### **Toxicology Data Management System**

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

Vehicle: FEED

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	Male			Female	
#Uterus: Sarcoma Stromal or Polyp Stromal					
			8/50 (16%)		
Overall Incidence		Total	8/50 (16%)	Mean 16%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Squamous Cell Carcinoma			0/50 (00/)		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Granular Cell Tumor Benign			0(50 (00))		
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 01/20/2018

### **Study Summary**

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

Contract/Lab: All Laboratories

Species: RATS

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

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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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0/90 (0%) 0/90 (0%)  0/90 (0%) 0/90 (0%)  nonuclear, or Undifferer 0/90 (0%) 0/90 (0%)	Mean 0%	SD 0% SD 0% SD 0%	Total Total Total	0/90 (0%) 0/90 (0%) 0/90 (0%) 0/90 (0%) 0/90 (0%)	Mean 0%  Mean 0%  Mean 0%	SD 0% SD 0% SD 0%
0/90 (0%)  0/90 (0%)  0/90 (0%)  nonuclear, or Undifferer  0/90 (0%)  0/90 (0%)	Mean 0%  ntiated  Mean 0%	SD 0% SD 0%	Total	0/90 (0%) 0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
0/90 (0%) 0/90 (0%) nonuclear, or Undifferer 0/90 (0%) 0/90 (0%)	Mean 0%  ntiated  Mean 0%	SD 0% SD 0%	Total	0/90 (0%) 0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
0/90 (0%)  nonuclear, or Undifferer 0/90 (0%) 0/90 (0%)	ntiated  Mean 0%	SD 0%		0/90 (0%)		
0/90 (0%)  nonuclear, or Undifferer 0/90 (0%) 0/90 (0%)	ntiated  Mean 0%	SD 0%		0/90 (0%)		
nonuclear, or Undifferer 0/90 (0%) 0/90 (0%)	ntiated  Mean 0%	SD 0%		0/90 (0%)		
0/90 (0%) 0/90 (0%)	Mean 0%		Total	` ,	Mean 0%	SD 0%
				` '		
phocytic, Mixed, NOS, or 2/90 (2%)	r Undifferentiated Ce			5/90 (6%)		
2/90 (2.22%)	Mean 2.22%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%
3/90 (3.33%)	Mean 3.33%	SD 0%	Total	4/90 (4.44%)	Mean 4.44%	SD 0%
2/90 (2%)				0/90 (0%)		
2/30 (2/0)		CD 00/	Total	` ,	Mean 0%	SD 0%
	3/90 (3%) 3/90 (3.33%) 2/90 (2%)	3/90 (3%) 3/90 (3.33%) Mean 3.33% 2/90 (2%)	3/90 (3%) 3/90 (3.33%) Mean 3.33% SD 0% 2/90 (2%)	3/90 (3%) 3/90 (3.33%) Mean 3.33% SD 0% Total 2/90 (2%)	3/90 (3%) 3/90 (3.33%)  Mean 3.33%  SD 0%  Total 4/90 (4.44%)  2/90 (2%)  0/90 (0%)	3/90 (3%) 3/90 (3.33%) Mean 3.33% SD 0% Total 4/90 (4.44%) Mean 4.44%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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									
Overell Insidence	Tatal	2/90 (2%)	Mana 0.000/	CD 00/	Tatal	0/90 (0%)	Mana 00/	CD 00/	
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
*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: Pheochromocytoma Benig		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 Comp									
		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 Maligr	nant								
		1/88 (1%)		00.00		0/86 (0%)		05 00/	
Overall Incidence	Total	1/88 (1.14%)	Mean 1.14%	SD 0%	Total	0/86 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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, Complex	, <b>Malignant, NOS</b> 11/88 (13%)				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%
*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 Beniç	gn	1/90 (1%)				1/90 (1%)		
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Brain: Oligodendroglioma, Gliom						0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
*Brain: 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%
*Clitoral/Preputial Gland: Carcinoma		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: Carcinoma or Adenoma								
		0/88 (0%)				0/87 (0%)		
Overall Incidence	Total	0/88 (0%)	Mean 0%	SD 0%	Total	0/87 (0%)	Mean 0%	SD 0%
*Epididymis: Sarcoma								
Overall Incidence	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Eve.								
#Eye: Leiomyoma		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%
		` '				0/90 (0 /6)		
*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: Colon/Rec Granular Cell Tumor Beni	tum:							
	9	0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Large: Colon/Rec								
-		0/90 (0%)				0/90 (0%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 88

			Male				Female	
#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								
		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
#Intestine Small: Site Unspec								
		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 Unspec 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								
•		0/90 (0%)				1/90 (1%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Islets, Pancreatic: Adenoma		<b>-</b> (22)				7/00 (00)		
		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 01/20/2018

cport	Date.	01/20/2010	'

			Male				Female	
*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 Transition								
		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: 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		4/00 (40()				4/00 (40)		
	<b>-</b>	1/90 (1%)		<b>OD</b> 00/	<b>-</b>	1/90 (1%)		OD 00/
Overall Incidence	Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0.000 (00.0)				2(22)		
		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 90

			Male				Female	
*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: 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%
*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%
*Liver: Hepatocellular Carcinoma c						7/90 (8%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	7/90 (7.78%)	Mean 7.78%	SD 0%
*Liver: Hepatocellular Carcinoma,						7/90 (8%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	7/90 (7.78%)	Mean 7.78%	SD 0%
*Lung: Alveolar/Bronchiolar Adenc	oma							
		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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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**: 91

			Male				Female					
*Lung: Alveolar/Bronchiolar Carcinoma  0/90 (0%)  0/90 (0%)												
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar C	arcinoma or Alv	eolar/Bronchiolar Adeno	oma									
		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												
		0/90 (0%)				0/90 (0%)						
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				
#Lymph Node, Mesenteri 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						•••••						
		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: Adenoma		0/00 /02/				0/00 /00/						
Overall In aldon as	Tatal	0/90 (0%)	Mana 00/	CD 00/	Tatal	8/90 (9%)	Mana 0 000/	CD 00/				
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	8/90 (8.89%)	Mean 8.89%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 92

			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								
		0/90 (0%)				16/90 (18%)		
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%)				62/00 (700()		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	63/90 (70%) 63/90 (70%)	Mean 70%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma o		2/90 (2%)				64/90 (71%)		
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	64/90 (71.11%)	Mean 71.11%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, (						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	` '	Moon 00/	SD 00/	Total	` ,	Moon 00/	CD 00/
Overail incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 93

			Male				Female	
#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 Squamous Cell Carcino								
		0/90 (0%)				2/90 (2%)		
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	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%
*Ovary: Cystadenoma						1/90 (1%)		
Overall Incidence					Total	1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Granulosa Cell Tumor	Benign							
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
*Ovary: Granulosa Cell Tumor	Malignant					0/00 /00/		
Overall Incidence					Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System** 

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

Route: Whole Body Exposure

Vehicle: AIR

**Page:** 94

Report Date: 01/20/2018

Strain: Harlan Sprague-Dawley Length of Study: CHRONIC

			Male			Female			
*Ovary: Granulosa Cell Tumor: Ber	nign, Maligna	ant, NOS							
Overall Incidence					Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%	
*Ovary: Granulosa-Theca Tumor B									
	cing.					0/90 (0%)			
Overall Incidence					Total	0/90 (0%)	Mean 0%	SD 0%	
*Ovary: Sertoli Cell Tumor Benign									
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%	
						` '			
*Ovary: Thecoma Benign						0/00 (09/)			
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%	
*Ovary: Tubulostromal Carcinoma									
						0/90 (0%)			
Overall Incidence					Total	0/90 (0%)	Mean 0%	SD 0%	
*Pancreas: Adenoma				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
		18/90 (20%)	••	05 00/		0/90 (0%)		00.00	
Overall Incidence	Total	18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 95 Report Date: 01/20/2018

			Male			Female			
*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	1								
		18/90 (20%)				0/90 (0%)			
Overall Incidence	Total	18/90 (20%)	Mean 20%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%	
*Parathyroid Gland: Adenoma									
		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%	
*Pituitary Gland: Pars Dis Adenoma	talis or Unspec	ified Site:							
		17/89 (19%)				43/90 (48%)			
Overall Incidence	Total	17/89 (19.1%)	Mean 19.1%	SD 0%	Total	43/90 (47.78%)	Mean 47.78%	SD 0%	
*Pituitary Gland: Pars Dis 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%	
*Pituitary Gland: Pars Dis Carcinoma or Adenoma	talis or Unspec					•••••			
Ca. Onionia or Adonomia	-	17/89 (19%)				44/90 (49%)			
Overall Incidence	Total	17/89 (19.1%)	Mean 19.1%	SD 0%	Total	44/90 (48.89%)	Mean 48.89%	SD 0%	
		` '	-			` /	-		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 96

			Male				Female				
*Pituitary Gland: Pars Intermedia: Adenoma											
		0/89 (0%)				0/90 (0%)					
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
*Pituitary Gland: Pars Interm Carcinoma or Adenoma											
		0/89 (0%)				0/90 (0%)					
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
*Prostate: Adenoma		2/90 (2%)									
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%							
*Prostate: Carcinoma or Adenoma		2/90 (2%)									
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%							
*Salivary Glands: Schwannoma Malignant											
		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: 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%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 97 Report Date: 01/20/2018

#Skeletal Muscle: Sarcoma  0/90 (0%)  Overall Incidence Total 0/90 (0%) Mean 0% SD 0%	Total	0/90 (0%) 0/90 (0%)	M 00/	
,	Total	` '	Mana 00/	
Overall Incidence Total 0/90 (0%) Mean 0% SD 0%	Total	0/90 (0%)	M 00/	
			Mean 0%	SD 0%
#Skin: Basal Cell Adenoma				
1/90 (1%)		0/90 (0%)		00.00
Overall Incidence Total 1/90 (1.11%) Mean 1.11% SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or Basosquamous 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, Basosquamous Tumor Benign, or Trichoepithelioma 1/90 (1%)		0/90 (0%)		
Overall Incidence Total 1/90 (1.11%) Mean 1.11% SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma  0/90 (0%)		0/90 (0%)		
Overall Incidence Total 0/90 (0%) Mean 0% SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)  0/90 (0%)		0/90 (0%)		
Overall Incidence Total 0/90 (0%) Mean 0% SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 98

			Male				Female				
#Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma											
,, or		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 Carci Adenoma, Papilloma, S	noma, Carcinom Sq Papilloma, Ke	na, Basosq. Tumor (M or eratoacanthoma, Trichoe	· B), Basal Cell Adenor epithelioma	na,							
		8/90 (9%)				0/90 (0%)					
Overall Incidence	Total	8/90 (8.89%)	Mean 8.89%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Fibroma 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: Fibroma, Fibrosarcoma Hemangiopericytoma Overall Incidence		oma, Myxosarcoma, Ma 5/90 (6%) 5/90 (5.56%)			Total	5/90 (6%) 5/90 (5.56%)	Mean 5.56%	SD 0%			
#Skin: Fibroma, Fibrosarcoma	a, Sarcoma, Myx	oma, Myxosarcoma, or 5/90 (6%)	Malignant Fibrous His	tiocytoma		5/90 (6%)					
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	5/90 (5.56%)	Mean 5.56%	SD 0%			
#Skin: Fibrosarcoma		1/90 (1%)				0/90 (0%)					
Overall Incidence	Total	( /	Mean 1.11%	SD 0%	Total	` '	Moon 09/	SD 00/			
	Total	1/90 (1.11%)				0/90 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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:** 99

			Male				(90 (0%) Mean 3.33% SD 0%  (90 (0%) Mean 0% SD 0%  (90 (0%) Mean 0% SD 0%  (90 (0%) SD 0%			
#Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Malignant Fibrous Histiocytoma  3/90 (3%)  3/90 (3%)										
Overall Incidence	Total	3/90 (3.33%)	Mean 3.33%	SD 0%	Total	3/90 (3.33%)	Mean 3.33%	SD 0%		
#Skin: Hemangioma										
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: Hemangiosarcoma	•••••									
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: Keratoacanthoma		5/90 (6%)								
Overall Incidence	Total	5/90 (5.56%)	Mean 5.56%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%		
#Skin: Lipoma								•••••		
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: Malignant Fibrous Histic	ocytoma	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%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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 Schwannoma (malignant or NOS)											
Near on Brosar coma or o	onwannoma (n	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:											
Neurofibrosarcoma, Neu	rofibroma, or S	Schwannoma (benign, ma 0/90 (0%)	alignant or NOS)			0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			
#Skin: Sarcoma											
		2/90 (2%)				2/90 (2%)					
Overall Incidence	Total	2/90 (2.22%)	Mean 2.22%	SD 0%	Total	2/90 (2.22%)	Mean 2.22%	SD 0%			
#Skin: 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%			
#Skin: Squamous Cell Carcinon	ma										
		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:											
Squamous Cell Carcinon or Carcinoma	na, Basal Cell (	Carcinoma, Basosquamo	ous Tumor (malignan	t or NOS),							
		0/90 (0%)				0/90 (0%)					
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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 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												
oquamous oen i apinoma (	or r apinoma	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, Overall Incidence	Papilloma, S	6quamous Cell Carcinom 7/90 (8%) 7/90 (7.78%)	na or Keratoacanthom Mean 7.78%	sD 0%	Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma, Overall Incidence			Mean 7.78%	SD 0%	Total	0/90 (0%) 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		4/00 /40/				0/00 (00/)						
Overall Incidence	Total	1/90 (1.410)	Mean 1.11%	CD 00/	Total	0/90 (0%)	Maan 00/	CD 00/				
Overali incidence	Total	1/90 (1.11%)	wean 1.11%	SD 0%	Total	0/90 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> 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: 01/20/2018

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

Male **Female** \*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%) SD 0% Mean 1.11% #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% #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 Carcinoma or Papilloma Squamous 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% #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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

\*Thymus:

\*Thymus:

\*Thymus:

**Thymoma Benign** 

**Thymoma Malignant** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

..... \*Thyroid Gland: C-Cell: Carcinoma or Adenoma

\*Thyroid Gland: C-Cell: Carcinoma

Adenoma

\*Thyroid Gland: C-Cell:

.....

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

SD 0%

Male **Female** 0/88 (0%)1/87 (1%)Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) SD 0% Mean 1.15% 0/88 (0%)1/87 (1%) Total 0/88 (0%) Mean 0% SD 0% Total 1/87 (1.15%) Mean 1.15% SD 0% Thymoma: Benign, Malignant, NOS 0/88 (0%)2/87 (2%)Total 0/88 (0%) Mean 0% SD 0% Total 2/87 (2.3%) Mean 2.3% SD 0% 8/89 (9%)6/90 (7%)Total 8/89 (8.99%) Mean 8.99% SD 0% Total 6/90 (6.67%) Mean 6.67% SD 0% 2/89 (2%)0/90 (0%)Total 2/89 (2.25%) Mean 2.25% SD 0% Total 0/90 (0%) Mean 0% SD 0%

Total

6/90

6/90 (6.67%)

(7%)

Mean 6.67%

SD 0%

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Report Date: 01/20/2018

Total

10/89

10/89 (11.24%)

(11%)

Mean 11.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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											
	0/89 (0%)				1/90 (1%)						
Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%				
ell:											
	0/89 (0%)				1/90 (1%)						
Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%				
	1/90 (1%)				1/90 (1%)						
Total	1/90 (1.11%)	Mean 1.11%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%				
1	0/90 (0%)				1/90 (1%)						
Total	0/90 (0%)	Mean 0%	SD 0%	Total	1/90 (1.11%)	Mean 1.11%	SD 0%				
	a Squamous				4/00 (40%)						
Total	` ,	Moon 0%	SD 0%	Total	` '	Moon 1 119/	SD 0%				
างเลเ	0/90 (0%)	iviean u%	JU U%	าบเลเ	1/90 (1.11%)	iviean 1.11%	עט עס 0%				
	0/00 (0%)				0/00 (00/)						
Total	0/90 (0%)	Mean 0%	SD 0%	Total	` '	Maan 00/	SD 0%				
	Total  Total  Total  Total  Total  Total	0/89 (0%) Total 0/89 (0%)  Pill:  0/89 (0%)  Total 0/89 (0%)  1/90 (1%)  Total 1/90 (1.11%)  0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)  Total 0/90 (0%)	O/89 (0%) Total 0/89 (0%) Mean 0%  Fil:  O/89 (0%)  Total 0/89 (0%)  Mean 0%  1/90 (1%)  Total 1/90 (1.11%)  Mean 1.11%  O/90 (0%)  Total 0/90 (0%)  Mean 0%  O/90 (0%)  Total 0/90 (0%)  Mean 0%  O/90 (0%)  Total 0/90 (0%)  Mean 0%	O/89 (0%)   Mean 0%   SD 0%	Total   0/89 (0%)   Mean 0%   SD 0%   Total	1/90 (1%)   1/90 (1%)   1/90 (1%)   1/90 (1.11%)	1/90 (1%)   1/90 (1.11%)   1/90 (1				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: 105

			Male				Female	
*Urinary Bladder: Leiomyosarcoma								
•		0/89 (0%)				1/88 (1%)		
Overall Incidence	Total	0/89 (0%)	Mean 0%	SD 0%	Total	1/88 (1.14%)	Mean 1.14%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	3/90 (3%) 3/90 (3.33%)	Mean 3.33%	SD 0%
#Uterus: Hemangiosarcoma						(201)		
Overall Incidence					Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Uterus: Leiomyosarcoma								
Overall Incidence					Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%
#Uterus: Polyp Stromal								
Overall Incidence					Total	16/90 (18%) 16/90 (17.78%)	Mean 17.78%	SD 0%
						10/00 (17.7070)		
#Uterus: Sarcoma Stromal								
Overall Incidence					Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: 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: Sarcoma Stromal or Polyp Stromal					
Overall Incidence		Total	16/90 (18%) 16/90 (17.78%)	Mean 17.78%	SD 0%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	2/90 (2%) 2/90 (2.22%)	Mean 2.22%	SD 0%
#Uterus: Squamous Cell Carcinoma			0/90 (0%)		
Overall Incidence		Total	0/90 (0%)	Mean 0%	SD 0%
#Vagina: Granular Cell Tumor Benign			0/90 (0%)		
Overall Incidence		Total	0/90 (0%)	Mean 0%	SD 0%
#Vagina: Polyp					
Overall Incidence		Total	0/90 (0%) 0/90 (0%)	Mean 0%	SD 0%
#Vagina: Schwannoma Malignant			4/00 (49/)		
Overall Incidence		Total	1/90 (1%) 1/90 (1.11%)	Mean 1.11%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS

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

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: Whole Body Exposure

Vehicle: AIR

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			Male				Female	
#Zymbal's Gland: 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%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied